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

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PhD Thesis

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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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LITERARY OVERVIEW

Definitions

Non-specific chronic low back pain

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 [1].

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) [1].

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 syndrom [2].

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 [3]. These values also depended on age and sociological status, the point prevalences and lifetime prevalences could reach even 79.2% [4].

The longer someone is forced to take sick leave due to low back pain, the less likely they will return to work. It has been shown that less than half of those who have not been working for 6 months due to low back pain less will return to work and after two years this ratio is almost zero. Consequently a proper on time diagnosis is crucial in order to prevent the patient from long-term disability and sick leave [1,2].

In the diagnosis of LBP, first line doctor needs to analyse initial history and conduct physical examination of the patient. Other risk factors such as psychosocial and workplace-related symptoms could be important in assessing the pain progress. For chronic, non-specific low back pain there is no strong supporting evidence for routine imaging [5]. First line of defence for

therapeutic options for chronic lumbar region pain, based on the existing evidence are as follows: education, home exercises, self-management physiotherapy, balneotherapy and multidisciplinary pain management. Furthermore, additional therapeutic options that could provide positive experiences alongside the above-mentioned are: mineral-rich mud compresses, behavioural therapy (cognitive behaviour therapy), drug therapies (NSAIDs, weak opioids and muscle relaxants), spine schools, mobilization and manipulation, acupuncture and massage therapies, noradrenergic treatment, or noradrenergic treatment with serotoninergic antidepressants and capsaicin patch [6–8]. More and more studies seem to be showing that, thanks to the wide range of therapeutic options for LBP patients, surgical intervention has become unavoidable in fewer and fewer cases, and only where patients have "red flags" symptoms, which suggest a potentially serious underlying ailment. After the 2007 American College of Physicians guideline, it appeared in the recommendation in 2013 new evidences of nonpharmacologic treatment options for low back pain. Evidence continues to support the effectiveness of exercise, psychological therapies, multidisciplinary rehabilitation and nonpharmacologic treatment [9–11].

Physical and Rehabilitation Medicine Section recommendation for nonpharmacological modalities are education, back schools, exercise, massage, spinal manipulation, cognitive-behavioral therapy and multidisciplinary biopsychosocial rehabilitation in an interdisciplinary rehabilitation team [12].

With regards to balneo- and hydrotherapy, for the past few decades, evidence-based studies have overtaken simple and unempirical experience and suggest that these therapies actually lead to statistically significant improvement in the condition of patients suffering from LBP.

During the analysis of previous studies found a systemic review on LBP that overviewed hydro- and balneotherapy papers published between 1990 and 2008 could not draw any conclusions regarding balneotherapy because of the diversity of outcome measures, the absence of proper control groups, and poor study design [13].

An other review from 2012 found that balneotherapy might be beneficial, but the evidence is yet insufficient to make a definitive statement about it [14].

Against these in 2009 Falagas et al. selected 29 RCTs included 1720 receiving balneotherapy patients and 8 of these evaluated balneotherapy in osteoarthritis, 4 in fibromyalgia, 4 in

ankylosing spondylitis, 4 in rheumatoid arthritis, 3-3 in psoriatic arthritis and in chronic low back pain, and one in Parkinson's disease. 17 out of 29 studies confirmed, that pain decreased significantly compared with the control group and the analgesic effect of balneotherapy lasted for 3 months in 9 studies of longer duration [15].

Further favorable results were found by Pittler et al. estimated in a meta-analysis of 5 RCTs of 580 patients the effect of balneotherapy in chronic back pain in 2006. Active treatment consists of complex balneotherapy in 5 RCTs, but immersion in thermal mineral water only in one RCT. The controls were patients on the waiting list for balneotherapy, and/or received drugs and exercised. The authors concluded that the results are promising as regards the decrease of pain, and emphasized the need for further research [16].

Since 2005, two tap water-controlled RCTs have evaluated the effect of balneotherapy on chronic low back pain, and described the significantly better effects of balneotherapy on pain and mobility in chronic low back pain [17,18].

Balneo- and hydrotherapy

The history of hydrotherapy and balneotherapy treatments dates back thousands of years whilst healing by water ("sanus per aquam") 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 (or hydrotherapeutic) procedures for various therapeutic purposes in addition to the physical properties of water, absorption of dissolved minerals through the skin may also 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 [19]. 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.

In Hungary, the name “medicinal water” is assigned by official institution, whose tasks include the declaration of mineral water as medicinal water if it meets certain criteria and its beneficial effects can be proved by clinical trials [20,21].

Mineral waters can be classified in several ways. The most widely accepted classification method is based on the chemical composition. Mineral waters are classified as: salty (rich in calcium-chloride, magnesium-chloride), carbonated (sour waters), alkaline or calcined lime (sodium-hydrogen-carbonated, magnesium- hydrogen-carbonated), rich in iron, iodine, bromide, sulfate, sulfide and radioactive waters [20,22–24]. Waters could be categorized as hypothermal (<35°C), isothermal (35-36°C) or hyperthermal (>36°C) [19].

In Hungary, mineral water is called thermal water if its temperature is at least 20°C and is from a spontaneously bursting well or at least 30°C from a drilled well.

In countries where thermal water is not available the medical use of tap water is frequent and is also referred to as hydrotherapy [22].

Nowadays, when more and more patients are hospitalized due to side effects of different drug treatments balneo- and hydrotherapy treatments represent an important alternative option.

Several studies had tried to determine the ideal number of balneotherapy treatments a patient should receive for the effectiveness be optimal A review found that for the effectiveness of balneotherapy treatment a minimum of 10 sessions are required, occurring over at least ten days, while the optimal amount is 10 to 21 sessions over a period of two or three weeks [25–28].

In Hungary, a wide range of balneotherapeutic options are available. A standard therapeutic course consists of 15 – 20, 20 to 40 minute sessions [23]. Balneotherapy usually serves as part of a complex physiotherapeutic treatment.

There are several studies where positive effects of balneotherapy on pain is proved [29].

At the molecular level, more and more data are available on the effectiveness of balneotherapy

Drawing the consequence of the treatment the balneotherapy, it has been confirmed to be beneficial in chronic back pain and has been shown to alter the functions of proteins such as modulation of gene expression, differentiation, angiogenesis, tissue repair, acute and chronic inflammatory response [30].

A meta-analysis of randomized controlled trials (RCTs) about the effect of spa therapy on treating low back pain found a significant reduction in pain level based on visual analogue scale (VAS) [31].

The indication for balneotherapy procedures is very wide and not limited to the musculoskeletal disorders only [23,24]. It is reported to be used in various other fields such as for dermatological diseases (psoriasis, atopic dermatitis) [32–34], management of gynaecological problems [35] or for the treatment of chronic venous insufficiency [36,37]. There are also positive experience for the use of balneaotherapy in case of chronic occlusive arterial disease [37] or psychiatric conditions (generalized anxiety disorder) [38], or multiple sclerosis [39] as well as in the rehabilitation of oncology patients [40].

Traction therapy

The origin of dry stretching treatments can be traced back to Gallenus (AD 200). It is defined as an underwater weight bath traction therapy, when the traction of the spine and the lower extremities are extended with or without weights in indifferent water temperature in a vertical position.

Several theories exist on the mechanism of traction therapy, but probably more dimensional mechanism may be involved. The theories regarding the spinal elongation actual physiologic effects states that it acutely decreases lumbar lordosis while concomitantly increases the intervertebral disc height inhibits nociceptive impulses, improves mobility, decreases mechanical stress, reduces muscle spasmor spinal nerve root compression (due to osteophytes), releases luxation of a disc or capsule from the zygo-apophysial joint, and releases adhesions around the zygoapophysial joint and the annulus fibrosus [41].

A more recent neurophysiological research suggests that stimulation of proprioceptive receptors in the vertebral ligaments and in the mono segmental muscles may modify higher cerebral centres as well as peripheral structures for postural control [42,43].

In 2012, Dr. Prasad and his colleagues showed that 77% of patients on a waiting lists for discus hernia surgery, who received traction and physical therapy together did not finally require surgery after their treatment [44].

Also, 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 back pains, but the evidence is not yet clear as to which kind of therapy is recommended to whom and when. For example, there are questions as to whether mechanical lumbar traction should be recommended in combination with other treatments or alone, and under which conditions [45].

According to studies, minimal forces can still be expected to produce positive results for dry traction therapy, as even low traction forces can produce intervertebral separation due to flattening of lumbar lordosis, and relaxation of spinal muscles [46–49].

When in a study, it had been tried to determine the changes of the lumbal spin during the underwater traction therapy by MRI, found the changes were not significant [50]. Nevertheless, other biomechanical studies found that despite the fact that no significant change can be detected with MRI was confirmed with underwater ultrasound exeminations the efficacy of weightbath therapy [51–53].

There is also some data about the adverse effects of traction. In a few cases it was reported to cause a minimal danger to nerve impingement in heavy traction (i.e. lumbar traction forces exceeding 50% of the total body weight). Other risks mentioned for lumbar traction are respiratory constraints due to the traction harness or increased blood pressure during inverted positional traction [43].

Evidence of the effect of hydrotherapy and balneotherapy

One of the most important effects during thermal mineral bath treatments is related to the properties of the hydrotherapy. The efficacy of hydrotherapy could be explained by the watery environment, the basic physical attributes of water i.e. its density, specific weight, hydrostatic pressure, buoyant force, viscosity and temperature [23].

We call immersion when the body is dipped into water up to substernal height in a vertical position. During immersion, the physical characteristics of the water cause physiological changes.

If the human body is immersed in water, it will be exposed to buoyancy. Different parts of the body and organs are affected by different forces depending on their density, which are the

result of gravity and water pressure, as well as buoyancy forces. Under water therapies due to the decrease of the gravitational force on the spine, the joints and the muscles help to eleviate in musculoskeletal pain and muscle weakness.

Hydrostatic pressure is dependent on the density of the liquid, the acceleration due to gravity, and the depth within the liquid [39]. Immersion leads to the circulation becoming centralized which increases cardiac output without increasing heart rate and exerts a diuretic effect via a reflex mechanism, stretching of the volume receptors increases the secretion of atrial natriuretic factor and decreases the secretion of antidiuretic hormone, which leads to natriuresis [14,54–58]. If the patient is immersed into water up to neck level, the cardiac output enhances muscle blood flow [57,59].

