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Spa therapy and balneotherapy for treating low back pain: meta-analysis of randomized trials

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Objectives. **Low back pain is a major public health concern and complementary treatments are frequently used for this condition. The objective of this systematic review and meta-analysis was to assess the evidence for or against the effectiveness of spa therapy and balneotherapy for treating low back pain.**

Methods. **Systematic searches were conducted on Medline, Embase, Amed Cochrane Central, the UK National Research Register and ClincalTrials.gov (all until July 2005). Hand searches were performed and experts contacted. Methodological quality was assessed using a standard scale.**

Results. **Five randomized clinical trials met all inclusion criteria. Quantitative data synthesis was performed. The data for spa therapy, assessed on a 100 mm visual analogue scale (VAS), suggest significant beneficial effects compared with waiting list control groups (weighted mean difference 26.6 mm, 95% confidence interval 20.4–32.8, $n = 442$) for patients with chronic low back pain. For balneotherapy the data, assessed on a 100 mm VAS, also suggest beneficial effects compared with control groups (weighted mean difference 18.8 mm, 95% confidence interval 10.3–27.3, $n = 138$).**

Conclusions. **Even though the data are scarce, there is encouraging evidence suggesting that spa therapy and balneotherapy may be effective for treating patients with low back pain. These data are not compelling but warrant rigorous large-scale trials.**

KEY WORDS: Complementary medicine, Alternative medicine, Spa therapy, Balneology, Systematic review, Meta-analysis.

Low back pain is a major public health concern in many countries and there is a lack of agreement as to when it becomes chronic [1–5]. Chronic low back pain has been described as back pain that lasts longer than 7–12 weeks [5]. In the UK, estimates indicate that low back pain is the largest single cause of absence from work and is responsible for 12.5% of all sick days [5]. Among patients receiving care in the USA, the proportion receiving physician care increased from 64% in 1987 to 74% in 1997, whereas those obtaining care from physical therapists increased from 5% to 9% during the same period [6]. Complementary therapies are popular and frequently used by patients with low back pain [7]. Two such treatment options are balneotherapy and spa therapy. They are used particularly in European countries and the costs are, at least in part, reimbursed by health insurance systems (e.g. Germany) [8]. In contrast to hydrotherapy, which generally employs normal tap water, balneotherapy is defined as the use of baths containing thermal mineral waters from natural springs at a temperature of at least 20°C and with a mineral content of at least 1 g/l. Spa therapy additionally employs physiotherapeutic interventions at a spa resort [9, 10]. In countries such as the UK and the USA these treatments are also used but are viewed as complementary. Elsewhere, they have traditionally been considered as part of the conventional medical system (e.g. Germany). Balneotherapy and spa therapy are associated with considerable costs and it is therefore reasonable to ask whether they are supported by good evidence. The objective of this systematic review and meta-analysis was to assess the evidence for or against the effectiveness of balneotherapy and spa therapy for treating low back pain.

Methods

Database search

The following databases were searched: Medline, Embase, Cochrane Central, Amed, the National Research Register, UK (http://www.update-software.com/projects/nrr/), and ClincalTrials.gov, USA (http://clinicaltrials.gov/). We used the search terms 'balneotherapy', 'balneology', 'spa therapy' and 'kur' (German term for spa treatment). Each database was searched from its inception until July 2005. To identify additional published or unpublished studies, we conducted hand searches of conference proceedings (FACT – Focus on Alternative and Complementary Therapies 1996–2005), relevant medical journals (*Alternative and Complementary Therapies* 1995–2005, *Forschende Komplementärmedizin Klassische Naturheilkunde* 1994–2005 and *Physikalische Medizin, Rehabilitationsmedizin und Kurortmedizin* 1993–2005) and our own collection of papers. Hand searches also included the bibliographies of all retrieved articles and contact with experts. There were no restrictions regarding the language of publication.

Selection

All trials that reported that the sequence of allocation was randomized [randomized clinical trials (RCTs)] testing balneotherapy or spa therapy for treating patients with low back pain were included. Trials reported in duplicate were excluded. Titles and abstracts of identified articles were assessed

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independently by at least two authors and hard copies of all potentially relevant articles were obtained for further evaluation (M.H.P., M.Z.K., M.K., E.E.).

Validity assessment

Methodological quality was evaluated using the system developed by Jadad [11]. The quality was assessed independently by two authors (M.H.P., E.E.).

