Therapy With Mud Compresses for Knee Osteoarthritis

Comparison of Natural Mud Preparations With Mineral-Depleted Mud

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Mud pack therapy is an alternative mode of treatment for rheumatic diseases. It is based on the application of heated mud packs to the entire body or to specific areas, such as over joints. The aim of the current study was to evaluate the efficacy of treatment with mud compresses at patients' homes for osteoarthritis of the knee.

Fifty-eight patients with osteoarthritis of the knee were enrolled in a prospective, double-blinded, controlled study. Forty patients were treated with natural mineral-rich mud compresses and 18 patients were treated with mineral-depleted mud compresses. Mud compresses were applied 5 times each week during 3 weeks for a total of 15 treatments. Patients were assessed at baseline, at completion of the 3-week treatment period, and twice after the conclusion of the treatment period—after 1 month and after 3 months.

The main outcome measures were the Lequesne Index of severity of knee osteoarthritis, patient self-assessment of pain, and severity of knee pain on a visual analog scale. A reduction of 20% or more in the pain scores was considered clinically significant.

In the group treated with natural mud compresses, a significant reduction in knee pain was observed at all assessments. Similarly, improvement in the Lequesne Index was seen at the end of therapy and a month after treatment. In the control group, given mineral-depleted mud compresses, no significant change in knee pain was seen at any assessment. Improvement in the Lequesne Index was seen 1 and 3 months after completion of the therapy, but not at the end of therapy. Seventy-two percent of the patients in the treatment group had an improvement of >20% in self-assessment of knee pain, compared with 33% in the control group ($p = 0.005$).

The data suggest that treatment with mud compresses, but only in their natural form, temporarily relieves pain in patients with osteoarthritis of the knees. We believe that treatment with mud compresses might augment conventional medical therapy in these patients. **(J Clin Rheumatol 2002;8:197–203)**

Key words: Mud compresses, Osteoarthritis, Balneology

Osteoarthritis (OA) is the most common form of arthritis, with symptomatic knee OA occurring in approximately 11% of adults aged 65 years and older (1). No curative therapy is available for this disease and therefore many patients attempt alternative modes of treatment, including spa therapy.

Balneotherapy has a role in the treatment of patients with inflammatory and noninflammatory joint diseases in many countries. The Dead Sea region is Israel's major health resort area; the wide spectrum of therapies offered in the region includes mud packs whose composition is unique to the region.

Mud pack therapy, alone or in combination with other modalities of balneotherapy, has been reported in randomized, double-blinded, controlled studies to improve symptoms of rheumatoid arthritis, psoriatic arthritis, fibromyalgia, and OA (2–7).

The relative contribution of the various components of mud pack treatment, namely, heat, mineral content, trace elements, and other physical properties of the mud packs, is unclear. The mechanism

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of action also is unclear. In this study, we assessed the contribution of mineral content to the efficacy of treatment with mud packs.

Therapy with mud packs, as practiced in the health resort area, is relatively expensive and cannot be practically applied at the patient's home because it requires the assistance of a therapist for the application of the mud on the patient's body, a treatment room with a shower to remove the mud at the end of the treatment session, and sterilization equipment for the crude mud. A specialized system to deliver the crude mud to the treatment site is required; 5 to 10 kg of mud is used for each treatment session.

These limitations, which make mud pack therapy possible only after travel to the health resort site, led the Ahava Company at the Dead Sea to develop mud compresses that replace the mud packs used at the health resort. These compresses can be used in the patient's home without the assistance of a therapist and without any special equipment. The mud compresses are heated in a microwave oven or in a pot of hot water, and then placed over painful joints. In contrast to mud packs, mud compresses do not soil the body.

Mud compresses are composed of three layers: the innermost layer, in contact with the target joint, is a porous fibrous cloth, which allows the diffusion of certain liquids but almost completely prevents the migration of nonsoluble solid matter. The middle layer is an absorbent material on which the Dead Sea mud has been spread. The external layer is a nonpermeable plastic sheath.

The aim of this study was to assess the efficacy of home application of mud compresses in patients with OA of the knees.

PATIENTS AND METHODS

Fifty-eight patients with primary OA of the knees and fulfilling the diagnostic criteria defined by Altman et al. (8) were included. All patients had been symptomatic for at least 12 months before inclusion in the study. Radiographic evidence (Kellgren grade) of moderate or severe OA was required. The patients were randomized into 2 groups: group 1 (40 patients) was treated with mineral-rich mud compresses; group 2 (18 patients) was treated with mineral-depleted compresses and served as a control group.