Diving in water also has been shown to have beneficial effects on deeper muscle structures. The oxygen supply of the tissues increase, which may redound to the healing of muscle, joint, or even the bone injuries [14].

There are also evidences on how the sympathetic nervous system activity reacts to an immersion in cool water. It raises the baseline activity, with a drop in sympathovagal balance which may represent lead to a physiologic stress response, while warm water immersion produced a rise in tha activity of the sympathetic nervous system [60].

The analgesic effect of hydrotherapy could be explained by the gate control theory. This modulation of pain through thermoreceptors and mechanoreceptors has been described as early as 1965 [61]. Skin thermo- and mechanoreceptors stimulated by the temperature and the hydrostatic pressure of water activate inhibitory interneurons acting on ascending nociceptive neurons, which in turn leads to the blockage of pain signal conductance [61].

The thermodynamic characteristics of water and mud also play an important role.

The temperature induces changes in the neuroendocrine regulation can lead to the changes of adrenocorticotropic hormone, cortisol, prolactin and growth hormone secretion too [62].

The heat retaining capacity and heat conduction of the water and mud is high, therefore, able to keep the temperature (warm or cold) and easily can passes it to its environment [54,60,63].

Also beneficial effect of heat has been shown during physical therapy treatment, where the detectable serum beta-endorphin levels increase with decreasing pain, suggesting an important role for endogenous opioids [64]. Thermal effect induces changes in the neuroendocrine

regulation. Heat as stress factor stimulates the secretion of adrenocorticotropic hormone, cortisol, prolactin, and growth hormone [62].

Studies involving mud-pack treatments showthat heat also increase serum cortisol and catecholamine levels, which may play a role in the anti-inflammatory effects [65–67].

Thermal stimulation increases the extensibility of collagen-rich tissues, such as tendons, fasciae and articular capsules, which may improve the range of motion of joints [68], reducing muscle tone and joint circumference which contributes to reduction of the musculoskeletal pain [69,70].

Beyond to the aquatic environment, the substances dissolved in the water exert important effects during balneotherapy [68,71,72].

Evaluation of the effects of balneotherapy and the tools of health assessment

Patient-reported outcome measures (PROMs) are questionnaires measuring the patients' views of their health status. [73]. The PROs provide intrinsic knowledge about a patient's health, functional status, symptoms, treatment preferences, satisfaction, and quality of life.

The rutin examination of the musculoskeletal disorders is not different from other medical examination. There are many disease-specific and general health questionnaires. Ususally these survey forms are validated and standardized.

The assessments of a patient with low back pain diseases include evaluation of pain, function, and the quality of life. General pain or disability can also be evaluated using a visual analog scale (VAS). A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. The pain VAS is measure of pain intensity.

The simple VAS is a straight horizontal line of fixed length, usually 100 mm.

The VAS pain scale along the the line with the descriptor extremes "no pain at all" and "my pain is as bad as it could possibly be" in patients with a variety of conditions.

The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health) [74].

A study compared measurements of pain of a vertical, a horizontal visual analogue scales of pain. They found correlation between the 2 scales, but the scores from the horizontal scales tended to be slightly lower than those from vertical scales [75].

The Oswestry Disability Index (ODI) is one of the most commonly recommended condition specific outcome measure for spinal disorders. This index originated from the Oswestry Low Back Pain Questionnaire to quantify disability for low back pain.

The Oswestry Disability Index (ODI), a self-reported questionnaire which measures the patients' perceived level of disability in 10 everyday activities (e.g., pain intensity, the changing status of pain, personal hygiene, lifting, walking, sitting, standing, sleeping, social activity, and travelling). The patients scored between 0 and 5 for each of the 10 questions leading to a total score between 0 and 50 that is then expressed in percentage. This questionnaire is validated and has reliability in Hungary [76].

In an RCT involving 289 patients treated surgically or non-surgically it was determinde that the minimal clinically important difference was 10 units for Oswetry Disability index score [77–79].

The EuroQoL five dimensions questionnaire (EQ-5D) is a standardised measure of health status. This self-administered questionnaire is an accepted, and widely used, standardized instrument for evaluating general health status. There are three versions of the instrument: EQ-5D-5L, EQ-5D-3L, EQ-5D-Y. For decades, these have been widely used in clinical trials, population studies and real-world clinical settings. EQ-5D-3L has a descriptive system questionnaire with five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), where patients are asked to rate their health problems from 3 levels (no problems, some problems, extreme problems).

The EQ-5D-5L is a descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants choose from a scale of 1 to 5 based on the level of difficulty they encounter during such situation (no problem, slight problem, moderate problem, severe problem, and extreme problem).

The EQ contains a VAS records scale of 0–100, the patient's self-rated health on a vertical visual analogue scale, where the endpointsare labelled 'The best health you can imagine' and

‘The worst health you can imagine’. The VAS can be used as a quantitative measure of health outcome that reflect the patient’s own judgement [80,81].

AIMS OF THE THESIS

To evaluate the effects of balneo- and hydrotherapy in chronic low back pain.

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.

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

Objectives

The aim of our study was to determine the impact of the usage of calcium-magnesium-bicarbonate content thermal mineral water of thermal bath on chronic low back pain.

Materials and methods

Design

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.

Participants

The study was conducted at the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service in Budapest, Hungary. Participants were selected from patients in the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service as well as from visitors of the Dagály Thermal Baths. Participants from the visitors of the Dagály Thermal Bath were recruited by a written advertisement in the bath. The medical examination was carried out at the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service. The balneotherapy was practiced in the Dagály Baths. This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: 164-1/20169).

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.

Intervention

During the study, all participants received their usual or necessary medications. For ethical considerations, participants were allowed to perform physical therapy and receive massage, TENS, and ultrasound treatments, as they would have normally done regardless of their participation in the study and these were documented. Participants did not receive any systemic steroid therapy or injections into the affected area. The study group received 3 weeks of balneotherapy on top of the routine outpatient treatments. This group was treated 15 times during the 3-week period with thermal mineral water by bathing in the Dagály Thermal Bath for at least 20 min per occasion. The water temperature was 38°C. Appearance on balneotherapy with the precise dates has been recorded on the study panel. In the pool, the participants could sit, swim or move freely. The control group received the necessary routine outpatient treatment but did not receive balneotherapy.

The thermal and mineral water in the Dagály Thermal Bath originates from the Budapest B-14th OKK deep-drilled Peace well. The depth of the well is 125.9m; the water flow is through 118.9–125.6m from a filtered section. The total dissolved mineral content of the water exceeds 1000mg/ml (1080mg/ml). The water is rich in calcium-magnesium-sodium-bicarbonate, with high hardness (total hardness 259 CaOmg/l, 25.9nkf) thermal water (water temperature: 38°C).

Outcomes

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 [78]. This form has validity and reliability in Hungary [79].

Furthermore, there was a questionnaire on the quality of life, known as the EuroQol Five Dimensions Questionnaire (EQ-5D). The EQ-5D also included a 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) [81].

Both groups member patients filled out the above questionnaires after enrollment, 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.

Randomization

The creation of initial homogeneous patient groups followed the statistical principle of minimization [82,83]. The statistician has received the information by email. 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 two groups were thus homogenous in terms of these parameters. Patients were examined by independent examiners at each visit. The questionnaires (VAS scales of low back pain at rest and during activity; and the Oswestry and EuroQoL-5D) were self-administered. During balneotherapy, an independent person was available. The statistical processing of the data was carried out by an independent person.

Statistical analysis

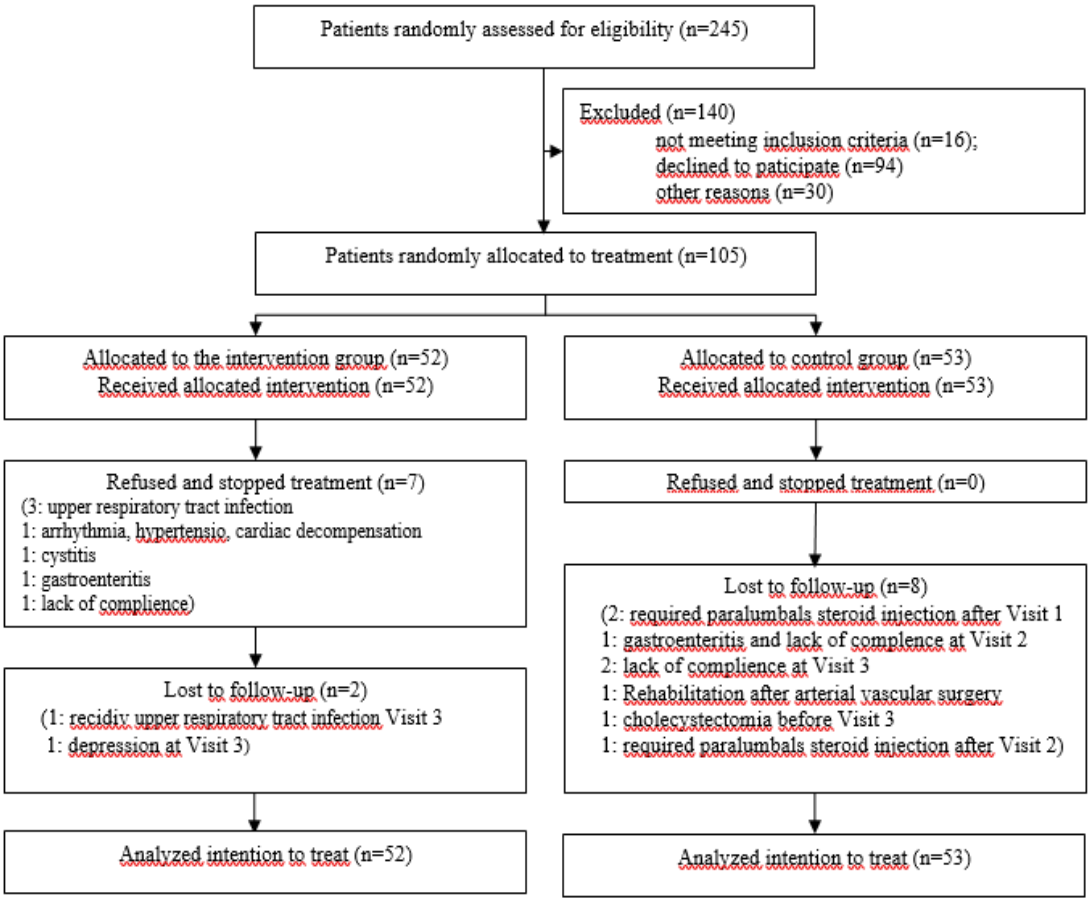
Statistical processing was done using the IBM SPSS 24 software system. A comparison of age-independent sample t test was performed. The number of patients requiring NSAIDs, opioids, muscle relaxants, and paracetamols for low back pain was compared by McNemar's test. Other parameters were processed using 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" [84,85]. The significance level was $p < 0.05$.