Data abstraction

Data abstraction was performed systematically and independently (M.H.P., M.Z.K., M.K.) according to design, quality, sample size, intervention, water characteristics, results, adverse events and concomitant treatment (Table 1). Disagreements in the evaluation of studies were largely due to reading errors and were resolved through discussion. Quantitative data synthesis was performed. The mean change of pain measured on a 100 mm visual analogue scale (VAS) compared with baseline was defined as the primary end-point, and was used to assess the difference between the intervention groups and the control groups (M.H.P.). Means and 95% confidence intervals (CIs) were calculated using standard meta-analysis software (RevMan 4.2.8; Update Software, Oxford, UK). Summary estimates of the treatment effect were calculated using a random effects model. The χ^2 test for heterogeneity was performed to determine whether the distribution of the results was compatible with the assumption that intertrial differences were attributable to chance variation alone.

Results

The literature searches identified 60 potentially relevant articles (Fig. 1). Abstracts were assessed and 10 papers were retrieved for further evaluation [12–21]. No unpublished studies were identified. Five publications were excluded because they were not reported as randomized [12, 13], did not test balneotherapy or spa therapy [14], did not report a clinical trial [15] or were a duplicate publication [16]. Five trials [17–21] met all inclusion criteria (Table 1). All trials provided data that were suitable for statistical pooling. The methodological quality was on average adequate, given that patient blinding was not possible [11]. In most trials the mineral content of the water was relatively low.

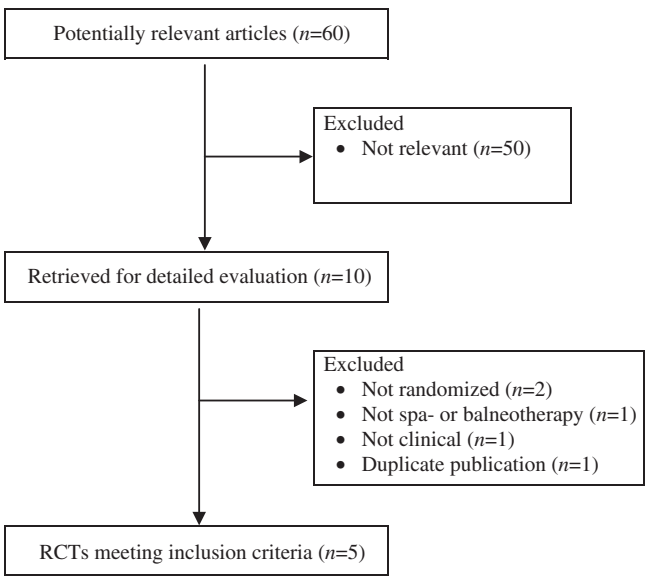

FIG. 1. Flowchart of trial selection process.

Three RCTs tested the effectiveness of spa therapy (Fig. 2). These trials included 454 patients suffering from chronic low back pain. In all studies, pain was assessed using a 100 mm VAS. The meta-analysis suggested significant differences in favour of spa therapy compared with waiting list control groups (weighted mean difference, 26.6, 95% CI 20.4–32.8, $n=442$). There was no visual or statistical evidence of heterogeneity ($P=0.17$, χ^2 test). Results for the Schober index, assessing lumbar flexibility, suggested no significant intergroup differences (weighted mean difference 3.6 mm, 95% CI –2.7–9.8, $n=442$). In all three trials there was no mention of adverse events.

Two RCTs tested the effectiveness of balneotherapy using a 100 mm VAS (Fig. 3). The meta-analysis suggested significant intergroup differences in favour of balneotherapy compared with control groups (weighted mean difference 18.8 mm, 95% CI 10.3–27.3, $n=138$). There was no visual or statistical evidence of heterogeneity ($P=0.24$, χ^2 test). There was no mention of adverse events in one trial, and another [20] reported the occurrence of no adverse events in the treatment group.

Discussion

The data from this systematic review and meta-analysis suggest significant differential effects in favour of spa therapy and balneotherapy for reducing low back pain and corroborate other reviews on the topic [15]. However, the volume of the evidence is small and includes a total of only five RCTs assessing 674 patients. The variation in the treatment regimen (Table 1), which was expected, did not cause enough heterogeneity to lead us to abandon statistical data pooling. None of the reviewed trials reported any adverse events and it seems that, where adequate facilities are available, spa therapy and balneotherapy are beneficial options when administered under close supervision.

The paucity of evidence from RCTs is in stark contrast to the popularity of these treatments among patient populations and to the expenditure by health insurers on such interventions. The findings of our meta-analyses support data from previous systematic reviews, which identified the need for further studies some 7 yr ago [e.g. 22, 23]. Methodological difficulties in assessing complex interventions relating, for instance, to the design of adequate control groups, blinding and the expense involved may be some of the reasons for the small number of studies carried out so far. Nonetheless, this meta-analysis has shown that good-quality trials are possible and it is hoped that our findings will encourage further systematic research. Future studies should be randomized and careful attention should be paid to the concealment of treatment allocation, as was done in all studies on spa therapy. Adequate sample sizes should be assessed, ideally administering similar regimens under similar conditions. In contrast to other opinions [24], we believe that balneotherapy and spa therapy are good examples of complex interventions for which it is possible and relevant to distinguish specific from non-specific effects.

