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ORIGINAL ARTICLE

Effects of mud-bath treatment on fibromyalgia patients: a randomized clinical trial

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Abstract The efficacy of balneotherapy in fibromyalgia syndrome (FS) has been well demonstrated, while controlled studies using mud packs are lacking. We performed a randomized clinical trial to evaluate the effects and the tolerability of mud-bath treatment in FS patients, who are poor responders to pharmacological therapy. Eighty patients with primary FS, according to ACR criteria, were randomly allocated to two groups: 40 were submitted to a cycle of 12 mud packs and thermal baths, and 40 were considered as controls. At baseline, after thermal treatment and after 16 weeks, patients were evaluated by FIQ, tender points count, VAS for "minor" symptoms, AIMS1 and HAQ. Control patients were assessed at the same time periods. A significant improvement of all evaluation parameters after mud-bath therapy and after 16 weeks was observed. Mud packs were well tolerated and no drop-outs were recorded. Our results suggest the efficacy and the tolerability of mud-bath treatment in primary FS.

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Introduction

Fibromyalgia syndrome (FS) is a common musculo-skeletal disorder characterized by otherwise unexplained chronic widespread pain, a lower pain threshold, high tender points count (tenderness on examination at specific, predictable anatomic sites known as tender points), sleep disturbances, fatigue, headache, irritable bowel syndrome, morning stiffness, paraesthesia of the extremities, frequent psychological distress and depressed mood [1]. Consequently, FS has a negative impact on working capacity, family life, social functioning and quality of life.

Because of the unknown aetiology and the unclearly understood pathogenesis, there is no standard therapy regime for FS. A variety of medical treatments, including antidepressants, opioids, analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), sedatives, muscle relaxants and antiepileptics have been used to treat FS [1, 2]. Patients often resort to complementary or alternative therapies. Non-pharmaceutical treatment modalities, including exercise, physical therapy, massage, acupuncture, osteopathic manipulation, patient education and cognitive behavioral therapy can be helpful [3].

The efficacy of spa therapy in rheumatic diseases has been bolstered by ancient tradition, due to the chronicity and side effects of many therapies. However, despite the long history and popularity, only few randomized controlled trials demonstrating its effects in patients with rheumatic diseases have been performed [4–12]. Therefore, thermal therapy is still being discussed and its role in modern medicine is still not clear [13].

Among thermal treatments, balneotherapy has been commonly used for FS [14–18], whereas mud packs have been rarely employed.

The mechanisms of action of mud packs and baths are not completely known, and it is difficult to distinguish the effects of thermal applications from the benefits that could be derived from a stay in the spa environment [19].

The primary aim of this multicentric study was to assess the effects of the combination of mud packs and thermal baths (with two types of mineral waters), evaluated by a single-blind, controlled randomized trial, in patients with primary FS. The secondary aim was to verify the tolerability of mud packs, since no trial using this thermal treatment has been performed in FS.

Patients and methods

The multicentre study has been performed at the Rheumatology Divisions of Cagliari, Napoli, Padova e Siena (Italy). Patients with FS were recruited and sent to nearby thermal spas: Sardara Terme (bicarbonate–sulphate water), Agnano Terme (salt–brome–iodine water), Montegrotto Terme (salt–brome–iodine water) and Rapolano Terme–Antica Querciolaia (bicarbonate–sulphate water).

Patients selection

Eighty patients with primary FS, who fulfilled the ACR criteria [20] were included in the study (each Rheumatology Division enrolled 20 patients). They were 78 females and 2 males, aged between 22 and 60 years with FS duration of 10–40 months. All patients were on pharmacological therapy (antidepressant agents, benzodiazepines, muscle relaxants and /or analgesic drugs), for at least 3 months, with poor results: despite this treatment they remained symptomatic and at baseline they had at least 11 of the 18 tender points specified in the ACR criteria [20]. The demographic characteristics of the patients are summarized in Table 1.

Table 1 Demographic characteristics of FS patients submitted to mud-bath therapy (MBT) and of controls

	MBT patients (Group I)	Controls (Group II)
No. of patients	40	40
Age in years (mean ± SD)	46.2 ± 10.5	48.6 ± 9.4
Sex F/M	39/1	39/1
Disease duration in years (mean ± SD)	2.21 ± 1.35	2.30 ± 1.42
Married	35 (87%)	33 (82.5%)
Education years (mean ± SD)	12.7 ± 6.4	13.1 ± 7.2

Exclusion criteria were FS associated with other diseases and severe co-morbidity of heart, lung, liver, cerebrum, thyroid gland or kidney, acute illness, juvenile diabetes, varices, systemic blood diseases, neoplasms, pacemaker, pregnancy or nursing. Patients submitted to spa treatments in the year before the start of the trial were also excluded.

At baseline all patients underwent a general medical evaluation and a rheumatological examination by the same physician at the University Divisions. Demographic and clinical data were collected on a questionnaire.