The mineral-depleted compresses were made by repeated rinsing of the Dead Sea crude mud through a porous membrane, using fresh water. The rinsing process was repeated 5 times, and the remaining mud was tested for mineral content and then used for the production of mineral-depleted mud compresses. The appearance, size, shape, weight, and texture of both compress types were identical. Patients were randomly assigned to the treatment and control groups. The study was double blinded—neither patients nor physicians were aware of which type of compress a patient received.

The concentrations of major ions in the mineral-rich mud compresses and in the mineral-depleted compresses are described in Table 1. The mud compresses also contained many trace elements present in the Dead Sea mud, including boron, manganese, cobalt, zinc, copper, bromine, rubidium, strontium, and others. Levels of these trace elements were not measured.

The patients, in their homes, heated the compresses to 30°C–35°C in a microwave oven or in a pot of hot water and then applied them on both knees. Mud compresses were applied 5 times each week (Sundays through Thursdays) during 3 weeks for a total of 15 treatments; the duration of each treatment was 20 min. Patients were instructed to apply the mud compresses in the evening. Mud compresses were not applied during weekend days for religious reasons because observant Jews cannot use electrical appliances during Sabbath.

Assessments

All patients were examined and assessed by trained rheumatologists 4 times: 3 days before commencement of treatment (assessment 1), 3 weeks later, at the end of the treatment period (assessment 2), and 1 (assessment 3) and 3 months after the end of the treatment period (assessment 4).

Outcome Measures

The clinical indices assessed at each examination included (a) the Lequesne Index of severity of knee OA (9), the score of which ranges from 0 to 24; (b) patient self-assessment of knee pain on a score from 0 to 100, where 0 indicates no pain and 100 intractable pain; (c) severity of knee pain on a visual analog

TABLE 1. Typical values of mineral-rich mud and mineral-depleted mud (mg/L)

Constituent	Mineral-rich mud	Mineral-depleted mud
Mg	32,503	116.6
Na	31,734	95.4
Ca	23,547	56.1
K	6,835	54.1
Cl	190,000	1,200.0
Total salinity	284,625	1,523.0

scale of 0–10, in which 0 signifies no pain and 10 signifies the most severe pain; (d) assessment of range of movements for each knee, using the Flexitometer, which is designed to measure the range of joint movement; (e) presence or absence of soft tissue swelling; and (f) presence or absence of effusions or crepitus.

We defined a 20% or more reduction in the scores of patient self-assessment of knee pain and severity of knee pain on a visual analog scale, compared with their corresponding scores at assessment 1, as a clinically significant improvement.

Throughout the treatment and follow-up period, patients in both groups continued to receive all regular medications, including analgesics and nonsteroidal anti-inflammatory drugs. However, they were not allowed to change their medications during the study.

Statistical Analyses

Statistical analyses were performed using the SPSS software. Paired *t* tests, chi-square tests, and Fisher's exact test were used, as appropriate, to compare clinical indices at each evaluation in each group with the values at the baseline evaluation before initiation of treatment.

RESULTS

The demographic and clinical characteristics of the patients are summarized in Table 2. There was no significant difference between the two groups in any of these characteristics.

Outcome Measures Within Groups

Table 3 and Figure 1 summarize the values of the Lequesne Index of severity of knee OA and patients' self-assessments of pain (scale 0–100) and of knee pain severity on a visual analog scale (0–10) at all 4 assessments. In the treatment group, the data in Table 3 and Figure 1 show a pattern of reduction in the scores of all indices at the end of treatment and 1 month after conclusion of the therapy. At 3 months after therapy, however, a worsening in all scores was observed. In the control group, the Lequesne Index scores showed continuous reduction, even after 1 month. However, an increase in the pain scores was observed in this group.

For each patient, the differences between their scores at assessments 2–4 and assessment 1 were calculated. The means of differences of the Lequesne Index and patients' self-assessment of pain and of knee pain severity in both groups, at assessments 2 and 3 compared with assessment 1, are shown in Table 4. The table indicates that a significant reduction in the scores of the index of severity of knee OA (Lequesne Index) was observed in the treatment group at the end of therapy and at the 1-month follow-up. A significant reduction in knee pain by visual analog scale was observed in all posttreatment assessments, but a significant reduction in the pain self-assessment scale was seen only in assessment 3. Taken together, the data suggest reduction in all measures 1 month after completing the therapy. Three months after conclusion of the treatment, a significant reduction was observed only in the visual analog scale scores.