Results

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.

The data of the participants of the study group were only evaluated at Visit II if they participated in a minimum of 80% of the treatments (i.e., bathing at least 12 times). From the balneotherapy group, after the study started, balneotherapy was suspended for seven patients: three patients with upper respiratory tract infection; one person with cardiac arrhythmia, hypertension, and cardiac decompensation; one person with cystitis; one person with gastroenteritis; and one person became unavailable. In addition, two persons did not appear for Visit III: one person due to depression and one person because of a persistent upper respiratory tract infection. In the control group, three patients did not appear at Visit II: two persons received paralumbal steroid infiltration after Visit I and one person suffered from gastroenteritis. In addition, five patients did not appear for Visit III: two persons lacking compliance; one person due to complications from an arterial vascular surgery; one person needed a cholecystectomy; and one person due to paralumbal steroid infiltration.

Fig. 1; Disposition of the patients



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 (Table 1).

Table 1. Demographic characteristics of patients

Group	Age (years) Mean (SD)	Gender (n)	
		Male	Female
Balneotherapy	62.935 (± 9.3)	30	22
Control	60.49 (± 11.81)	28	25

In the group treated with balneotherapy, four patients requested and received other treatment: one person had physiotherapy 10 times starting after Visit I; one person had electrotherapy 10 times from Visit II; one person had electrotherapy and massage treatment 10-10 times from Visit II; and one person continued his ongoing electrotherapy after Visit I.

In the control group, three persons requested and received other treatment: two persons had electrotherapy and massage 10-10 times starting from Visit I; one person had 10 massages starting from Visit II.

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) (Table 2).

Table 2. Developments in the clinical parameters, quality of life, and medicine requirements in the balneotherapy and the control group ($p<0.05$)

	Group	Visit I.		Visit II.		Visit III.		p (I-II)	p (I-III)	p (II-III)
		Mean ± SD	p value	Mean ± SD	p value	Mean ± SD	p value			
VAS level of low back pain at rest	Balneotherapy	52.63 ± 21.02	0.331	34.00 ± 24.17	**0.001**	33.50 ± 26.58	**0.004**	**<0.001**	**<0.001**	0.406
	Control	48.04 ± 24.38		49.62 ± 19.19		46.49 ± 22.47		0.851	0.448	0.297
VAS level of low back pain during activity	Balneotherapy	64.46 ± 18.94	0.117	44.83 ± 23.64	**0.001**	39.83 ± 27.72	**<0.001**	**<0.001**	**<0.001**	0.091
	Control	61.36 ± 16.39		59.79 ± 17.73		58.87 ± 19.48		0.99	0.51	0.991
Oswestry index	Balneotherapy	33.96 ± 19.94	0.47	23.25 ± 17.34	**0.016**	22.49 ± 19.62	**0.006**	**<0.001**	**<0.001**	0.665
	Control	31.17 ± 20.02		32.30 ± 19.48		32.26 ± 18.54		0.325	0.317	0.621
EQ-5D index	Balneotherapy	0.524 ± 0.205	0.147	0.675 ± 0.231	**0.019**	0.696 ± 0.226	**0.003**	**<0.001**	**<0.001**	0.236
	Control	0.583 ± 0.225		0.570 ± 0.212		0.545 ± 0.241		0.476	0.038	0.026
EQ-VAS	Balneotherapy	57.13 ± 18.39	0.246	72.69 ± 17.20	**0.002**	71.92 ± 19.68	**0.001**	**<0.001**	**<0.001**	0.761
	Control	60.85 ± 22.10		59.96 ± 21.39		57.89 ± 21.35		0.417	0.026	0.095
Analgetikum	Balneotherapy	18	0.142	10	**0.003**	9	**0.001**	**0.008**	**0.012**	**1**
	Control	26		25		28		1	0.727	0.453

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) (Table 2).

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) (Table 2).

The EuroQuol-5D index on quality of life also exhibited significant imprment 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) (Table 2).

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) (Table 2).

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) (Table 2).

Discussion

The short- and long-term favorable effects of the thermal water of Budapest B-14 (Peace well) 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 EuroQuol-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 waters [86,87]. During balneotherapy, mechanical and thermal effects might also occur similarly to those at hydrotherapy [55]. 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 [22,54–56,61,88–90].

Although the skin absorption of mineral water is minimal [91], the chemical effect of mineral water is apparent during balneotherapy. This specific chemical effect of balneotherapy as opposed to hydrotherapy is shown in studies published after Pittler's meta-analysis. For example, the results of controlled double-blind studies on tap water in patients with low back pain can be deduced from this specific chemical effect of balneotherapy as opposed to the effect of hydrotherapy [17,18,92].

The beneficial effects of hydrotherapy and balneotherapy on anxiety, depression, and mood have also been described; thus, it can be assumed that this may also play a role in the alleviation of the pain and the improvement in the quality of life [38].

Limitation of the study

A single-blind method was used in our study; therefore, the patients knew the treatment they received. Being all questionnaires self-reported, the assessor was the patient; thus, blinding of assessor was not possible. The influence of placebo effect could not be investigated.

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

Objectives

The primary objective was to measure the hypothesis that underwater traction therapy has favorable effects on LBP (by using adjustments to the therapy based on pain parameters).

Our secondary aim was to analyze whether this treatment method could result in an improvement in the quality of life.

Materials and methods

Design

Controlled follow-up of multicentre randomized comparative study. We used regular outpatient care clinics to recruit patients. We randomly created three groups. Our study protocol followed the principles of the Helsinki declaration. The study participants read and signed the package leaflet and the consent statement before starting the trial.

Participants

Patients suffering from low back pain were selected into three groups at random: receiving a combination of the NSAID medication and underwater traction therapy either traction therapy or only NSAID.

Enrolments 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 lumbal spinal X-ray taken within a year was required to be presented.

Exclusion criteria were the following: osteoporotic vertebral compression fractures, severe spondylolisthesis (grade 2 or above, that mean a vertebral body has slipped forward over the body beneath it more than 50%), malignancy, pain due to inflammatory spinal disease, severe neurological deficit associated with the lower back or general contraindications to balneotherapy (i.e. decompensated cardiopulmonary status, unbalanced endocrinological disease, urine and stool incontinent, infectious disease, fever condition, extensive inflammation/injury/absence of the skin, other severe interstitial and urogenital diseases, decompensated psychosis and neurosis, pregnancy, unconsciousness, and lack of compliance). This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: Number: 21396—3/2017/EKU, Clinical trial registration ID: NCT03488498).

Intervention

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).

Outcomes

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. VAS scores were expressed in millimeters (0 = no pain; 100 = excruciating pain).

Functional disability was assessed by using the Oswestry Disability Index (ODI), a self-reported questionnaire which measures the patients' perceived level of disability in 10 everyday activities (e.g., pain intensity, the changing status of pain, personal hygiene, lifting, walking, sitting, standing, sleeping, social activity, and travelling). The patients scored between 0 and 5 for each of the 10 questions leading to a total score between 0 and 50 that is then expressed in percentage. This questionnaire is validated and has reliability in Hungary [76].

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. This self-administered questionnaire is an accepted, and widely used, standardized instrument for evaluating general health status. This system is composed of five dimensions: mobility, selfcare, usual activities, pain/discomfort, and anxiety/depression. Participants choose from a scale of 1 to 5 based on the level of difficulty they encounter during such situation (no problem, slight problem, moderate problem, severe problem, and extreme problem). Answers along each dimension are rated as a 1-digit number that is combined into a 5-digit number to create an overall score which describes the patient's generic health state. The EQ-5D-5L also included an EQ-VAS scale of 0–100, where respondents rated their general health status (0 being the worst and 100 being the best possible health status) [81].

Furthermore, during the visits, checks for the criteria of inclusion/exclusion and recording the possible side effects were performed.

Randomization

The statistical processing of the data was carried out by an independent person. The study was single blinded: The statistician had received the anonymous information by e-mail.

The groups were created to be homogeneous based on age by the statistician. Patients were examined by independent examiners at each visit. The required sample size per group based on the precalculation test with a power of 80% was 32.

Power test based on VAS during activity values was measured at visit II [93,94]. The surveys (VAS scales of low back pain at rest and during activity and the Oswestry and EuroQol-5D-5L) were self-administered. 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.

Statistical analysis

Statistical processing was done using the IBM SPSS 25 software system.

The dataset was first cleaned from missing values (Table 3).

To detect the improvement of the patients, we calculated the differences between the later and earlier values of the variables. To test the statistical differences of the improvement in the three groups, we ran a one-way repeated measures ANOVA model. We used degrees of freedom correction by Greenhouse-Geisser epsilon (GGeps) to manage the violation-of sphericity ($\varepsilon > 0.62$). 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.

Statistical significance was set at the 0.05 probability level for all tests and is expressed as $p \leq 0.05$ (*), as $p \leq 0.01$ (**), or as $p \leq 0.001$ (***). For the per-protocol analysis, missing values were not replaced and were omitted from the calculation.

