Effectiveness of Spa Therapy in Chronic Low Back Pain: A Randomized Clinical Trial

FLORENCE CONSTANT, JEAN FRANÇOIS COLLIN, FRANCIS GUILLEMIN, and MICHEL BOULANGÉ

ABSTRACT. ***Objective.*** To assess the overall effectiveness of spa therapy compared with usual routine drug therapy in chronic low back pain (LBP).

Methods. One hundred and twenty-one patients were randomly allocated to treatment (n = 59) and control (n = 62) groups. In the treatment group, patients underwent routine drug therapy and spa therapy 6 days/week for 3 consecutive weeks in Saint-Nectaire, France. In the control group, patients received routine drug therapy. Effectiveness was assessed based on clinical measures, duration and intensity of pain, Roland and Morris' disability questionnaire, the patient's overall evaluation of back health, and drug consumption (analgesic and antiinflammatory). Groups were compared using analysis of covariance with repeated measures.

Results. At 3 weeks, patients in the treatment group had significant improvement in all outcome variables ($p < 0.0001$) except for the Schober index and analgesic and antiinflammatory drug consumption. At 6 months, improvement was still significant for the same outcome variables ($p < 0.0001$), plus a significant reduction in analgesic consumption.

Conclusion. This study suggests both immediate and 6 month effectiveness of spa therapy in chronic LBP. Spa therapy may be beneficial in the management of chronic LBP. (*J Rheumatol 1995;* **22:1315–20)**

Key Indexing Terms:
BALNEOTHERAPY CLINICAL TRIAL LOW BACK PAIN FUNCTIONAL DISABILITY

From various studies in North America and in Europe, it is estimated that 60 to 90% of the adult population suffers from low back pain (LBP) at least once in a lifetime[1-4]. Chronic LBP has a significant impact on functional ability[5,6], restricting occupational activities, with marked socioeconomic repercussions[7-9].

Functional disability (FD) is an important dimension of quality of life in LBP sufferers. It has been studied as a function of the natural history of the disease and used as an outcome for treatment effect[10-14]. In particular, Roland and Morris have developed a questionnaire measuring the functional impact of LBP[15].

Different therapies are used in chronic LBP, namely, antiinflammatory and analgesic drugs, kinesitherapy, and various types of physiotherapy. Spa therapy has also been used for many years in the treatment of chronic LBP with no scientific evidence of its effectiveness[16-18], as recently emphasized[19]. Mainly performed in Europe, spa therapy is an alternative treatment for several chronic diseases. It comprises a set of treatments administered together in a unique setting during a fixed period of time. In recent years, the effectiveness of spa therapy has been assessed in therapeutic trials in several rheumatic diseases[20-24] although randomized clinical trial methodology is difficult to implement in this field[25].

Short and longterm positive effects of spa therapy in chronic LBP were suggested in a previous randomized trial[26]. To confirm these results and to quantify the overall impact of spa therapy, we conducted a randomized clinical trial of spa therapy in chronic LBP sufferers using physical measures, functional disability, and drug consumption as outcome variables.

MATERIALS AND METHODS

This six month, prospective, single blind, randomized controlled clinical trial of spa therapy in chronic LBP was performed at the spa resort of Saint-Nectaire, France, from April to November, 1993.

Patient selection. Patients were randomly allocated to receive either an immediate 3-week course of spa therapy (treatment group) or a spa therapy postponed for a 6-month period (control group). Thus, all patients were assured of a spa therapy treatment. The postponement of spa therapy in the control group was for ethical and methodological reasons only. The outcome of this treatment in the control group is not reported here.

The patients living within 40 km of the spa resort were recruited by general practitioners (GP) in the Saint-Nectaire area. GP did the primary screening on the basis of clinical data and other investigations and then, referred patients to the physician investigator (FC), who verified patient eligibility criteria.

Patients of both sexes without age limitation were included in the study. They experienced chronic LBP, a syndrome defined as pain between the 12th rib and the gluteal fold, lasting for at least one year.

The exclusion criteria were common contraindications to spa therapies[27]:

From the Institute of Hydrology and School of Public Health, University of Nancy I, Faculty of Medicine, Nancy, France.

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F. Constant, MD; J.F. Collin, PharmD, PhD, Institute of Hydrology; F. Guillemin, MD, PhD, School of Public Health; Professor M. Boulangé, MD, Institute of Hydrology.

Address reprint requests to Dr. F. Constant, Service d'Hydrologie et de Climatologie Thérapeutiques, Faculté de Médecine, Université de Nancy I, BP 184, 54505 Vandoeuvre-les-Nancy Cedex, France.

