ORIGINAL REPORT

EFFECT OF THERMAL WATER AND ADJUNCTIVE ELECTROTHERAPY ON CHRONIC LOW BACK PAIN: A DOUBLE-BLIND, RANDOMIZED, FOLLOW-UP STUDY

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Objective: The aim of this study was to evaluate the effectiveness of thermal mineral water, compared with tap water in the treatment of low back pain.

Methods: This randomized, double-blind, controlled, followup study included 71 patients who underwent 20-minute daily treatment sessions with medicinal water or with tap water, both at a temperature of 34°C, on 21 occasions. Both groups underwent additional adjunctive electrotherapy. Outcome measures were visual analogue scale scores, Schober's sign, Domján's signs, Oswestry disability and Short Form-36 questionnaire. The study parameters were administered at baseline, immediately after treatment, and after 15 weeks.

Results: After treatment, there was a significant improvement in all parameters in the thermal water group. This improvement was still evident after 15 weeks. The improvement in the control group was less substantial compared with baseline values. Comparison of the 2 treatments revealed a statistically significant difference in 3 outcome parameters (visual analogue scale scores III, IV and Schober's index). In the subset of patients who completed the study according to the protocol, the greater efficacy of treatment with thermal water was also confirmed by the other study parameters.

Conclusion: In the group treated with thermal water, improvement occurred earlier, lasted longer and was statistically significant.

Key words: chronic lumbar pain, thermal water, double-blind controlled study.

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INTRODUCTION

Low back pain affects almost 80% of the population over a lifetime. In 90% of cases, symptoms resolve over a period of 2–4 weeks, but recur within one year in 60–80% of patients (1–3). Chronic low back pain is defined as symptoms persisting longer than 7–12 weeks (4).

Chronic lumbar pain is usually accompanied by musculoskeletal pain of other localization, manifestations of the involvement of other organs, and anxiety, as well as by enhanced dysfunctional perception and pain management in chronic cases. In the USA, health expenditure on low back pain totals \$50 billion a year, of which 80% constitutes indirect costs (5). A variety of treatment options is available for the management of chronic low back pain. The usefulness of some of these, particularly exercise and spinal manipulation, has been substantiated by abundant evidence (6).

Balneotherapy involves spending time in an indoor pool filled with mineral water at temperature of 31–34°C. Different types of mineral water may be used in this therapy (7).

Balneotherapy, a medical specialty utilizing the beneficial effects of medicinal waters, evolved especially in countries rich in thermal springs. In addition to its physical properties, the mode of action of thermal water probably involves transcutaneous absorption of mineral solutes. Balneotherapy comprises mud therapy, oral administration of mineral water, and the therapeutic use of naturally occurring gases (8, 9). Hydrotherapy, by contrast, is based on the physical properties of water; this treatment modality is in use all over the world, primarily for the management and rehabilitation of patients with musculoskeletal disorders. This modality does not require the use of thermal water; it is administered using tap water. The terms "spa" (salus per aquam) or "health resort" therapy are used as more familiar and prevalent synonyms of "balneotherapy" (8, 9). Treatment with thermal water is essentially used for the management of musculoskeletal disorders (10). Today, balneotherapy is one component within the framework of complex physiotherapy. The number of studies on the effects of thermal water in the treatment of chronic low back pain is relatively small. The single meta-analysis available in English (11) evaluated pooled data from only 5 studies (12–16). The first single-blind study (17) was published concomitantly with the above meta-analysis. No double-blind studies have been reported so far.

The aim of the current study was to evaluate the effectiveness of thermal mineral water compared with tap water in the treatment of patients with low back pain, with pain level, mobility and quality of life as primary end-points. Secondary end-points were to record changes in the dose requirements of analgesics and explore the safety profile of treatment.

PATIENTS AND METHODS

This study was implemented in observance of the rules of good clinical practice.

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Inclusion criteria

The study was conducted at the spa of Celldömölk in Hungary, which opened in 2005. Male and female patients aged 25-70 years living in and around the town of Celldömölk who presented with chronic lumbar pain of more than 12 weeks' duration were included in the study. Subjects were recruited by 3 local general practitioners (GPs). The 3 GPs and the investigators cross-checked the inclusion and exclusion criteria among themselves before the launch of the study. The GPs invited patients with chronic lumbar pain to participate in the study. Enrolled patients completed the balneotherapy treatment as outpatients, with no change in their daily routine or work attendance. The GPs were on call to deal with potential adverse reactions or other treatment-related problems. All subjects were informed about the purpose, conditions and course of the study prior to inclusion. Patients were given written explanation of the treatment prior to giving their written informed consent. The study protocol was approved by the Regional Research Ethics Committee.