Table 3. Summary of the statistical test results

	Eliminated	Total n	n of analysis	GGeps	Groups		
					1	2	3
VAS activity	14	176	162	0.62	42	81	39
EQ-5D-5L	25	176	151	0.65	38	80	33
EQ-5D-5L-VAS	31	176	145	0.67	35	74	36
VAS relax	16	176	160	0.62	42	82	36
OSWESTRY	24	176	152	0.69	39	78	35

Results

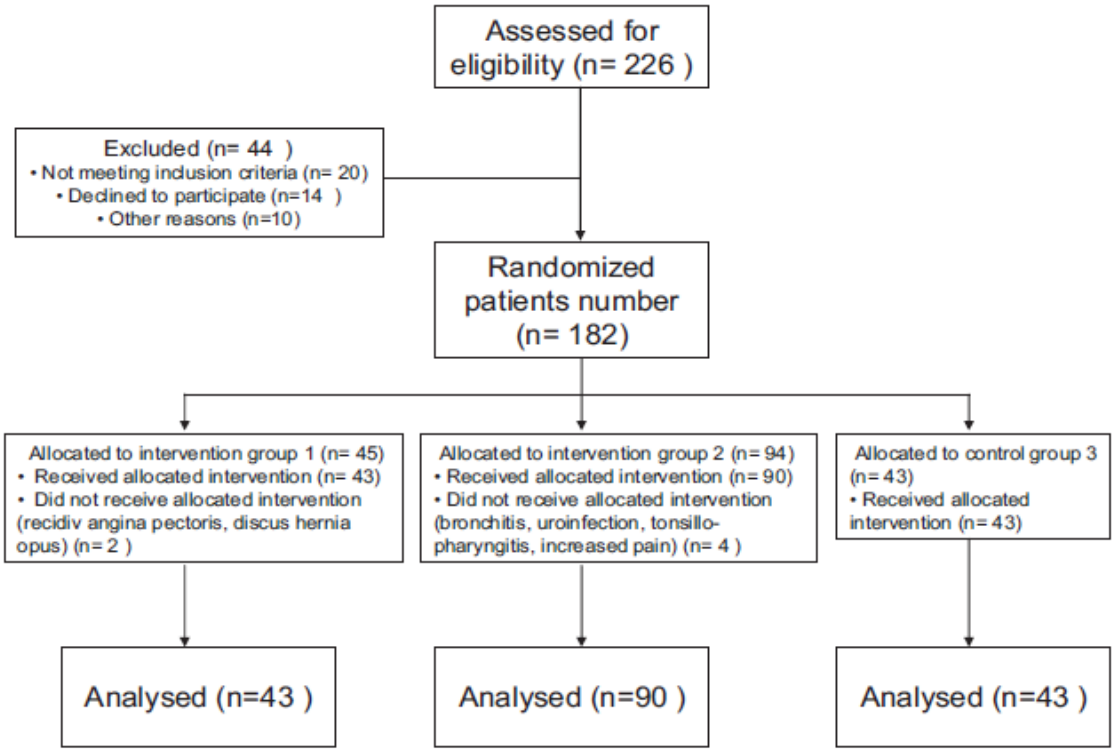
Patient selection and randomization were conducted from June 2017 till January 2019. Participants were aged between 18 and 85 years with more than 3 months of low back pain and selected from outpatient clinics.

Patients participated in three visits: for the first time before the study (Visit I), 3 weeks later, i.e. right after the underwater traction therapy treatments (Visit II), and 12 weeks (Visit III), i.e. after the first visit, after completion of the therapy.

The three groups were comparable in terms of age and baseline clinical characteristics. For the groups where NSAID medications were administered, the doses were provided at a therapeutic level. A total of 226 patients were recruited for the study, and 176 were included in the data analysis. (Figure 2.)

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.

Figure 2. Flow diagram of participants



The demographics characteristics are summarized in Table 4.

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

Table 4. Summary of the demographic's characteristics

Groups	Age (Years), mean (SD)	Gender (n)	
		Male	Female
1. NSAID and underwater traction	58.65 ± 12.83	17	26
2. Underwater traction	61.28 ± 11.01	40	50
3. NSAID /Control/	55.14 ± 13.83	13	30

The VAS values at rest of the chronic low back pain patients decreased significantly in both groups 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 (Table 5).

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 (Table 5).

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 (Table 5). 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 (Table 5).

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

Table 5. Results of the statistical analyses

Change in measured parameter between visits		Group effect	Groups (Mean, SD)		
			1.	2.	3.
VAS Relax	I - II	F(2;157)=4.38*	-25.14 ± 22.76	-23.41 ± 23.01	-11.8 ± 13.86
	II - III		1.09 ± 16.84	-1.43 ± 14.48	-1.56 ± 15.8
	I - III		-24.05. ± 19.84	-24.84 ± 21.8	-13.36 ± 15.64
VAS Level During Activity	I - II	F(2;159)=9.44***	-29.48 ± 24.8	-29.32 ± 22.12	-11.9 ± 14.04
	II - III		-1.00 ± 18.66	-1.19 ± 18.78	-1.77 ± 17.24
	I - III		-30.48 ± 23.27	-30.51 ± 20.23	-13.67 ± 20.32
EQ5D	I - II	F(2;148)=2.94 ns	0.14 ± 0.19	0.14 ± 0.18	0.07 ± 0.15
	II - III		0.01 ± 0.10	0.01 ± 0.09	-0.01 ± 0.13
	I - III		0.15 ± 0.19	0.15 ± 0.18	0.07 ± 0.2
EQ5D-VAS	I - II	F(2;144)=6.47**	15.77 ± 18.39	18.41 ± 16.44	7.03 ± 15.26
	II - III		3.63 ± 10.84	2.53 ± 11.11	0.86 ± 8.71
	I - III		19.40 ± 18.53	20.93 ± 19.17	7.89 ± 15.01
Oswestry	I - II	F(2;149)=1.99 ns	-0.14 ± 0.14	-0.11 ± 0.12	-0.10 ± 0.11
	II - III		0.00 ± 0.10	-0.02 ± 0.08	0.01 ± 0.08
	I - III		-0.14 ± 0.15	-0.14 ± 0.14	-0.08 ± 0.11

ns: not significant, *p<0.05, **p<0.01, ***p<0.001

Discussion

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 occurs. Non-specific low back pain is also a major public health issue in the world.

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 analyzed in a large number of randomized trials, which led us to investigate the impact of underwater traction therapy on LBP.

The origins of traction therapy date back to the time of Hippocrates, who used the Hippocratic ladder for traction. Gallenus applied axial stretching for spinal distortions as part of his therapy. In Hungary, underwater traction therapy has a history of about 60 years.

Until now, only a few studies have been conducted in different traction therapy fields. Current theories regarding its actual physiologic effects indicate that it acutely decreases lumbar

lordosis while it concomitantly increases the intervertebral disc height [41]. Land-based traction therapies have shown uncertain results, such as form motorized lumbar traction, supine traction, and gravitational traction procedure [95,96]. Nevertheless, these weight tractions also increase tension on the posterior longitudinal ligament that increases the force that has been suggested to temporarily reduce the central, posterior displacement of bulging or herniated intervertebral discs and decreases the symptoms [97,98].

Blood supply to vertebral bodies may also improve during traction therapy, which will enhance the primary source of perfusion from vertebral bodies [99].

The effect of traction therapy of the lumbar spine was examined with an MRI in a middle-aged population that showed that traction may significantly improve fluid flow, for at least a short-term, which in turn may influence nutritional inflow and waste product outflow within the matrix of the intervertebral discs [100].

Meanwhile, in small sample size, weight bath traction hydrotherapy study using controlled lumbar MRI did not find detectable anatomical improvements after the treatments, but the lumbar pain intensity did improve [50].

An elongation of lumbar segments (next to each spinous processes) was reported in an underwater traction trial using a subaqual ultrasound measuring method that found that as age progresses, the extensibility of spinal segments decreases [53,101]. The report showed that after the age of 35 the elongation capacity decreases with aging [101].

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.

Limitation of the study

The limitations of this study were the difficulties in blinding the control group due to the nature of the therapy. The number of participants per each group was not identical; a bias possibly resulted from the multicenter selection. The disadvantage of paper-based questionnaires is that missing data does not immediately appear; thus, it is difficult to recover in the future. To confirm our findings, more follow-up studies will be required.

The customization of hanging weights based on patient parameters could also increase the efficiency of underwater traction therapy.

CONCLUSIONS and NEW RESULTS

I. 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.

II. 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 of non-specific low back pain to replace NSAID therapy that has common side effects. Based on our results, for patients suffering from chronic low back pain, underwater weight bath traction therapy has a favorable impact on the pain level at rest as well as during activity. With proper treatment indications this therapy could even shorten the time on patients spend on sick leave.

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Figure 1. The disposition of the patients of non-specific low back pain to the thermal water therapy

Figure 2. Flow diagram of participants of non-specific low back pain to the underwater traction therapy

LIST OF ABBREVIATIONS

CI: Confidence interval

EQ -5D: EuroQoL five dimensions questionnaire

EQ VAS: EuroQoL visual analogue scale

GGeps: Greenhouse-Geisser epsilon

ITT: Intention-to-treat

LBP: Low back pain

NSAID: Non-steroidal Anti-Inflammatory Drug

ODI: Oswestry Disability Index

PROM: Patient-Reported Outcome Measures

RCT: Randomized controlled trial

TENS: Transcutaneous electrical nerve stimulation

SD: Standard deviation

VAS: Visual analogue scale

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APPENDIX

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

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

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ORIGINAL PAPER

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

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Abstract
The aim of this study was to investigate the effects of balneotherapy on chronic low back pain. This is a minimized, follow-up study evaluated according to the analysis of intention to treat. The subjects included in the study were 105 patients suffering from chronic low back pain. The control group ($n = 53$) received the traditional musculoskeletal pain killer treatment, while the target group ($n = 52$) attended thermal mineral water treatment for 3 weeks for 15 occasions on top of the usual musculoskeletal pain killer treatment. The following parameters were measured before, right after, and 9 weeks after the 3-week therapy: the level of low back pain in rest and the level during activity are tested using the Visual Analog Scale (VAS); specific questionnaire on the back pain (Oswestry); and a questionnaire on quality of life (EuroQual-5D). All of the investigated parameters improved significantly ($p < 0.001$) in the target group by the end of the treatment compared to the base period, and this improvement was persistent during the follow-up period. There were no significant changes in the measured parameters in the control group. Based on our results, balneotherapy might have favorable impact on the clinical parameters and quality of life of patients suffering from chronic low back pain.

Keywords Balneotherapy · Mineral water · Chronic low back pain · Controlled · Randomized trial · Thermal water

Introduction

Non-specific low back pain (LBP) 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) (van Tulder et al. 2002). The majority of acute low back pain improved within 4 to 6 weeks without treatment but ca. 10–15% of them are converted into chronic pain (Balagué et al. 2012). About 84% of people have at least one episode of low back pain during their lifetime (WHO Scientific Group on the Burden of Musculoskeletal Conditions at the Start of the New Millennium 2003). Studies show that after the first painful episode occurs, there is a tendency for the pain to recur in 44 to 78% of the cases (Airaksinen et al. 2006).

According to a 2010 data, among non-infectious diseases, chronic back pain is already the main cause of total disability and systematic reviews have shown that global point prevalence of LBP was 9.4% (WHO Scientific Group on the Burden of Musculoskeletal Conditions at the Start of the New Millennium 2003; Balagué et al. 2012; Murray et al. 2012).