After confirming the fulfilment of the above defined screening criteria and after written informed consent, patients were randomized 1:1 and allocated to two groups: group I (40 patients) submitted to mud-bath treatment and group II controls (40 patients).

All selected patients came from areas near the thermal spas and continued to live at home to carry out their daily routines.

Intervention

Group I patients were submitted to 12 generalized mud packs and 12 thermal baths over a period of 2 weeks. The mud was applied on the body surface at a temperature of 40–45°C for 15 min daily in the morning, followed by immersion in thermal water at 37–38°C for 10 min.

Group II patients continued only the pharmacological treatment.

Patients were evaluated before (T0) and immediately at the end (T1) of the spa therapy cycle, and 16 weeks thereafter (T2). Control patients were also assessed at the same time periods (T0, T1 and T2).

All patients were examined and evaluated at each University Division by investigators independent of the spa staff, who were blind to the mode of treatment.

Clinical assessments at each visit included:

1. Evaluation tests specific for FS:
   - Fibromyalgia impact questionnaire (FIQ) [21, 22];
   - Visual analogue scale (VAS) for “minor” symptoms of FS (headache, fatigue, sleep disturbances, gastro-intestinal symptoms); 0 indicates no symptoms whereas 100 is the worst condition;
   - Tender points count (determined by digital pressure) [20];
2. Other evaluation parameters:
   - Health assessment questionnaire (HAQ) [23, 24];
   - Arthritis impact measurement Scales (AIMS1) [25, 26].

For the whole period of the study it was recommended that the patients should not modify their pharmacological

treatment. In this period, the use of other drugs was not permitted in both groups of patients and only paracetamol was administered orally if necessary.

All adverse events, whether spontaneously reported by the patients or observed by the physicians at the thermal spas, were recorded, noting the severity and the possible correlations with the therapy. If serious adverse events occurred the patient was excluded from the study.

The study protocol was carried out according to the Principles of the Declaration of Helsinki and was approved by the Ethics Committee of each participating University Centres.

Statistical analysis

Mann–Whitney test was used to compare evaluation parameters (FIQ, VAS for "minor symptoms, tender points count, HAQ and AIMS1) of the two groups of patients at baseline.

Wilcoxon test was performed to evaluate the variables at each time points. A "*P*" value of less than 0.05 was considered significant.

All statistical analyses were performed with SPSS 12.0 software (SPSS Inc., MA, USA).

Results

The primary aim of this study was to evaluate the effects of a cycle of mud-bath therapy in primary FS.

Data at baseline demonstrate that the clinical picture were similar in the two groups of patients and no significant difference was observed in the evaluation parameters (Table 2).

Patients submitted to mud-bath therapy underwent an evident improvement at the end of the thermal treatment cycle (T1) and all evaluation parameters were significantly reduced in comparison to baseline. The improvement remained significant after a follow-up period of 16 weeks (T2): $P < 0.0001$ for FIQ, HAQ and tender points count, $P < 0.002$ for AIMS1, $P < 0.001$ for VAS for "minor" symptoms of FS. In particular the tender points count was less than 11 in 25 patients (62.5%) at T1 and in 27 (67.5%) at T2. The results of the specific FS evaluation tests are summarized in Table 3, those of the other evaluation parameters are reported in Table 4.

No significant changes in the evaluation parameters were observed in the control group: HAQ, AIMS1, FIQ and VAS for "minor" symptoms of FS remained unchanged after 2 and 16 weeks (Tables 2, 3). Tender points count was less than 11 in two patients (5%) at T1 and in three (7.5%) at T2.

Regarding the secondary aim of the study, such as the tolerability of mud packs, no patient reported any exacerbation of the symptoms and the hot applications were well tolerated in all cases. No drop-outs were recorded during spa therapy and all patients completed the study.

Discussion

The efficacy of spa therapy in the rheumatic diseases is still controversial. We performed a randomized clinical trial in

Table 2 Evaluation parameters in FS patients submitted to mud-bath therapy (MBT) and in controls at baseline

	MBT patients (Group I)	Controls (Group II)	*P**
Fibromyalgia impact questionnaire (FIQ)	61.00 ± 16.71	66.82 ± 18.60	NS
VAS for "minor" symptoms	65.64 ± 1.51	69.12 ± 17.94	NS
Tender points count	13.83 ± 2.74	14.00 ± 2.32	NS
Arthritis Impact Measurement Scales (AIMS1)	2.76 ± 1.09	2.98 ± 1.05	NS
Health Assessment Questionnaire (HAQ)	0.77 ± 0.47	0.94 ± 0.53	NS

* Mann–Whitney test

Table 3 Evaluation tests specific for FS (mean ± SD) at baseline (T0), after 2 weeks (T1) and 16 weeks (T2) in mud-bath treated patients (MBT) and in controls