For the control group, there was no improvement in the self-assessment of pain on either scale 1 month after completion of treatment. However, a significant improvement in the Lequesne Index was observed 1 and 3 months after completion of treatment.

Outcome Measures Between Groups

Table 5 shows the number of patients in the treatment and control groups who had a reduction of

TABLE 2. Demographic and clinical characteristics of patients with osteoarthritis by treatment group

	Treatment (mineral-rich) (n = 40)	Control (mineral-depleted) (n = 18)	*p* Value
Age (yr)[a]	64.7 ± 7.9	64.8 ± 7.3	0.933
Sex			
Number of women (%)	33 (83)	16 (89)	
Number of men (%)	7 (17)	2 (11)	0.709
Weight (kg)[a]	75.9 ± 10.9	75.1 ± 11.2	0.777
Disease duration (yr)[a]	10.9 ± 7.5	10.7 ± 7.2	0.933
Kellgren grade			
Grade 2	26 (66)	8 (44)	0.11
Grade 3	13 (33)	10 (56)	
Number of patients treated with			
NSAIDs (%)	23 (58)	9 (50)	0.595
Pain killers[b] (%)	33 (83)	15 (83)	1.0
Narcotics (%)	0	0	1.0

NSAID = nonsteroidal anti-inflammatory drug.
[a] Mean ± standard deviation.
[b] Pain killers include paracetamol, propoxyphene, and codeine.

TABLE 3. Scores of the three outcome measures at the four assessments, by treatment group (mean ± standard deviation)

		Lequesne Index	Self-assessment	Visual analog scale
Assessment I (before therapy)	Natural treatment	12.98 ± 4.2	60.1 ± 17	6.41 ± 2.15
	Control	13.78 ± 3.9	54.7 ± 21	6 ± 2.15
Assessment II (end of therapy)	Natural treatment	11.32 ± 4.4	55.3 ± 19.5	5.7 ± 1.9
	Control	12.7 ± 5.2	62.8 ± 22	6.58 ± 2.2
Assessment III (1 mo after therapy)	Natural treatment	11.2 ± 4.9	48.4 ± 20.2	5.04 ± 2.14
	Control	12.5 ± 4.7	58.8 ± 23	6.4 ± 2.18
Assessment IV (3 mo after therapy)	Natural treatment	12.03 ± 5.2	56 ± 18	5.3 ± 2.16
	Control	11.56 ± 4.7	59 ± 16	6.33 ± 2.47

Self-assessment refers to patients' evaluation of the severity of knee pain on a scale of 1–100; the visual analog scale is on a scale of 1–10.

20% or more in the scores of patient self-assessment of knee pain and severity of knee pain on a visual analog scale at all posttreatment assessments. The table indicates that at all assessments, the number of patients who had improved was higher in the natural treatment group compared with the control group. Seventy-two percent of the patients in the treatment group had a reduction of 20% or more in the scores of self-assessment of knee pain at any of the assessments, compared with 33% in the control group ($p = 0.005$). A statistically significant difference in the number of patients who had ≥20% improvement on visual analog scale scores was seen only at 1 month after treatment. However, there was a trend ($p = 0.08$) suggesting a difference in the number of patients who had improved at 1 of the 3 posttreatment assessments not seen at all assessments (60% in the treatment group vs. 33% in the control group).

No significant improvement or deterioration was observed in either group in the following parameters: assessment of the range of movements for each knee, existence or absence of soft tissue swelling, and effusions or crepitus (data not shown).

DISCUSSION

In a previous study from our center (10), we reported a significant improvement in Lequesne Index in patients with osteoarthritis who were treated at the Dead Sea by bathing in a sulfur pool, bathing in Dead Sea water, or by a combination of sulfur pool and bathing in Dead Sea water. There was no improvement in the control group, who stayed in the Dead Sea area without receiving balneotherapy.

In this pilot study, we show an improvement in patients with knee OA treated with natural mineral–rich mud packs at their home. The improvement is documented by three different measures: the Lequesne Index of severity and self-assessments of pain score and severity of pain on a visual analog scale.

The improvement in the various outcome measures was assessed by comparing the posttreatment scores with those at the beginning of therapy, assessing improvement in each group separately. In addition, we compared the reduction of pain scores between the two groups.

Within groups, we have found an improvement in all measures that was maintained for 1 month after completing the therapy. Significant improvement in pain severity by visual analog scale was still observed 3 months after completion of the therapy.