Exclusion criteria

Patients with the following conditions were excluded from the study: acute pain; acute organic neurological deficit accompanying low back pain; confirmed osteoporosis, neoplastic or inflammatory lesion as the underlying cause of low back pain; decompensated cardiovascular disease; unstable hypertension, angina pectoris; uncontrolled endocrine disease (hyperthyroidism, hyperparathyroidism); other uncontrolled and unstable metabolic disorders (diabetes mellitus, hyperuricaemia, hyperlipoproteinaemia); acute febrile infections; cutaneous suppuration; pregnancy; decompensated psychosis/neurosis.

Patients who had received any kind of physiotherapy during the 3-month period prior to the study were similarly excluded.

Course of the study

Patients were randomized into either of the 2 treatment groups. One group was treated with thermal water, whereas the other group was treated with tap water. The water temperature was 34°C for both groups. Subjects underwent 20-min balneotherapy sessions daily for 3 weeks. Both treatment groups received additional electrotherapy under standardized conditions. Diadynamic current (long period current with waist electrodes of standard size, and discharge duration of 3 min) was applied 3 times per week, before the balneotherapy sessions. The patients were monitored continuously during the treatment sessions. The study protocol required patients to attend at least 80% of treatments, i.e. a minimum of 17 balneotherapy sessions.

Baseline and post-balneotherapy assessments were performed by either of 2 rheumatologists. The rheumatologists standardized the methodology of the measurements and tests by jointly examining nonparticipating patients prior to the study. The subjects were assessed 3 times: at baseline, after 3 weeks and after 15 weeks.

Randomization

Randomization was performed by an individual who was not involved in the implementation of the study. It was a simple randomization with a random-number table. Except for the bath attendants, neither the subjects, nor the investigators were aware of the randomly assigned treatment. The investigators examined the study subjects simultaneously, but in different offices. On the first occasion, patients were randomly assigned to an investigator. Subsequently, however, every investigator assessed the same subjects he/she had examined at the first visit. The professional performing the statistical analysis was aware of the randomization.

Evaluations

The properties of low back pain were appraised using 100-mm visual analogue scales (VAS), as follows.

- VAS I: the severity of low back pain at rest, as rated by the patient.
- VAS II: the severity of low back pain upon exertion, as rated by the patient.

- VAS III: perceived status, as rated by the patient.
- VAS IV: the patient's progress, as rated by the investigator.

The range of mobility of the lumbar spine was estimated by performing Schober's test and the Domján R and L tests (the right, left lateral flexion of the lumbar spine in cm) (18). The Oswestry index was used to asses the functions of the lumbar spine. The subjects' quality of life was evaluated with the Short-Form 36 (SF-36) questionnaire.

Thermal water composition

The water source used was the well "Cell-4" at Vulcan Spa, Celldömölk, Hungary. This is a very mild mineral water rich in solutes (sodium hydrogen carbonate and chloride), also containing fluoride and a substantial amount of iodides (Table I).

The appearance of the tap water was changed to resemble that of the thermal water; through the addition of extract of green walnut husks. The characteristic smell of the thermal water was simulated by using bathtubs located in the same hall as the treatments with thermal water were undertaken.

Statistical methods

Data were entered into and analysed with MS Excel software. Statistical comparisons were made using single-sample (paired) and 2-sample *t*-tests.

Intention-to-treat (ITT) analysis was performed. All patients were taken into account upon evaluation of the results. Retrospectively, the likelihood of absenteeism from study visits was not related to the absolute value of missing data and accordingly, these could be regarded as incidental deficiencies. Missing data of drop-outs were substituted with the last measured value in order to avoid over-estimation of the therapeutic effect. A separate analysis (a per protocol (PP) analysis) was carried out for patients who completed the full treatment course in compliance with study requirements. This afforded approximate assessment of efficacy variables following intervention under optimal circumstances. The level of significance was set at p < 0.05.

RESULTS

Recruitment of patients began in January 2007 and the study was launched at the end of February 2007.

Of the 71 patients included in the study, 64 completed more than 80% of the therapy course. Demographic and baseline clinical characteristics of patients in the ITT population are shown in Table II. The 2 treatment groups were similar with regard to demographic data and baseline clinical characteristics.