Among people on sick leave for more than 6 months with low back pain, less than half will be able to work again, and after more than 2 years of persistent illness, patients are no longer able to return to work (van Tulder et al. 2003). Because of the above, it is also important to treat chronic back pain with the aim of reduction of pain, and the improvement of the motion function (van Tulder et al. 2003). Therapy for chronic

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lumbar pain—based on the existing evidence—is physiotherapy and multidisciplinary (aka biopsychosocial) pain management in the first line. There are also some positive experiences with a brief educational intervention, behavioral therapy (cognitive behavior therapy), drug therapy (NSAIDs, weak opioids, and muscle relaxants), spine schools, mobilization and manipulation, acupuncture, massage, noradrenergic, or noradrenergic—serotoninergic antidepressants and capsaicin patch (van Tulder et al. 2003). Although hydrotherapy and balneotherapy are widely and traditionally used, there are no therapeutic guidelines for using them on chronic low back pain (van Tulder et al. 2003; Rubinstein et al. 2010).

This is partly due to the fact that Anglo-Saxon and Scandinavian countries do not use thermal, mineral water for medical purposes, and at the same time, the number of controlled reports on the effect of balneotherapy on chronic low back pain is still few (Chou et al. 2017).

Balneotherapy is a traditional treatment for chronic musculoskeletal disorders in European countries rich in thermal water, as well as in Japan, Israel, and the Maghreb countries. Consequently, the authors of medical databases, and most of the English publications on the balneotherapy impact on musculoskeletal disorders subject, are Italian, Turkish, French, German, Israeli, and Hungarian. Since Hungary leads as the richest in both mineral and thermal waters, thanks to its favorable geothermic conditions, balneotherapy has also become an accepted treatment measure (Bender et al. 2014).

For the past few decades, evidence-based studies in balneotherapy have overtaken simple and unempirical evidences for earlier experiences that were suggestive that balneotherapy was actually therapeutically significant. Several research studies provide clear and positive conclusions on the effects of thermal water on chronic lumbar pain. In the 2006 Pittler's Meta-analysis, the results of five randomized controlled trials were analyzed, showing the beneficial effects of balneotherapy for chronic low back pain (Pittler et al. 2006).

The analyzed studies investigated the effects of balneotherapy by comparing patients receiving only drug and physical therapies, who were usually on a waiting list for balneotherapy, to those also receiving balneotherapy. In their review, they found that, although relatively little data was available in this field, and extended studies were still needed, the results were encouraging in that balneotherapy does in fact reduce certain physical pains (Pittler et al. 2006).

Since the abovementioned meta-analysis, tap water-controlled studies were published showing that bathing in mineral water has a more favorable effect on pain, motion, and quality of life than bathing in tap water (Balogh et al. 2005; Kulisch et al. 2009; Tefner et al. 2012). Some recent work has also confirmed that balneotherapy used in addition to physiotherapy has a more favorable impact on the clinical parameters and quality of life of patients with chronic low back pain compared to physiotherapy alone (Dogan et al. 2011; Kesiktas et al. 2012; Onat et al. 2014).

Aim of the study

The aim of our study was to determine the impact of the usage of calcium-magnesium-bicarbonate content thermal mineral water of the Dagály thermal bath (aka. Budapest B-14, the "Peace well") on chronic low back pain. Our primary objective was to prove the hypothesis that bathing in thermal mineral water coming from Dagály thermal bath's "Peace well" has favorable effect of LBP using the change in the clinical parameters. Our secondary objective was to evaluate whether it also leads to the improvement in the quality of life.

Methods

Study design

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.

Our study protocol followed the principles of the Helsinki Declaration. The study participants read and signed the package leaflet and the consent statement before starting the trial.

This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: 164-1/20169). The study was also approved by the Institutional Research Committee of the Health Service of Józsefváros.

Participants

The study was conducted at the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service in Budapest, Hungary.

Participants were selected from patients on the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service as well as from visitors of the Dagály Thermal Baths. Participants from the visitors of the Dagály Thermal Bath were recruited by a written advertisement in the bath. The medical examination was carried out at the Department of Rheumatology and Physiotherapy of the Józsefváros Municipal Health Service. The balneotherapy was practiced in the Dagály Baths.

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 can be observed, which may be due to 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.

Those who were excluded from the study were for the following reasons: severe neurological deficit associated with the lower back; pain in the backbone due to osteoporosis, or other causes related to vertebral compression; malignancy; pain due to inflammatory spinal disease; severe spondylolisthesis (grade 2 or above); and general contraindications to balneotherapy: decompensated cardiopulmonary status, unstable hypertension, unbalanced endocrinological disease, fever condition, infectious disease, extensive inflammation/injury/absence of the skin, other severe interstitial, urogenital, and other diseases, urine and stool incontinent, decompensated psychosis and neurosis, unconsciousness, pregnancy, and lack of compliance.

Intervention

The control group received the necessary routine outpatient treatment according to the criteria detailed below. The study group received 3 weeks of balneotherapy on top of the routine outpatient treatments according to the specified criteria. The balneotherapy group was treated 15 times during the 3-week period with thermal mineral water by bathing in the Dagály Thermal Bath for at least 20 min per occasion. The water temperature was 38 °C. Appearance on balneotherapy with the precise dates has been recorded on the study panel. In the pool, the participants could sit, swim, and move freely. The control group did not receive balneotherapy.

During the study, all participants received the usual or necessary medications. For ethical considerations, participants were allowed to perform physical therapy and receive massage, TENS, and ultrasound treatments, as they would have normally done regardless of their participation in the study and these were documented. Participants did not receive any systemic steroid therapy or injections into the affected area. However, when steroid administration was requested by the patient, the patient was excluded from the study.

During the study, the control group was not allowed to receive balneotherapy throughout the whole period while the study group was not allowed balneotherapy in the follow-up period, only. Breaking of this condition would have resulted in exclusion from the study.

The thermal and mineral water in the Dagály Thermal Bath originates from the Budapest B-14th OKK deep-drilled Peace well. The depth of the well is 125.9 m; the water flow is through 118.9–125.6 m from a filtered section. The water layer is Eocene limestone. The total dissolved mineral content of the water exceeds 1000 mg/ml (1080 mg/ml). The water is rich in calcium-magnesium-sodium-bicarbonate, with high hardness (total hardness 259 CaO mg/l, 25.9 nkf) thermal water (water temperature: 38 °C—National Institute of Environmental Health, V.3834/14).

Outcome parameters

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 score them between 0 and 5. The obtained total score is between 0 and 50, and the result is expressed in percentage (Fairbank and Pynsent 2000). This form has validity and reliability in Hungary (Ormos et al. 2003).

Furthermore, there was a questionnaire on the quality of life, known as the EuroQol Five Dimensions Questionnaire (EQ-5D). This is a standardized instrument for measuring generic health status (health-related quality of life) and is a self-administered questionnaire. The questionnaire measures the health status of the respondents along five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Respondents should choose their answers from a scale of one to three (one: no problem, three: extreme problem).

The EQ-5D also included a 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) (Whynes and TOMBOLA Group 2008).

Balneotherapy group member patients filled out the above questionnaires after enrollment, before starting the balneotherapy treatment directly for the balneotherapy group members—(Visit I, week 0); after 3 weeks—directly after the completion of the balneotherapy treatment (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.

Sample size

The required participant number was calculated with G-power test based on VAS during activity values measured at Visit II in 12 cases. Based on that calculation, at least 60 patients had to be selected. By the conclusion of the study, the power of the study turned out to be 98% based on VAS during activity values at Visit III.

Randomization

The creation of initial homogeneous patient groups followed the statistical principle of minimization (Treasure and MacRae 1998; Scott et al. 2002). The statistician has received the information by email.

The control and study groups were created in accordance with the minimization principles based on VAS scores, at rest and during activity, and by age and sex. The two groups were thus homogenous in terms of these parameters. Patients were examined by independent examiners at each visit.

The questionnaires (VAS scales of low back pain at rest and during activity; and the Oswestry and EuroQoL-5D) were self-administered. During balneotherapy, an independent person was available. The statistical processing of the data was carried out by an independent person.

Statistical methods

Statistical processing was done using the IBM SPSS 24 software system. A comparison of age-independent sample *t* test was performed. 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" (Dziura et al. 2013; Molnar et al. 2008). The significance level was $p < 0.05$.

Statistical analysis was performed to assess both the development of the investigated clinical parameters within the balneotherapy group against, as well as to assess the differences between the progress of the balneotherapy and control group.

Results

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.

The study was conducted between September 2016 and February 2017. The patients were selected continuously. The balneotherapy was conducted in September and October 2016.

The data of the participants of the balneotherapy group were only evaluated at Visit II if they participated in a minimum of 80% of the treatments (i.e., bathing at least 12 times).

From the balneotherapy group, after the study started, balneotherapy was suspended for seven patients: three patients with upper respiratory tract infection; one person with cardiac arrhythmia, hypertension, and cardiac decompensation; one person with cystitis; one person with gastroenteritis; and one person became unavailable). In addition, two persons also did not appear for Visit III: one person due to depression and one person because of a persistent upper respiratory tract infection.

In the control group, three patients did not appear at Visit II: two persons received paralumbal steroid infiltration after Visit I and one person suffered from gastroenteritis. In addition, five patients did not appear for Visit III: two persons lacking compliance; one person due to complications from an arterial vascular surgery; one person needed a cholecystectomy; and one person due to paralumbal steroid infiltration (Fig. 1; the disposition of the patients).

Data from all participants was 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 (Table 1).

In the group treated with balneotherapy, four patients requested and received other treatment: one person had physiotherapy 10 times starting after Visit I; one person had electrotherapy 10 times from Visit II; one person had electrotherapy and massage treatment 10-10 times from Visit II; and one person continued his ongoing electrotherapy after Visit I. In the control group, three persons requested and received other treatment: two persons had electrotherapy and massage 10-10 times starting from Visit I; one person had 10 massages starting from Visit II.

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 difference between the two groups was significant in Visit II and Visit III as well ($p = 0.002$ and $p = 0.006$, respectively) (Table 2).