In the control group, no improvement in the self-assessment and visual analog scale scores was seen in any assessment, and no improvement in the Lequesne Index was found on completion of the therapy. A significant improvement in the Lequesne Index, however, was observed both 1 month and 3 months after completion of the treatment. The significance of this finding is not clear. It may be related to the small sample size rather than to a clinically significant finding. The Lequesne Index includes variables that assess pain during activity, as well functional status. Furthermore, because we have not included in the study a true placebo group (those who did not receive any treatment), the improvement in the control group may be the result of a placebo effect. The local heat of the compresses in both groups also could have played a role in the improvement.

Our data suggest a better outcome for patients treated with mineral-rich mud compresses compared with those treated with mineral-depleted mud packs. Whether this ef-

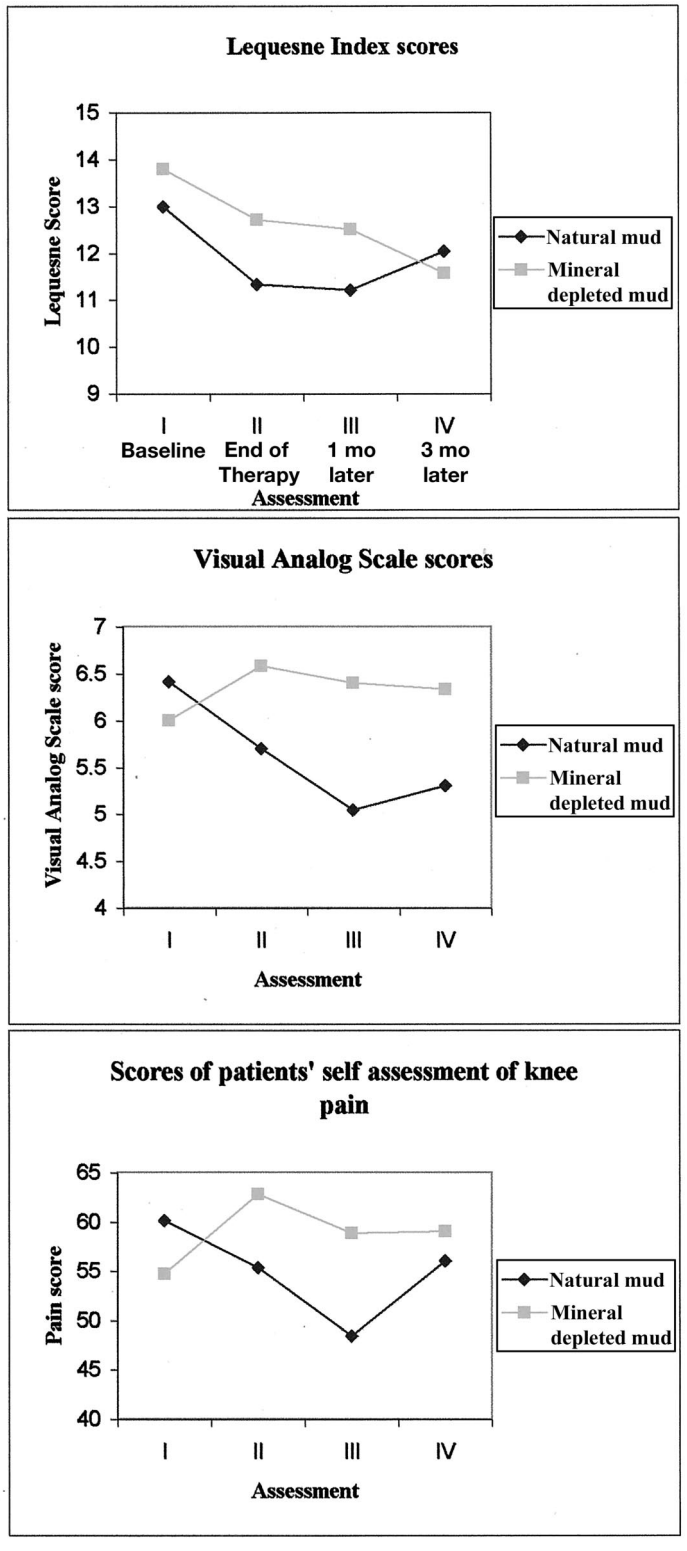

FIGURE 1. *Scores of outcome measures, at the four assessments, by treatment group.*

fect is the result of a "true" mud effect or other causes cannot be determined in this study.