Seven patients discontinued the treatment period after 3 weeks (5 patients in the thermal group, and 2 patients in the tap water group). A further 13 patients (2 from the thermal water group and 11 from the control group) did not return for

Table I. Mineral	composition	of t	hermal	water
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	Concentration (mg/l)
Mineral	
Sodium	950
Potassium	5.9
Calcium	5.5
Magnesium	1.7
Chlorine	530
Iodide	0.66
Hydrogen carbonate	1600
Fluoride	6.5
Total hardness of water	12 mg/CaO/l
Total solute content	3350 mg/l

Table II. Demographic data and other baseline clinical characteristics
of the 71 patients with low back pain in the intention to treat population,
by treatment group

	Thermal water group $(n=36)$	Control group $(n=35)$
Postoperative condition	6	7
Male/female, n	23/13	23/12
	Mean (SD)	Mean (SD)
Age, years	57.6 (7.9)	56.3 (7.5)
VAS I 0-100 mm	33.9 (19.7)	36.9 (18.8)
VAS II 0-100 mm	63.4 (20.2)	64.4 (17.7)
VAS III 0-100 mm	52.9 (18.6)	46.9 (20.9)
VAS IV 0-100 mm	47.8 (15.3)	47.3 (16.5)
Schober's	8.6 (3.9)	10.7 (4.61)
Domján R, cm	13.8 (3.1)	13.5 (3.7)
Domján L, cm	13.6 (3.1)	13.5 (4.2)
Oswestry	19.5 (9.6)	21.5 (13.5)
SF-36		
PF	58.5 (21.6)	59.6 (24.8)
RP	40.9 (23.9)	45.4 (27.1)
BP	52.7 (16.6)	54.1 (23.2)
GH	43.9 (17.6)	42.9 (16.8)
V	55.6 (21.3)	54.6 (24.8)
SF	73.6 (24)	71.8 (27.3)
RE	52.5 (28.7)	50.7 (24.6)
MH	68.4 (20.3)	66.1 (27)

PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; V: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health; SD: standard deviation; SF-36: Short-Form 36 questionnaire; VAS: visual analogue scale; Domján R and L tests: right and left lateral flexion of the lumbar spine, respectively, in cm.

the 15-week control visit. The disposition of the patients is presented in Fig. 1.

Interpretation of test results

ITT analysis at the end of 3 weeks treatment revealed a decrease in VAS scores for both groups. Within-group comparison to baseline showed significant improvement of pain at rest (VAS I, p < 0.01), lumbar pain on exertion (VAS II, p < 0.01), perceived status as rated by the subjects (VAS III, p < 0.01), as well as the patient's general condition as rated by the investigator (VAS IV, p < 0.01) for both treatment groups. The improvement remained significant for all 4 parameters after 15 weeks in the group treated with thermal water (p < 0.01). In the control group only 2 parameters, VAS II and VAS IV, scores remained significantly (p < 0.05) improved after 15 weeks.

Between-group analysis gave the following results. Within the 3-week study interval patients receiving thermal water therapy showed a significant therapeutic response, with a decrease in VAS IV scores compared with the control group (-14.8 (95% confidence interval (CI) -18.9 to -10.7) vs -8.2 (95% CI -14.1 to -2.4) p < 0.05). After week 15, the changes in VAS III scores between baseline and the end of the study were significantly greater in the thermal water group (-17.6 (95% CI -22.9 to -12.4) vs -5.2 (95% CI -13.9 to 3.4), p < 0.05).

A similar trend was revealed by the results of the tests evaluating the range of motion of the lumbar spine (Schober's, Domján's R-L, Oswestry). While the improvement shown by these 4 tests was still statistically significant after 3 weeks in the thermal water group, only the Domján R and L tests remained significantly improved in the control group (p < 0.05).

After week 15, however, only Domján L and Oswestry scores of the thermal water group were significantly superior compared with baseline values (p < 0.05). At the end of 3 weeks, there was no significant difference when comparing the test results between the thermal water and the control group. Significant improvement was seen after week 15 in the Schober's index in the thermal water group compared with the control group (0.08 (95% CI –1.12 to 1.29) vs –1.79 (95% CI –3.09 to –0.48) p < 0.05).