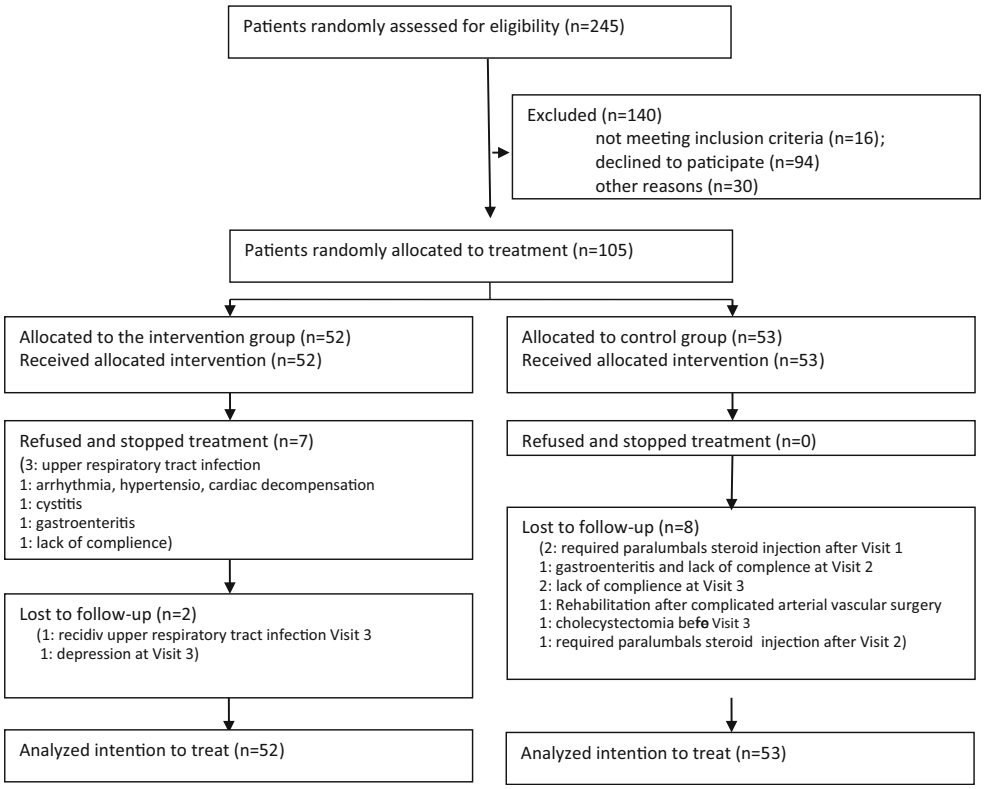

Fig. 1 The disposition of the patients

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. There were no significant changes in the VAS values of the control group. The difference between the two groups was significant at Visit II and Visit III as well ($p = 0.001$ and $p < 0.001$, respectively) (Table 2).

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 difference between the two groups thus was significant at Visit II and Visit III as well ($p = 0.016$ and $p = 0.006$, respectively) (Table 2).

The EuroQuol-5D index on quality of life also significantly improved 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) (Table 2).

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) (Table 2).

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) (Table 2).

Table 1 Demographic characteristics of patients

Group	Age (years) mean (SD)	Gender (*n*)	
		Male	Female
Balneotherapy	62.935 (± 9.3)	30	22
Control	60.49 (± 11.81)	28	25

Discussion

The short- and long-term favorable effects of the thermal water of Budapest B-14 (Peace well) 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 by the VAS scores, the Oswestry,

Table 2 Developments in clinical parameters, quality of life, and medicine requirements in the balneotherapy and the control group

	Group	Visit I		Visit II		Visit III		*p* 1–2	*p* 1–3	*p* 2–3
		Mean ± SD	*p*	Mean ± SD	*p*	Mean ± SD	*p*			
VAS level of low back pain at rest	Balneotherapy ($n = 52$)	52.63 ± 21.02	0.331	34.00 ± 24.17	*0.001**	33.50 ± 26.58	*0.004**	*<0.001**	*<0.001**	0.406
	Control ($n = 53$)	48.04 ± 24.38		49.62 ± 19.19		46.49 ± 22.47		0.851	0.448	0.297
VAS level of low back pain during activity	Balneotherapy ($n = 52$)	64.46 ± 18.94	0.117	44.83 ± 23.64	*0.001**	39.83 ± 27.72	*<0.001**	*<0.001**	*<0.001**	0.091
	Control ($n = 53$)	61.36 ± 16.39		59.79 ± 17.73		58.87 ± 19.48		0.990	0.510	0.991
Oswestry index	Balneotherapy ($n = 52$)	33.96 ± 19.94	0.470	23.25 ± 17.34	*0.016**	22.49 ± 19.62	*0.006**	*<0.001**	*<0.001**	0.665
	Control ($n = 53$)	31.17 ± 20.02		32.30 ± 19.48		32.26 ± 18.54		0.325	0.317	0.621
EQ-5D index	Balneotherapy ($n = 52$)	0.524 ± 0.205	0.147	0.675 ± 0.231	*0.019**	0.696 ± 0.226	*0.003**	*<0.001**	*<0.001**	0.236
	Control ($n = 53$)	0.583 ± 0.225		0.570 ± 0.212		0.545 ± 0.241		0.476	0.038	0.026
EQ-VAS	Balneotherapy ($n = 52$)	57.13 ± 18.39	0.246	72.69 ± 17.20	*0.002**	71.92 ± 19.68	*0.001**	*<0.001**	*<0.001**	0.761
	Control ($n = 53$)	60.85 ± 22.10		59.96 ± 21.39		57.89 ± 21.35		0.417	0.026	0.095
Number of patients taking medicines for low back pain	Balneotherapy ($n = 52$)	18	0.142	10	*0.003**	9	*0.001**	*0.008**	*0.012**	1.000
	Control ($n = 53$)	26		25		28		1.000	0.727	0.453

*$p < 0.05$

and the EuroQuol-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 effects of thermal mineral water for treatment of chronic musculoskeletal disorders nowadays are still subject of many investigations. By definition, mineral water contains mineral solutes in a concentration of 1 g/l at least (Bender et al. 2005).

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 waters (Karagülle et al. 2017; Dandinoglu et al. 2017). During balneotherapy, mechanical and thermal effects might also occur similarly to those at hydrotherapy (Fioravanti et al. 2011).

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 (Melzack and Wall 1965; O'Hare et al. 1985; Oosterveld and Rasker 1994; Pöyhönen and Avela 2002; Bender et al. 2005; Becker 2009; Kalpakcioglu et al. 2009; Fioravanti et al. 2011).

Heat influences the extensibility of collagen-rich tissues and the muscle spasm, presumably reducing pain and improving joint function (Oosterveld and Rasker 1994; Bender et al. 2005; Fioravanti et al. 2011).

Other studies found that balneotherapy decreased the level of inflammatory mediators and had a positive effect on the markers of antioxidant status and cartilage degradation (Fioravanti et al. 2011, 2015; Pascarelli et al. 2016). For example, the effects of balneotherapy on gastrointestinal motility and the effect of antioxidant in patients with rheumatoid arthritis were also demonstrated (Karagülle et al. 2017; Dandinoglu et al. 2017).

Although the skin absorption of mineral water is scarcely given (Shani et al. 1985), the chemical effect of mineral water is apparent during the balneotherapy. This specific chemical effect of balneotherapy as opposed to hydrotherapy is shown in studies published after Pittler's meta-analysis. For example, the results of controlled double-blind studies on tap water in patients with low back pain can be deduced from this specific chemical effect of balneotherapy compared to the effect of hydrotherapy (Balogh et al. 2005; Kulisch et al. 2009; Tefner et al. 2012).

The beneficial effects of hydrotherapy and balneotherapy on anxiety, depression, and mood have also been described; thus, it can be assumed that this may also play a role in the alleviation of the pain and the improvement in the quality of life (Dubois et al. 2010).

The favorable effects of TENS treatment for chronic low back pain based on a small number of placebo-controlled study are not yet supported (Khadilkar et al. 2008). Because of the low number of high-quality randomized controlled trials, and as only a small number of patients were included, the effects of ultrasound therapy on chronic low back pain have not been established yet either (Ebadi et al. 2014). The effects of massage treatment for chronic low back pain have been established that it does in fact relieve pain and improve motor functions that were verified in the short term (Furlan et al. 2015).

TENS, ultrasound, and massage treatments have become necessary for a small number of participants during our study and have shown similar patterns in the two groups, respectively. The beneficial effects of NSAIDs, opioids, and muscle relaxant drugs on systemic chronic low back pain were described and summarized (van Tulder et al. 2003; White et al. 2011; Enthoven et al. 2016) with the possible effects of paracetamol not found convincing from a meta-analysis (Saragiotto et al. 2016). No significant beneficial effects were found for antidepressant drugs (White et al. 2011).

In our study, the number of patients taking NSAIDs, opioids, muscle relaxants, and paracetamols decreased in the group receiving balneotherapy (and correlated with the improvement in clinical status), while showing an increased tendency in the control group.

The drawback of our study is that the specific effects of balneotherapy could not be judged. Similarly to our study, Dogan, Onat, and Kesiktas performed studies which described the combined effect of balneotherapy in addition to physiotherapy and physical therapy, compared to the effects of physiotherapy and physical therapy, alone on clinical parameters and the quality of life of patients with chronic low back pain (Dogan et al. 2011; Kesiktas et al. 2012; Onat et al. 2014). It is important to mention that the method "last observation carried forward" might produce a biased estimate of the treatment effect (Dziura et al. 2013; Molnar et al. 2008).

Consequently, bathing in the number B-14 well (Peace well), thermal mineral water proved to be a therapeutic option in the treatment of patients with chronic low back pain. However, using it for preventative purpose requires further testing.

Limitation of the study

A single-blind method was used in our study; therefore, the patients knew the treatment they received. Being all questionnaires self-reported, the assessor was the patient; thus, blinding of assessor was not possible. The influence of placebo effect could not be investigated.

Conclusion

It can be concluded that routine ambulatory care, coupled with bathing in Dagály 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.

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Compliance with ethical standards This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: 164-1/20169). The study was also approved by the Institutional Research Committee of the Health Service of Józsefváros.

Conflict of interest The authors declare that they have no competing interests.