Trials are also required to investigate the more fundamental question of whether spa treatments administered at a spa resort are more beneficial than the same treatments administered elsewhere. These differences are at the heart of spa therapy and are associated with considerable costs. At present, there is no convincing evidence that spa therapy administered at a spa resort is more effective than the same treatment regimen administered elsewhere, which could reduce costs [22]. Thus, a situation exists whereby some encouraging evidence suggests that spa therapy is effective for

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Table 1. Randomized controlled trials of spa therapy and balneotherapy for low back pain

First author, year	Design, quality score,[a] allocation concealment	Patients mean age, gender (M/F), LBP criteria	Intervention	Regimen, water mineralization, main constituents	Control	*n* (randomized/ analysed)	Main outcomes[b]	Intergroup differences	Concomitant treatment
Spa therapy[c]									
Guillemin, 1994 [17]	2 parallel groups, 2, adequate	58–59 yr, 41/63, LBP for at least 2 yr	15 min high-pressure shower at 36°C water temperature. Series of 3 min water showers with varying pressure and temperature (31–36°C)	6 times weekly for 3 weeks, <500 mg/l, sulphate, sodium	Waiting list	104/102	100 mm pain VAS, Schober index,	$P < 0.0001$ for all main outcomes	None
Constant, 1995 [18]	2 parallel groups, 3, adequate	52 yr, 32/94, pain between the 12th rib and the gluteal fold for at least 1 yr	10 min bath at 36°C with underwater flow, 20 min local mud application at 45°C, 2.5 min high-pressure shower at 36°C with a massage device and regulated pulse flow	6 times weekly for 3 weeks, 8073 mg/l, bicarbonate, chlorine, sodium	Waiting list	126/121	100 mm pain VAS, Schober index	$P < 0.0001$ and $P = 0.38$, respectively	Routine drug treatment
Constant, 1998 [19]	2 parallel groups, 2, adequate	52 yr, 81/143, pain between the 12th rib and the gluteal fold for at least 1 yr	10 min bath at 36°C with underwater flow, 15 min local mud application at 45°C, 20 min massage under flowing water at 36°C	Bath, mud treatment 6 times weekly for 3 weeks; massage every other day for 3 weeks, 510 mg/l, sulphate, chloride, sodium	Waiting list	224/219	100 mm pain VAS, Schober index, Quality of life	$P < 0.0001$, $P = 0.22$ and $P < 0.05$, respectively	Routine drug treatment
Balneotherapy[c]									
Konrad, 1992 [20]	4 parallel groups, 2, not reported	39–44 yr, 71/87, LBP with or without radiation for at least 1 months but no longer than 3 months	(A) Baths (B) Underwater massage (C) Underwater traction A, B, C in water at 37°C for 15 min	3 times weekly for 4 weeks, 901 mg/l, bicarbonate, sodium, carbon dioxide	NSAIDs only	170/158	100 mm pain VAS, analgesic consumption	$P < 0.01$ compared with baseline for both main outcomes in all intervention groups	Back school
Yurtkuran, 1997 [21]	2 parallel groups, 3, not reported	42 yr, 7/43, LBP without radiation for at least 1 month but ≤6 months	30 min bath in water at 37°C plus flexion exercises outside pool for 15 min	5 times weekly for 3 weeks, 1169 mg/l sodium bicarbonate	Flexion exercises	50/50	100 mm pain VAS, modified Schober index, finger-to-floor-distance	$P < 0.001$, $P < 0.001$ and ns, respectively	Neither group received medication nor any other physical therapy

LBP, low back pain; ns, not significant.

[a]Quality score (Jadad): maximum 5 points.

[b]The Schober test assesses the amount of lumbar spine flexion. A point is identified at the level of about L5. A mark is made 5 cm below and 10 cm above that point. The patient bends at the waist to full forward flexion. The distance between the two marks is measured; if <20 cm it indicates limitation of lumbar flexion.

[c]Studies were categorized according to the original authors' definition.