By the end of week 3 quality of life indicators, SF-36 items (PF: Physical Functioning, RP: Role Physical, BP: Bodily Pain, GH: General Health, V: Vitality, SF: Social Functioning, RE: Role Emotional, MH: Mental Health) improved significantly both in the thermal water and in the control group (p < 0.01) compared with baseline. The improvement in quality of life compared with baseline remained significant for both groups after 15 weeks. Although the improvement after week 15 was still significant compared with baseline, as shown by the PF, RP, BP, GH, V, RE items in the thermal water group (p < 0.01) and by the RP, V, RE items in the control group (p < 0.05), the outcome status of the 2 groups was not statistically different.

The 2 groups were also compared for patients who completed the full treatment course according to the study protocol. A total of 51 patients (29 in the thermal water and 22 in the control

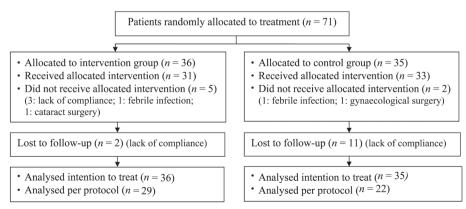


Fig. 1. Disposition of the patients.

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group) were analysed separately (PP analysis). The results were consistent with those of the ITT analysis, but between-group differences and the extent of the therapeutic response showed significantly greater improvement in the thermal water group. Means and 95% CI are shown in Table III. After 3 weeks, significant between-group differences were seen in the changes of VAS IV scores, in Schober's and Oswestry, as well as in SF-36 BP (p < 0.05). After week 15, however, the thermal water group proved significantly superior to controls with regards to the changes in VAS I scores, Schober's, and Domján's L indices compared with their baseline values (p < 0.05). After week 15, none of the SF-36 parameters indicated a significant change in the control group. Comparison of the 2 groups showed that the improvement of PF after week 15 was significantly greater in the thermal water group than in controls (p < 0.05).

No adverse reactions were observed during treatment sessions or during the whole study period. Potential changes in the efficacy of analgesic therapy could not be monitored, due to the small number of subjects who took analgesics regularly; statistical analysis of this parameter therefore proved unfeasible.

DISCUSSION

Overall, study parameters indicated a tendency for positive physiological changes in both groups. In the group treated with thermal water, improvement occurred earlier, lasted longer, and was statistically significant in more patients, both in withingroup and in between-group comparisons. Compared with controls, however, the statistically significant difference (in VAS III, VAS IV scores and Schober's index) between the groups was smaller than the (more substantial) improvement expected on theoretical grounds. While the analgesic effect of thermal water is well known, the short-term relief seen among controls emphasizes the beneficial, relaxing effect of hydrotherapy with hot water (8). In contrast to the ITT analysis, the PP analysis demonstrated the advantage of the thermal water group over controls, as reflected by the improvement in a greater number of study parameters (VAS IV, Schober's, Oswestry, SF-36 BP on week 3 and VAS I, Schober's, Domján L, SF-36 PF on week 15). Evidently, the statistical power of the PP analysis is weaker in a double-blind placebo-controlled trial; however, presenting the results of patients who have completed the study in compliance with the protocol was deemed important, to demonstrate the statistical significance of differences in addition to the statistical trend revealed.

The first controlled, double-blind study of balneotherapy was reported in the literature by Hungarian authors in 1989 (19). Since that time, an increasing number of papers have been published on the favourable effects of balneotherapy in a variety of musculoskeletal disorders including rheumatoid arthritis (20), ankylosing spondylitis (21), osteoarthritis (22, 23) and fibromyalgia (24). The cost-effectiveness of this treatment modality is well known (25). The majority of papers regard treatment with thermal water as an element of complex therapy, although there are also reports on monotherapy. In our study, adjunctive electrotherapy did not exert any substantial