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(1) acute diseases and acute flare-up of chronic diseases, (2) cancer, (3) evolutive pulmonary tuberculosis, (4) severe renal insufficiency, (5) alcoholic cirrhosis, (6) advanced senility and severe mental disorders, (7) decompensated cardiac insufficiency, and (8) badly controlled severe high blood pressure; and the following diseases: (1) inflammatory rheumatism (ankylosing spondylarthritis, spondylarthropathies, rheumatoid arthritis), (2) evolutive disc herniation requiring surgery, (3) sciatica or pain radiation below the gluteal fold.

Moreover, the patients who had undergone previous spa therapy within the 6 months were not included to avoid a possible residual effect of previous spa therapy.

Sequence of investigations. A coordinator was trained to inform patients and GP about the trial and to refer patients to the physician investigator, who worked independently of the spa resort staff. Patients were recruited within a 10-day period.

Every patient met the investigator, who checked the patient eligibility criteria. After inclusion, patients were randomly allocated to either the treatment or control group. To maintain blinded investigation, randomization was performed by the coordinator, based on a preestablished list of random numbers.

The appointments and the treatment course were managed by the coordinator to keep the investigator blinded throughout the study. Before each examination, patients were instructed not to mention whether they received spa therapy or conventional therapy.

The patients in both groups were examined by the same investigator 3 times. The first examination was at baseline, immediately before randomization, the 2nd was after 3 weeks (at the end of spa therapy) to assess short term effectiveness, and the 3rd occurred 6 months after baseline examination to assess middle term effectiveness.

The study protocol was approved by the Persons' Protection Committee in accordance with legislation and regulation on confidentiality and ethics. Every patient gave informed written consent.

Treatments. Control group. Patients received conventional care (routine drug therapy) from their physician (GP), with prescriptions including antiinflammatory and analgesic drugs as necessary.

Treatment group. Patients also received routine drug therapy from their physician (GP), with prescription as necessary.

In addition to conventional care, patients in this group received spa therapy. This therapy was administered 6 days/week for 3 consecutive weeks. It comprised a comprehensive set of standard treatments including spa mineral water and specific spa techniques such as those routinely administered in spa resorts. It consisted of a daily ambulatory treatment, including (1) a 10 min bath at 36°C with underwater flow, (2) a local application of mud at 45°C for 20 min, (3) a 2.5 min high pressure shower at 36°C with a massage device with regulated pulse flow. Saint-Nectaire mineral water is of mixed bicarbonate, chlorine, and sodium composition. Its total mineral content is 8073 mg/l and it emerges from the spring at a temperature of 38.5°C.

All patients enrolled lived within 40 km of the resort area, returned home every day, and continued activities of daily living (ADL).

Control and treatment groups. Rehabilitation therapy and physiotherapy were not permitted during the trial. No instructions were given regarding the practice of specific physical exercises.

Clinical assessment. At each examination, the following outcome variables were recorded by the investigator.

The Schober index. The Schober index was measured in standing position[28]. The spinal process of the L5 was located with the patient in a standing position and marked with a line and a 2nd line was drawn at a distance 100 mm below. This distance between the 2 lines was then measured in a position of maximum anterior flexion of the trunk. The Schober index is the difference between the 2 distances.

Finger-floor distance. Finger-floor distance was measured after anterior flexion of the trunk with knee extended.

Pain. Pain intensity was assessed with a 0–100 mm visual analog scale (VAS) varying from no pain (0) to intolerable pain (100). Daily duration of pain was noted.

Disability questionnaire[15]. FD was assessed with a validated French adaptation of the Roland and Morris disability questionnaire[29]. It is a self-administered questionnaire of 24 items with dichotomic responses. The final score varies from 0 (no disability) to 24 (severe disability). This questionnaire assesses FD in LBP in ADL on that particular day. The questionnaire was filled in at baseline, 3 week and 6 month examination times. It was also mailed to every patient at 2 and 4 months from baseline.

Patient evaluation. Overall patient evaluation of back health was recorded on a 0–100 mm VAS. The measure varies from very bad (0) to excellent (100).

Drug consumption. Drug consumption (analgesic and antiinflammatory) was recorded in a diary bearing drug names and daily dose. The number of tablets taken each week was noted in each category. The diary was filled in during the week preceding each FD assessment and returned to the investigator at each examination (baseline, 3 weeks, 6 months) and during the week preceding each 2 and 4 month assessment of FD and returned by mail.