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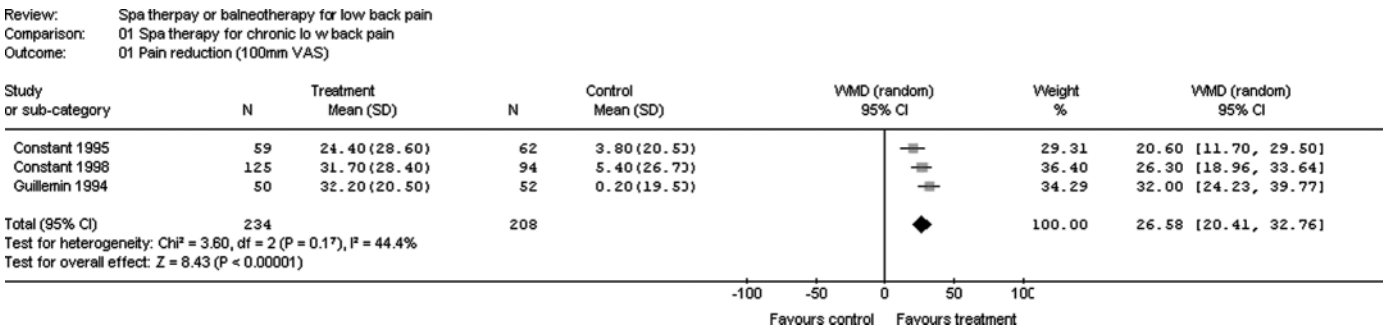

FIG. 2. Meta-analysis of RCTs WMD, weighted mean difference.

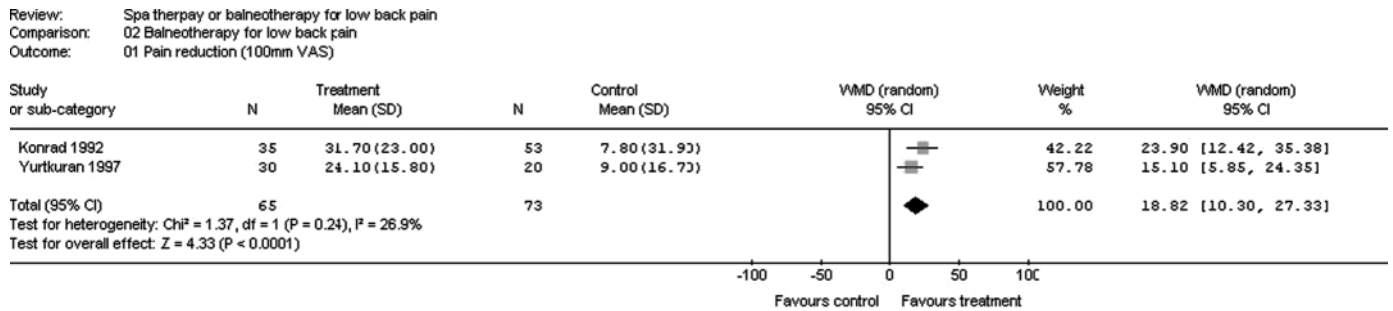

FIG. 3. Meta-analysis of RCTs WMD, weighted mean difference.

low back pain, while it is unclear whether these treatments have to be administered at a spa resort, as an integral part of spa therapy, or whether they can be administered elsewhere with the same therapeutic effects and at less cost.

In some countries, such as Germany, the spa sector has suffered through political decisions to cut back on reimbursement for such treatments (Kur) through the national health insurance system. The move was motivated by financial considerations but the paucity of compelling data on specific effectiveness and cost-effectiveness has also played a crucial role. Considering the potential role of balneotherapy and spa therapy, as shown in this meta-analysis, it is disappointing that more clinical trials have not been initiated. As always, the burden of demonstrating the worth of a medical intervention lies on the shoulders of those who claim that it works.

Limitations of our systematic review, and indeed systematic reviews in general, pertain to the potential incompleteness of the evidence reviewed. We aimed to identify all RCTs on the topic. The distorting effects on systematic reviews and meta-analyses arising from publication bias and location bias are well documented [25–28]. For this study, we searched databases with a focus on the American and European literature and those that specialize in complementary medicine, and we included hand searches. There were no restrictions in terms of publication language, and the appraisal of the clinical evidence was performed independently by two reviewers. We are therefore confident that our search strategy has located all relevant data on the subject. However, one can never be absolutely certain and a degree of uncertainty remains.

In conclusion, even though the data are scarce, there is some encouraging evidence suggesting that spa therapy and balneotherapy may be effective for treating patients with low back pain. These data are not compelling but warrant rigorous large-scale trials.

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Key messages

- Spa therapy and balneotherapy are used particularly in some European countries, e.g. Germany, where they are part of the conventional medical system and are, at least in part, reimbursed by health insurance systems.
- Our systematic review and meta-analysis assessed all data from RCTs testing spa therapy and balneotherapy for patients with low back pain.
- Even though the data are scarce, there is some encouraging evidence suggesting pain reduction in patients with low back pain.

The authors have declared that there are no conflicts of interest.

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