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ORIGINAL PAPER

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

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Abstract

Low back pain (LBP) is one of the most costly diseases in the developed world. This study aimed to investigate the effects of underwater traction therapy on chronic low back pain. The primary objective was to prove that underwater traction therapy has favorable effects on LBP. Our secondary objective was to evaluate whether it also leads to improvement in the quality of life. This is a prospective, multicenter, follow-up study. A total of 176 patients with more than 3 months of low back pain enrolled from outpatient clinics were randomized into three groups: underwater weight bath traction therapy and non-steroidal anti-inflammatory drugs (NSAIDs); weight bath; and only NSAIDs. The following parameters were measured before, right after, and 9 weeks after the 3-week therapy: levels of low back pain in rest and during activity were tested using the visual analogue scale (VAS), the Oswestry Low Back Disability Questionnaire, and the EuroQol-5D-5L Questionnaire.

The VAS levels improved significantly ($p < 0.05$) in both underwater weight bath traction therapy groups by the end of the treatment, whereas the improvement in the third group was not statistically significant. Furthermore, the improvements measured in the groups receiving traction therapy were persistent during the follow-up period. There were no significant changes in the Oswestry Index or the EuroQol-5D-5L without VAS parameters in any of the groups.

Based on our results, for patients suffering from LBP pain who underwent underwater weight bath traction therapy, there were favorable impacts on the pain levels at rest or during activity. Clinical trial registration ID: NCT03488498, April 5, 2018

Keywords Chronic low back pain · Controlled · Randomized trial · Traction therapy · Underwater therapy · Balneotherapy

Introduction

Low back pain (LBP) is one of the most costly diseases due to its high prevalence level that continuously increases parallel to the aging of the population in the developed world. Based on 165 studies in 54 systemic reviews in 54 countries, its prevalence was estimated to be around 12% of the populations on average, between 1980 and 2009 (Hoy et al. 2012). These values also depended on age and sociological status; the point prevalence and lifetime prevalence could reach 79.2% (Kent and Keating 2005). Non-specific lumbar pain is defined as lumbar pain without any known pathological lesions (e.g., tumor, infection, osteoporosis inflammatory disorder, radicular syndrome, fracture, or cauda equina syndrome) (van Tulder et al. 2002). Trials have shown that the possibility of recurrence of low back pain can range up to 44–78% (Airaksinen et al. 2006).

The range for the first line of defense for therapeutic options for chronic lumbar region pain, based on the existing evidence, is as follows: education, home exercises, self-management physiotherapy, balneotherapy, and multidisciplinary pain management. Other therapeutic options that could have positive effects as an addition to the aforementioned treatments are mineral-rich mud compresses, drug

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therapies (NSAIDs, weak opioids, and muscle relaxants), behavioral therapy, spine schools, mobilization and manipulation, acupuncture and massage therapies, noradrenergic treatment with serotoninergic antidepressants, and capsaicin patch (van Tulder et al. 2003; Abu-Shakra et al. 2014). There are already promising strategies on how to classify the non-specific lower back pain (NSLBP) not yet widespread (Dewitte et al. 2018).

More and more studies seem to be showing that, thanks to the wide range of therapeutic options for LBP patients, surgical intervention has become unavoidable in just certain cases where patients have "red flag" symptoms, which suggest a potentially serious underlying ailment.

With regard to balneo- and hydrotherapy, for the past few decades, evidence-based studies have overtaken simple and unempirical experience and suggest that these therapies actually lead to statistically significant improvement in patients' conditions (Karagülle and Karagülle 2015).

Also, 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 back pains, but the evidence is not yet clear as to which kind of therapy is recommended to whom and when. For example, there are questions as to whether mechanical lumbar traction should be recommended in combination with other treatments or alone, and under which conditions (Thackeray et al. 2016).

In 2012, Dr. Prasad and his colleagues proved that in a small number of those patients on waiting lists for discus hernia surgery, 77% of them who received combined traction and physical therapy did not require surgery (Prasad et al. 2012).

Another study showed that land-based therapeutic exercise in chronic LBP with nerve compression symptoms are not so effective in pain reduction if the patient first receives aquatic traction therapy (Simmerman et al. 2011).

In 2006, a study that included 24 randomized controlled trials (RCT) assessed the effectiveness of traction in LBP management and found that in mixed groups of patients with LBP with and without sciatica, traction therapy cannot be recommended (Clarke et al. 2006).

Two big sample surveys—one in the UK and the other in the USA—showed that various traction delivery modes were used in 41–76.6% of the cases in low back pain therapy (Harte et al. 2005; Madson and Hollman 2015).

Aim of the study

The aim of our study was to examine the effect of underwater traction therapy on chronic low back pain.

The primary objective was to measure the hypothesis that underwater traction therapy has favorable effects on LBP by using adjustments to the therapy based on pain parameters. Our secondary aim was to analyze whether this treatment method could result in an improvement in the quality of life.

Methods

Study design

In this controlled follow-up of multicentre randomized comparative study, we have analyzed the effects of underwater weight bath traction therapy on chronic low back pain.

We used regular outpatient care clinics to recruit patients. We randomly created three groups. Our study protocol followed the principles in the Helsinki declaration. The study participants read and signed the package leaflet and the consent statement before starting the trial. This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: Number: 21396—3/2017/EKU, Clinical trial registration ID: NCT03488498). The study was also approved by the Institutional Research Committees.

Participants

Patients suffering from low back pain were selected into three groups at random: receiving a combination of the NSAID medication and underwater traction therapy either traction therapy or only NSAID.

Participants were selected from patients in the Polyclinic of The Hospitaller Brothers of St John of God, the Aquarius Experience Bath in Sóstó, the Kenézy Gyula University Hospital Medical Department of Bath, the Hungarospa, and St. Andrew Hospital for Rheumatic Diseases in Hévíz.

Enrollment criteria were as follows: outpatients aged 18–85 with non-specific low back pain that persists for at least 12 weeks, showing degenerative symptoms, and suffering from moderately reduced mobility. Patient's pain intensity during activity should have been a minimum of 30 mm on the visual analogue scale (0–100 mm VAS).

Written information on the methodology and process they would be undergoing was provided to each participant, and an informed consent form was subsequently signed before the study. A two-way lumbal spinal X-ray taken within a year was required to be presented.

Exclusion criteria were the following: osteoporotic vertebral compression fractures, severe spondylolisthesis (grade 2 or above), malignancy, pain due to inflammatory spinal disease, severe neurological deficit associated with the lower back, general contraindications to balneotherapy: decompensated cardiopulmonary status, unbalanced endocrinological disease, urine and stool incontinent, infectious disease, fever condition, extensive inflammation/injury/absence of the skin,

other severe interstitial and urogenital diseases, decompensated psychosis and neurosis, pregnancy, unconsciousness, and lack of compliance.

Intervention

Patients were exposed to indifferent water (33–35 °C) for 15–20 min. At the different clinical centers, different components thermal – mineral waters were used but smooth tap water was not used in any of the pools. They 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 3–3 kg (kg) weights attached.

Fifteen weight bath therapy sessions were administered during the 3-week period. The duration of the first session was 15 min; this was extended to 20 min 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: (1) underwater weight bath traction therapy and non-steroidal anti-inflammatory drugs (NSAIDs) medication, (2) underwater weight bath traction therapy, and (3) only non-steroidal anti-inflammatory drug (NSAID) medication in therapeutic dose. The control group 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).

Outcome parameters

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. VAS scores were expressed in millimeters (0 = no pain; 100 = excruciating pain).

Functional disability was assessed by using the Oswestry Disability Index (ODI), a self-reported questionnaire which measures the patients' perceived level of disability in 10 everyday activities (e.g., pain intensity, the changing status of pain, personal hygiene, lifting, walking, sitting, standing, sleeping, social activity, and travelling). The patients scored between 0 and 5 for each of the 10 questions leading to a total score between 0 and 50 that is then expressed in percentage. This questionnaire is validated and has reliability in Hungary (Valasek et al. 2013).

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. This self-administered questionnaire is an accepted, and widely used, standardized instrument for evaluating general health status. This system is composed of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Participants choose from a scale of 1 to 5 based on the level of difficulty they encounter during such situation (no problem, slight problem, moderate problem, severe problem, and extreme problem). Answers along each dimension are rated as a 1-digit number that is combined into a 5-digit number to create an overall score which describes the patient's generic health state. The EQ-5D-5L also included an EQ-VAS scale of 0–100, where respondents rated their general health status (0 being the worst and 100 being the best possible health status) (Whynes and TOMBOLA Group 2008). Furthermore, during the visits, checking the criteria for inclusion/exclusion and recording the possible side effects were performed.

Sample size

The required sample size per group based on the precalculation test with a power of 80% was 32 persons.

Power test based on VAS during activity values was measured at visit II (Springate 2012; Kim 2013).

Randomization

The statistical processing of the data was carried out by an independent person. The study was single blinded: The statistician had received the anonymous information by e-mail. The groups were created to be homogeneous by age by the statistician. Patients were examined by independent examiners at each visit. The surveys (VAS scales of low back pain at rest and during activity and the Oswestry and EuroQol-5D-5L) were self-administered. 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.

Statistical methods

Statistical processing was done using the IBM SPSS 25 software system.

The dataset was first cleaned from missing values (Table 1).

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

To test the statistical differences of the improvement in the three groups, we ran a one-way repeated measures ANOVA model. We used degrees of freedom correction by Greenhouse-Geisser epsilon (GGeps) to manage the violation

Table 1 Summary of the statistical test results

	Eliminated	Total *n*	*n* of analysis	GGeps	Groups		
					1	2	3
VAS activity	14	176	162	0.62	42	81	39
EQ-5D-5L	25	176	151	0.65	38	80	33
EQ-5D-5L-VAS	31	176	145	0.67	35	74	36
VAS relax	16	176	160	0.62	42	82	36
OSWESTRY	24	176	152	0.69	39	78	35

of sphericity ($\varepsilon > 0.62$). 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.

Statistical significance was set at the 0.05 probability level for all tests and is expressed as $p \leq 0.05$ (*), as $p \leq 0.01$ (**), or as $p \leq 0.001$ (***). For the per-protocol analysis, missing values were not replaced and were missed from the calculation.

Results

From June 2017 to January 2019, patient selection and randomization were ongoing. Participants were aged between 18 and 85 years with more than 3 months of low back pain and selected from outpatient clinics.

Patients participated in three visits for the first time before the study, right after the underwater traction therapy treatments, and 12 weeks after the first visit, after completion of the therapy.

The three groups were comparable in terms of age and baseline clinical characteristics. For the groups where it was indicated that NSAID medications were administered, the doses were provided at a therapeutic level.

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 in the study.