Pain measures, FD and the patient overall evaluation of back health expressed the patient's perception of disease, while other outcome measures represented physician assessment of the disease severity.

Statistical analysis. The baseline characteristics in both groups were compared by Student's t test for continuous variables and the χ^2 test for categorical variables.

An analysis of covariance (ANCOVA) with repeated measures[30–32] was performed to compare the magnitude of change from baseline, at 3 week and at 6 month examination in each group, allowing to adjust for the effect of a possible baseline difference between groups. An ANCOVA with repeated measures was also adapted to take into account measures of FD and drug consumption repeated (thus correlated) in time in each subject in the trial. The treatment (spa) effect was assessed by the time × group interaction term.

Prior to analysis the underlying assumptions required for the use of an ANCOVA were checked: (1) the observations within each group were normally distributed with a common variance, (2) the sphericity assumption was not rejected, i.e., the correlation between the measurements for any 2 levels of the within factor (factor with repeated measures) is equal to the correlation between any other 2 levels, (3) within each group, the dependent variable had a linear relationship with the covariates, and (4) the slope of the regression line for each covariate was the same in each group (i.e., lines were parallel). Only the last assumption was not satisfied in every covariate, but such analysis is robust to nonfulfillment of this assumption[30].

All analyses were performed using BMDP software[31].

RESULTS

One hundred and twenty-eight patients were referred to the study center. After checking the eligibility criteria, the physician investigator excluded 2 patients from the trial. One patient had uncontrolled severe high blood pressure; one had an acute episode of LBP. Four patients withdrew from the treatment group before completing their spa therapy (3 for family reasons, one after an automobile accident). In the control group, one patient withdrew within the first week for personal reasons. There was no additional withdrawal of patients at other times of examination.

Baseline characteristics. In April, 1993, 126 patients were included in the study (94 women, 32 men, mean age 52 years). There was no statistically significant difference between groups at baseline examination either in demographic data or in clinical measures. The FD was not significantly

different in both groups (mean of both groups combined 8.9). All clinical indices were slightly worse in the treatment group (Table 1). The pretrial analgesic drug consumption (in the previous week) was not significantly different between groups (mean = 5.9 tablets taken in the past week). The pretrial nonsteroidal antiinflammatory drug (NSAID) consumption was significantly higher in the treatment group ($p = 0.04$).

Eighty-four percent of patients in the treatment group and 82 in the control group had never previously undergone a spa therapy. In the remainder, the preceding spa therapy occurred at least 12 months before.

Three-week results. The first postspa therapy examination took place at an average 28 days from baseline. It showed a statistically significant improvement in patients' health status in the treatment group ($n = 59$) compared to the control group ($n = 62$). In the treatment group, the pain duration decreased by 71.9%, pain intensity by 52.8%, finger to floor distance by 37%, and FD by 36.8%. Patient overall evaluation of back health improved by 70.3%. Schober index and analgesic and antiinflammatory drug consumption did not improve significantly (Table 1).

Six-month results. At 6 months, a significant improvement in the treatment group persisted, compared to the control group (Table 1). Pain duration, pain intensity, finger to floor distance and FD were still reduced, respectively, by 73, 48.4, 44.8, and 53.6% from baseline. Furthermore, analgesic drug consumption decreased significantly by 46.6%. Schober index improved and the antiinflammatory drug consumption decreased. These almost reached the significance level set for the analysis.

Change over time of FD and drug consumption. The overall response rate to the questionnaire and diary was 100% at each measurement time. An ANCOVA with 5 time repeated measures (baseline, 3 weeks, 2, 4 and 6 months) was performed for FD and drug consumption. It showed a significant decrease of FD ($p < 0.0001$), of analgesic drug consumption ($p = 0.001$), and of antiinflammatory drug consumption ($p = 0.002$) in the treatment group compared with the control group. Figure 1 shows the change of FD over time in both groups.

DISCUSSION

Our randomized controlled clinical trial demonstrated the overall positive effects of spa therapy at 3 weeks and 6

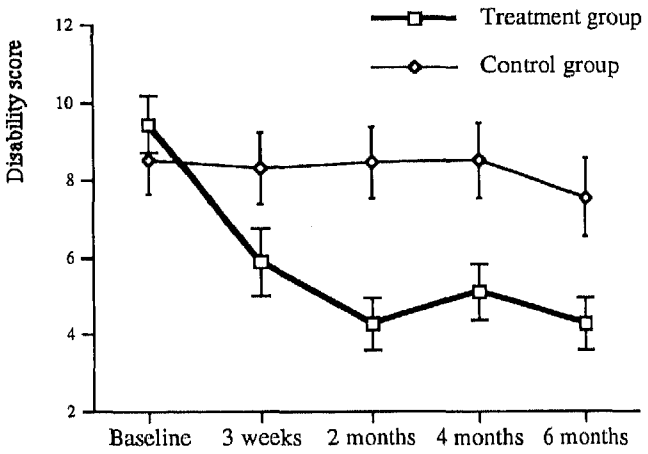

Fig. 1. Change in functional disability over time in both groups. The mean disability score is represented with its associated 95% confidence interval.