Table III.	Statistical analysis	of changes ove	Table III. Statistical analysis of changes over 3 and 15 weeks, compared with baseline; comparison of the nature of changes and of treatment groups	vith baseline; comparison of th	he nature of chang	es and of treatment groups		
	Baseline		Changes observed after 3 weeks	eks		Changes observed after 15 weeks	sks	
			Thermal water $n=36$	Control $n=35$	Comparison	Thermal water $n=36$	Control $n=35$	Comparison
	Thermal water Control n=36 $n=35Mean (SD) Mean (S$	Control $n = 35$ Mean (SD)	Mean 95% CI Nature of change	Mean 95% CI Nature of change	of between- group difference	Mean 95% CI Nature of change	Mean 95% CI Nature of change	of between- group difference
VASI	33.9 (19.7)	36.9 (18.8)	-13.2 -18.5 to -7.9	-9.97 -14.7 to -5.3	NS	-9.2 -14.8 to -3.7	-4.9 -11.1 to 1.3	NS
			<i>p</i> <0.01	p < 0.01		p<0.01 (_11_2_95% CT_18 to_4_5)*	NS (_0.6.95% C1 _8.4 to 7.2)*	(n < 0.05)
VAS II	63.4 (20.2)	64.4 (17.7)	-17.7 -24.9 to -10.5	-18.9 -26.7 to -11.2	NS	-19.9 -27.1 to -12.7	-11.2 -19.2 to -3.15	NS
VAS III	52.9 (18.6)	46.9 (20.9)	p < 0.01 -18.7 -24.9 to -12.8	p < 0.01 -12.1 -19.9 to -4.3	SN	$p^{<0.01}$ -17.6 -12.4 to -22.9	p < 0.05 -5.2 -13.9 to 3.4	p < 0.05
VA S IV	478(153)	473(165)	p<0.01 14.8	p<0.01		p < 0.01 (-19.3 95% CI -24.9 to -13.7)* -0 2 2	NS (-6.7 95% CI -17.9 to 4.6)* 7 7	(<i>p</i> =0.057)*
			-18.9 to -10.7 $p < 0.01$	-14.1 to -2.4 $p^{<0.01}$	p < 0.05	-13.7 to $-4.6p < 0.01$	-12.96 to $-1.4p < 0.05$	NS

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<i>p</i> <0.01 NS	–1.75 to 14.55 NS
	NS
*Results vielded by the ner motocol analysis and at variance with those of the intention to treat analysis	

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analgesic effect. Only a few studies have investigated the effects of diadynamic current (26). According to the, hitherto only, tap water-controlled, single-blind study of ours, long-term relief of pain, muscle spasm and tenderness of paravertebral muscles, as well as the improvement of the range of motion of the lumbar spine was significant in the group treated with thermal water (containing sulphur) only. In their study on outpatients undergoing therapy for low back pain, Konrad et al. (15) reported the results of treatment with 3 different modalities (thermal water, underwater jet massage, weight bath) in comparison with untreated controls. All 3 groups on active treatment improved, and one year later their analgesic dose requirements were lower than that of controls (15). According to Constant et al. (13), spa therapy enhanced the quality of life evaluated with the Duke Health Profile Questionnaire of 128 treated patients (compared with that of 96 controls) and improvement persisted 3 months later. Other French authors compared the effects of 3-week balneotherapy (15-min underwater jet massage in 36°C water, followed by 3-min showering with water of 31-36°C temperature) with that of outpatient management, in patients with low back pain. Analgesic use (upon prescription by the family practitioner) was allowed in both groups, but other modalities of physiotherapy were not. Assessments were undertaken at baseline, on day 26 of treatment, and 9 months after the end of therapy. Compared with controls, the improvement of several parameters (VAS score, Schober's sign, lumbar spine mobility, reduction of analgesic requirements) was evident immediately after treatment, and (except for the Waddell disability score) proved lasting even 9 months later (12). Another French study randomized 121 patients with low back pain into 2 groups treated with either balneotherapy (for 10 min, followed by packing with 45°C mud for 20 min, and then, high-pressure showering for 2.5 min) or with pharmacotherapy only. Study parameters (Schober's index, finger-floor distance, pain scale scores, Roland & Morris Disability Questionnaire, analgesic requirements) were substantially improved immediately after treatment and 6 months later, thereby demonstrating the long-term effect of balneotherapy (13). Several papers have discussed the methods developed for measuring the efficacy of spa therapy (27, 28). In contrast to previous appraisals of spa therapy, our study compared thermal water with tap water, and not with pharmacotherapy of other treatment modalities. By doing so, medicinal water containing mineral solutes was shown to be a more effective treatment than tap water, which exerts physical only effects.

In conclusion, treatment with hot water is an effective treatment modality for the management of chronic lumbar pain. In view of the differences between the groups treated with thermal vs tap water, balneotherapy with the former may be regarded as a more effective basic treatment modality, as well as an efficient adjunct to pharmaco- and physical therapy, owing to the addition and enhancement of positive effects. This modality is another proven adjunct to the therapeutic armamentarium comprising, among others, drug treatment and physical therapy. In view of the enormous burden imposed on society by low back pain, other degenerative musculoskeletal disorders, as well as dermatological and metabolic disease, familiarizing patients and their doctors with this treatment modality seems justified and useful (29).

The authors have declared no conflicts of interest.

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