A total of 226 patients were recruited for the study, and 176 were included in the data analysis. Figure 1 shows 2 patients who were not able to complete the weight bath treatment in the first group (one of them incurred angina pectoris and was excluded from the study and another who had discus hernia opus developed worsening symptoms before the treatment).

Four patients were not able to complete the weight bath treatment in the second group for various reasons that included the following: bronchitis, uroinfection, tonsillopharyngitis, increased pain in the back spine.

In the third group, all of the patients were able to complete the study, although 3 of them requested and received TENS supplemental therapy.

The demographics characteristics are summarized in Table 2.

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

Outcome measures

The study endpoints were to assess differences in pain levels in the visual analogue scale.

The primary endpoint was to determine treatment effectiveness after 3 months following the underwater weight bath traction therapy.

Statistical analyses

The VAS values at rest of the chronic low back pain patients decreased significantly in the groups 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 in group 2 and group 3 became significant (Table 3).

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 NSAID medication group were found to be significant during visit II as well as visit III (Table 3).

The Oswestry functional disability index change was not significant between the visits in any of the three groups (Table 3). The EuroQol-5D-5L quality of life index change

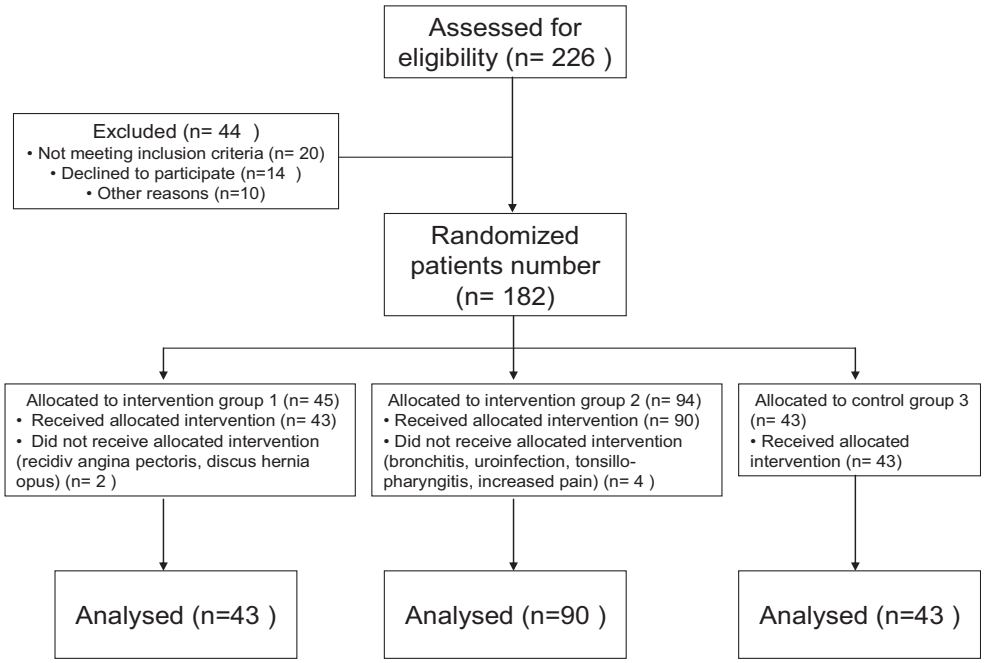

Fig. 1 Flow diagram of participants

was not significant between either of the visits in any of the three groups.

The EuroQol-VAS change showed that the current general health status also improved in the underwater traction therapy groups ($p < 0.01$) while there were no changes in group 3. The differences between the groups were significant during visit II and visit III (Table 3).

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

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Discussion

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 occur. Non-specific low back pain is also a major public health issue in the world.

The lifetime prevalence of low back pain could reach 38.9% (Hoy et al. 2012) It is estimated that about 11–12% of the total population suffers from a disability and functional decline due to low back pain (Airaksinen et al. 2006).

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 analyzed in a large number of randomized trials, which lead us to investigate the impact of underwater traction therapy on LBP. The origins of traction therapy date back to the time of Hippocrates, who used the Hippocratic ladder for traction. Gallenus applied axial stretching for spinal distortions as part of his therapy. In Hungary, underwater traction therapy has a tradition history of about 60 years.

As of now, only a few studies in different traction therapy fields have been run. Current theories regarding its actual physiologic effects indicate that it acutely decreases lumbar lordosis while it concomitantly increases the intervertebral disc height (Pellecchia 1994).

Land-based traction therapies have shown uncertain results, such as form motorized lumbar traction, supine traction, and gravitational traction procedure (Clarke et al. 2006;

Table 2 Summary of the demographic characteristics

Groups	Age (years), mean (SD)	Gender (*n*)	
		Male	Female
1. NSAID and underwater traction	58.65 ± 12.83	17	26
2. Underwater traction	61.28 ± 11.01	40	50
3. NSAID /Control/	55.14 ± 13.83	13	30

Table 3 Results of the statistical analyses

Visits		Group effect	Groups (mean, SD)		
			1	2	3
VAS relax	I–II	$F(2;157) = 4.38$*	$n = 42$	$n = 82$	$n = 36$
			− 25.14 ± 22.76	− 23.41 ± 23.01	− 11.8 ± 13.86
	II–III		1.09 ± 16.84	− 1.43 ± 14.48	− 1.56 ± 15.8
	I–III		− 24.05 ± 19.84	− 24.84 ± 21.8	− 13.36 ± 15.64
VAS level during activity	I–II	$F(2;159) = 9.44$***	− 29.48 ± 24.8	− 29.32 ± 22.12	− 11.9 ± 14.04
	II–III		− 1.00 ± 18.66	− 1.19 ± 18.78	− 1.77 ± 17.24
	I–III		− 30.48 ± 23.27	− 30.51 ± 20.23	− 13.67 ± 20.32
EQ-5D-5L	I–II	$F(2;148) = 2.94$ ns	0.14 ± 0.19	0.14 ± 0.18	0.07 ± 0.15
	II–III		0.01 ± 0.10	0.01 ± 0.09	− 0.01 ± 0.13
	I–III		0.15 ± 0.19	0.15 ± 0.18	0.07 ± 0.2
EQ-5D-5L-VAS	I–II	$F(2;144) = 6.47$**	15.77 ± 18.39	18.41 ± 16.44	7.03 ± 15.26
	II-III		3.63 ± 10.84	2.53 ± 11.11	0.86 ± 8.71
	I-III		19.40 ± 18.53	20.93 ± 19.17	7.89 ± 15.01
Oswestry	I–II	$F(2;149) = 1.99$ ns	− 0.14 ± 0.14	− 0.11 ± 0.12	− 0.10 ± 0.11
	II–III		0.00 ± 0.10	− 0.02 ± 0.08	0.01 ± 0.08
	I–III		− 0.14 ± 0.15	− 0.14 ± 0.14	− 0.08 ± 0.11

Macario and Pergolizzi 2006). Nevertheless, these weight tractions also increase tension on the posterior longitudinal ligament that increases the force that has been suggested to temporarily reduce the central, posterior displacement of bulging or herniated intervertebral discs and decreases the symptoms (Ozturk et al. 2006; Unlu et al. 2008).

Blood supply to vertebral bodies may improve during traction therapy, which will enhance the primary source of perfusion from vertebral bodies (Boos et al. 2002).

The effect of traction therapy of the lumbar spine was examined with an MRI in a middle-aged population that showed that traction may significantly improve fluid flow, for at least a short-term, which in turn may influence nutritional inflow and waste product outflow within the matrix of the intervertebral discs (Mitchell et al. 2017).

Meanwhile, in small sample size, weight bath traction hydrotherapy study using controlled lumbar MRI did not find detectable anatomical improvements after the treatments, but the lumbar pain intensity did improve (Oláh et al. 2008).

However, if we studied the overall impact of swimming, it would most probably be evident that while swimming has beneficial effects on muscles and the spine, in general, because muscles actively engaged in swimming contract, the stretching in the spine is less effective than in an inactive, relaxed position during hydrotraction suspension. Simmerman et al. showed in a crossover trial with 30 participants that the aquatic vertical traction results in short-term improvements of the low back pain (Simmerman et al. 2011).

An elongation of lumbal segments (next to each spinous processes) was reported in an underwater traction trial using a subaqual ultrasound measuring method that found that as age progresses, the extensibility of spinal segments decreases (Kurutz 2006a, b). The report showed that after the age of 35 the elongation capacity decreases with aging (Kurutz 2006b).

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 of intervention. In our findings, the decline in the VAS scale of pain in rest or during activity of LBP patients and the change in the EQ-5D-5L VAS values were significant in those patient groups that underwent traction therapy, proving the improvement in pain sensitivity. However, the Oswestry and the long-term EQ-5D-5L index remained unchanged—as these indexes might have lower sensitivity to change in patients' pain level—indicating that education and guided physiotherapy may additionally be required to improve quality of life. Furthermore, analysis showed that the NSAID medications were not efficient in improving the chronic low back pain that confirmed the results of several earlier investigations.

A study involving a large number of participants investigated the effects of NSAIDs on chronic non-specific low back pain and found it to be minimally significant in terms of pain reduction. After analyzing the Cochrane overview of 13 clinical trials, there was only a low level of evidence regarding the pain-reducing effects of NSAIDs (Enthoven et al. 2016). A larger meta-analysis reviewing the period between 2007 and 2015 looked at the effects of drug treatments for acute and

chronic lower back pain and found that NSAIDs had fewer benefits in chronic lower back pain than previously observed (Chou et al. 2017).

Limitations of the study

The limitations of this study were the difficulties in blinding the control group due to the nature of the therapy.

The number of participants per each group was not identical; a bias possibly resulted from the multicenter selection. The disadvantage of paper-based questionnaires is that missing data does not immediately appear; thus, it is difficult to recover in the future.

To confirm our findings, more follow-up studies will be required.

The customization of hanging weights based on patient parameters could also increase the efficiency of underwater traction therapy.

Conclusion

The underwater weight bath therapy is a conservative and easily accessible treatment method for the treatment of low back pain. Based on our results, for patients suffering from chronic low back pain, underwater weight bath traction therapies have a favorable impact on the pain level at rest as well as during activity.

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Compliance with ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Ethics Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This study was approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKEB) (SE TUKEB Number: 21396—3/2017/EKU).

Informed consent was obtained from all participants prior to being included in the study.

Conflict of interest The authors declare that they have no conflict of interest.

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