	FIQ		VAS		Tender points count	
	MBT	Controls	MBT	Controls	MBT	Controls
Baseline	61.00 ± 16.71	66.82 ± 18.60	65.64 ± 1.51	69.12 ± 17.94	13.83 ± 2.74	14.00 ± 2.32
Week 2	46.83 ± 20.82	68.18 ± 17.26	53.17 ± 9.23	68.66 ± 16.98	9.67 ± 5.31	14.24 ± 2.72
*P**	<0.0001	NS	<0.001	NS	<0.0001	NS
Week 16	43.64 ± 19.82	66.41 ± 18.40	53.44 ± 7.99	70.88 ± 6.13	9.17 ± 4.16	14.53 ± 2.67
*P**	<0.0001	NS	<0.001	NS	<0.0001	NS

* Wilcoxon test

Table 4 Other evaluation parameters of FS (mean ± SD) at baseline (T0), after 2 weeks (T1) and 16 weeks (T2) in mud-bath treated patients (MBT) and in controls

	HAQ		AIMS1	
	MBT	Controls	MBT	Controls
Baseline	0.77 ± 0.47	0.94 ± 0.53	2.76 ± 1.09	2.98 ± 1.05
Week 2	0.55 ± 0.49	1.02 ± 0.54	2.46 ± 1.13	3.08 ± 1.12
*P**	<0.0001	NS	<0.002	NS
Week 16	0.63 ± 0.49	1.05 ± 0.54	2.23 ± 1.08	3.01 ± 1.09
*P**	<0.001	NS	<0.002	NS

* Wilcoxon test

primary FS using mud packs, followed by immersion in thermal water.

Our results show the beneficial effects of a cycle of mud-bath applications in a group of patients with FS, who are poor responders to pharmacological treatments. All evaluation parameters significantly reduced at the end of the spa therapy cycle and remained stable after 16 weeks in comparison to baseline. The favourable effects extended to several domains including pain, fatigue, general health and physical functioning.

Some aspects of our study are criticisable and could constitute a potential bias, in particular the impossibility of a double-blind design using mud packs. However, our data suggest that mud-bath therapy may be a useful therapeutic tool in primary SF.

The results of our study are in agreement with other trials previously performed in spas, but it is important to underline that randomized trial on the effects of mud packs have never been performed in FS.

Altan et al. [27] investigated the addition of balneotherapy to relaxations exercises demonstrating pain relief and significant improvement in FS evaluation parameters during follow-up (12 and 24 weeks). Evick et al. [16] showed decrease of FIQ, pain intensity and number of tender points lasting 6 months after a cycle of balneotherapy. Buskila et al. [14] and Neumann et al. [15] reported beneficial effects respectively on the FS-related symptoms and on the quality of life in FS patients submitted to balneotherapy at the Dead Sea.

Recently Dönmez et al. [17] concluded that the addition of spa therapy performed in Izmir (thermal baths and pressure shower with thermal water) to pharmacological treatment had beneficial effects in FS patients persisting after 3, 6 and 9 months. Zijlstra et al. [18] demonstrated an improvement in fibromyalgia symptoms and quality of life in the year subsequent to a cycle of thermal treatment in a Tunisian spa resort; differences from the controls were statistically significant after 3 months, but not after 6 and 12 months.

The mechanisms by which spa therapy improve the symptoms of FS are not fully understood [19]. The effects of mud packs and thermal baths are, in part, related to temperature. Hot stimuli may influence muscle tone and pain intensity, helping to reduce muscle spasm and to increase the pain threshold in the nerve endings. Moreover, the body surface is stimulated by heat and hydrostatic pressure of water and these stimuli could decrease the pain sensation in affected subjects [28, 29]. Mineral water may also exert a beneficial influence on the oxidant–antioxidant system [30, 31] and this effect could be beneficial, since oxidative stress disorders have been described in FS [32].

Total body mud packs also provoke a neuroendocrine reaction in response to thermal stress, characterized by a significant increase in serum levels of pituitary hormones and opioid peptides such as endorphins. This effect leads to an intense, progressive improvement of muscular and articular pain [33, 34]. The pituitary activation could be particularly useful in FS, in which an altered reactivity of the hypothalamic-pituitary axis has been observed [35, 36].

Other specific factors may also contribute to the clinical improvement observed after spa therapy, including changes of environment, pleasant scenery and the absence of work duties [13, 19]. In our study, however, in order eliminate these factors, all patients were residents in the areas near the thermal spas and they continued their work activities without modifying their life styles.

Another aspect that often contributes to amplifying the effect of spa therapy is the frequent association of physiokinesitherapy. These treatments were excluded from the protocol of this study.

Finally, despite the poor tolerance of physical treatments by FS patients, mud packs and thermal baths were well tolerated in our study and no patient withdrew from spa therapy.

Further studies on large patient groups with longer follow-up periods need to be performed in order to strengthen these results.

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