Table 1. *Baseline characteristics of patients, and change at 3 weeks and 6 months*

	Baseline Value			3 Week Change**			6 Month Change**		
	Treatment Group $n = 63$ mean (SD)	Control Group $n = 63$ mean (SD)	p*	Treatment Group $n = 59$ mean (SD)	Control Group $n = 62$ mean (SD)	p***	Treatment Group $n = 59$ mean (SD)	Control Group $n = 62$ mean (SD)	p***
Daily duration of pain (h)	8.9 (5.2)	7.5 (4.9)	0.14	−6.4 (5.7)	−1.4 (3.4)	<0.0001	−6.5 (4.8)	−1.3 (4.7)	<0.0001
Pain intensity (VAS) (0–100 mm)	46.2 (20.2)	42.1 (21.6)	0.27	−24.4 (28.6)	−3.8 (20.5)	<0.0001	−22.4 (28.0)	+1.0 (22.6)	<0.0001
Finger-floor distance (cm)	11.6 (10.7)	10.7 (11.3)	0.62	−4.3 (10.9)	+2.4 (6.4)	<0.0001	−5.2 (8.4)	+1.0 (9.6)	<0.0001
Schober index (mm)	30.6 (8.9)	31.0 (10.1)	0.78	+4.4 (8.1)	+3.1 (8.8)	0.38	+8.8 (8.4)	+4.7 (8.1)	0.025
Overall patient evaluation of back health (VAS) (0–100 mm)	39.1 (16.2)	44.1 (20.2)	0.13	+27.5 (22.8)	+5.4 (21.8)	<0.0001	+28.7 (24.6)	+1.6 (24.6)	<0.0001
Disability questionnaire (0–24)	9.5 (4.1)	8.4 (4.8)	0.21	−3.5 (4.4)	−0.1 (2.7)	<0.0001	−5.1 (4.4)	−0.9 (3.4)	<0.0001
Drug consumption (number of tablets taken each week)									
Analgesic	7.5 (11.6)	4.4 (7.3)	0.07	−4.0 (9.2)	−0.5 (6.2)	0.016	−3.5 (11.6)	+2.1 (11.5)	0.0116
NSAID	4.6 (8.8)	1.9 (5.2)	0.04	−1.9 (8.0)	+0.0 (5.6)	0.10	−2.0 (8.9)	+1.9 (8.4)	0.028

* p Value for between group baseline comparisons.

** Change over time of outcome variables is the mean of differences (3 weeks − baseline) and (6 months − baseline).

*** p Value for between group changes over time at 3 weeks and 6 months from ANCOVA with repeated measures (α level = 0.012 to account for multiple testing).

SD: Standard deviation.

months for the treatment of chronic LBP in a French setting. There was evidence of an immediate effect in all the outcome variables except Schober index and analgesic and antiinflammatory drug consumption. At 6 months there was a persistent significant effect as assessed by the same variables, plus a reduction in analgesic drug consumption. The change in Schober index and antiinflammatory drug consumption approached statistical significance.

The finger to floor distance decreased significantly at 3 weeks and 6 months, while Schober index did not. However, as Waddell[33] emphasizes, lumbar flexion as measured by Schober index is often not modified in chronic LBP and although this index has been widely used since the 1940s to assess the severity of chronic LBP, it has not been subjected to proper validation. In our previous study[26] we observed a moderate significant improvement of Schober index and a diminution of the finger to floor distance at 9 months.

Using the LBP specific disability questionnaire as outcome measure, there was a significant reduction of an average 5 points at 6 months on a scale ranging from 0 to 24. This change was considered clinically important because it represented significant improvement in the ability to perform 5 ADL, e.g., including to put on shoes, to get up from a chair, to remain standing, to walk for a long period of time and to go up steps.

All the subjective measures, i.e., pain duration and intensity, and FD (measured by the disability questionnaire) decreased significantly after spa therapy. Thus one of the objectives of treatment in chronic LBP was achieved, namely, relief of pain and the recovery of function[33]. Overall patient evaluation of back health improved. These results expressed the perception of patients and confirmed the impact of spa therapy on patients well being.

Analgesic drug consumption decreased significantly at 6 months in the treatment group. No specific instruction was given regarding drug prescription and consumption. So, this decrease was probably linked to improvement of the patients' overall state of health. However, the interpretation of such a decrease is probably more complex because of the interrelations between spa therapy, drug consumption, and FD. Our results were consistent with other studies in chronic LBP[22,26], which showed a persistent decrease in drug consumption in the treatment group at 9 months and one year. Our study documents the impact of spa therapy on drug consumption accurately recorded in the 7 days before each of 5 repeated measures. The changes in drug consumption are studied in relation to health status outcomes relevant to the condition.

Our trial was designed simply to assess the overall effectiveness of spa therapy, without consideration of its possible mechanisms of action. Nevertheless, it seems likely that the effectiveness of spa therapy results from a combination of many factors. First, the effects of mineral water may be related to its mineral content, temperature, and mode of administration (internal or external)[18,34-36]. Second, the specific techniques (bath, shower, thermal mud application, etc.) may contribute to the effect of spa therapy[21,23,37]. Furthermore, patients undergoing classical spa therapy may benefit from additional treatments such as physiotherapy procedures, which were not assessed in this trial. Third, the change of climate and lifestyle are often said by patients and physicians to account for a part of the spa therapy effect. This assumption has never been investigated, but such a potentially confounding effect was avoided since recruited patients lived in the area close to the spa resort and returned home every day, so that their daily lifestyle and climate exposure was unchanged.

Because our objective was to document the effect of spa therapy as a whole, it was not possible to use a double blind study methodology. However, it was possible to limit methodological biases. To avoid measurement bias, a coordinator was responsible for randomization, organization of appointments and course of treatment, so that the investigator was blinded for the duration of the study. The investigator had no access to patient records at the times of clinical assessment.

Because our control group received conventional care and our treatment group received conventional care plus spa therapy, we cannot exclude that the difference observed between groups is partly due to placebo effect. The observed effectiveness of our spa therapy might be the result of 3 factors[38]: (1) the specific effects of treatment attributable to spa therapy (mineral water, specific spa techniques, social and physical environment), (2) the natural history of chronic LBP and regression to the mean, and (3) the nonspecific effects of treatment attributable to factors other than active components (the placebo effect). For these reasons, one would ideally wish to administer a placebo treatment to the control group. Unfortunately, we were unable to design a suitable placebo for spa therapy as this comprises a comprehensive set of different treatments administered together in a unique setting. However, the duration of beneficial effect (6 months) in relation to the short duration of spa therapy (3 weeks), might suggest the hypothesis that it is not solely the result of a placebo effect. Moreover, from a purely practical perspective, it is perhaps unnecessary to distinguish between specific and placebo effects, given that there is no clear effective longterm treatment available for chronic LBP and no substitute for spa therapy. An important point is the suggestion that patients derive clinical benefit from spa therapy. It is easier to assess the effect of mineral water in a double blind design because placebo (tap) water is available. Two double blind placebo randomized controlled trials conducted to test the effectiveness of thermal water compared to tap water (one in arthrosis of the knee[24], the other [20] in patients with rheumatoid arthritis) showed significant improvement in the thermal water group compared to the tap water group.

In our trial, we elected to study a group of patients with a chronic LBP syndrome representative of those attending spa resorts. They were therefore heterogeneous with respect to underlying pathology, although degenerative disease of the spine was probably the most common diagnosis.

In view of a possible residual effect of spa therapy, we decided not to include the patients who had undergone a spa therapy in the previous 6 months. Of the patients in the study, 83.3% had never undergone spa therapy. The remainder (16.7%) had previously undergone a spa therapy but this was more than one year before their inclusion in the trial. The fact that the patients were volunteers, as is the case in many trials, might have resulted in an autoselection bias.

In conclusion, our trial suggests that there is an immediate and 6 month overall benefit of spa therapy (specific spa techniques and spa mineral water combined) on pain, FD, and analgesic drug consumption in chronic LBP. The disability questionnaire specific for LBP points to a clinically important functional improvement. It would be interesting to examine more closely the relationships between functional disability and drug consumption after spa therapy. Such complementary analysis would require the use of sophisticated statistical models to account for possible interrelations between FD and drug consumption.

Our study suggests that spa therapy may be beneficial in the management of chronic LBP although the mechanism of action remains unclear.

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