Previous studies have shown that mud pack treatment alone (11, 12) or in combination with other balneologic treatments (4, 5) is effective in OA. Some of these studies are uncontrolled or retrospective, reducing their clinical significance.

The beneficial effect of mud pack treatment has been ascribed mainly to heat alone and to the ability of mud to maintain heat for a relatively prolonged time. Short-term thermal stress is known to alleviate pain. Heat increases the secretion of norepinephrine, cortisol, and growth hormone. In addition, the analgesic effect of heat can at least partially be attributed to increased concentrations of β-endorphin (13, 14).

A group of Italian researchers has shown that treatment with mud packs or mud baths causes a decrease in interleukin-1 levels and in tissue necrosis factor-α, thereby reducing cartilage inflammation and tissue destruction. Similarly, insulin-like growth factor-1, known to have cartilage protective properties, was found to be elevated after mud pack therapy (15, 16).

A different group of researchers showed that serum levels of prostaglandin E_2 and leukotriene B_4, known to possess potent inflammatory and algesic properties, were found to be decreased after mud pack therapy (17). An additional study by the same researchers demonstrated that mud pack therapy might increase the serum antioxidant defenses in patients with OA (18).

The mechanism responsible for these changes in anti-inflammatory factors is unknown. Theoretically, various components of mud, particularly trace elements, could be absorbed systemically through the skin. Various trace elements are known to affect the immune system and inflammatory arthritides such as rheumatoid arthritis. A decrease in serum zinc levels has been described in patients with rheumatoid arthritis (19–21). Shani et al. (22) found a significant increase in serum concentrations of bromine, rubidium, calcium, and zinc in patients with psoriatic arthritis who bathed in the Dead Sea. We did not measure levels of trace

TABLE 4. Mean of the paired differences between the scores of the outcome measures at assessments II to IV, and at assessment I

		Lequesne Index M (SE) (CI)	Self-assessment M (SE) (CI)	Visual analog scale M (SE) (CI)
Assessment II (end of therapy)	Natural treatment	−1.65, (0.42) (−2.5, −0.8)[b]	−4.87 (3.7) (−12.5, 2.7)	−0.77 (0.38) (−1.5, 0)[a]
	Control	−1.06 (0.74) (−2.6, 0.5)	8.1 (3.5) (7.6, 15.4)[a]	0.58 (0.4) (−0.26, 1.43)
Assessment III (1 mo after therapy)	Natural treatment	−1.75 (0.61) (−3.0, −0.5)[b]	−11.5 (3.5) (−18.6, −4.5)[a]	−1.4 (0.49) (−2.4, −0.4)[b]
	Control	−1.22 (0.59) (−2.4, −0.04)[a]	4.2 (3.8) (−12.1, 3.8)	0.63 (0.58) (−0.6, 1.9)
Assessment IV (3 mo after therapy)	Natural treatment	−0.95 (0.62) (−2.2, 0.3)	−3.85 (3.6) (−11.2, 3.5)	−1.2 (0.42) (−2.1, −0.4)[b]
	Control	−2.2 (0.84) (−4, −0.45)[a]	4.7 (5.4) (−16, 6.6)	0.55 (0.84) (−1.2, 2.34)

M = mean of paired differences; SE = standard error; CI = confidence intervals.
Self-assessment refers to patients' evaluation of the severity of knee pain on a scale of 1–100; the visual analog scale is on a scale of 1–10.
Negative values indicate improvement, and positive values suggest worsening in the scores.
[a] $p \leq 0.05$ compared with baseline assessment.
[b] $p \leq 0.01$ compared with baseline assessment.

TABLE 5. Number of patients who had >20% reduction in the pain scores (number [%])

	Natural treatment group	Control group	*p* Value
Self-assessment of knee pain			
Assessment II (end of therapy)	14 (36)	1 (6)	0.01
Assessment III (1 mo after therapy)	23 (59)	2 (11)	0.003
Assessment IV (3 mo after therapy)	14 (36)	4 (22)	0.3
Any assessment (II–IV)	28 (72)	6 (33)	0.005
Visual analog scale			
Assessment II (end of therapy)	12 (33)	2 (13)	0.1
Assessment III (1 mo after therapy)	15 (42)	2 (13)	0.05
Assessment IV (3 mo after therapy)	14 (40)	4 (26)	0.37
Any assessment (II–IV)	21 (60)	5 (33)	0.08

elements in the serum of patients in the current study. We are unaware of studies examining trace element levels in soft tissues or synovial fluid.

The assessment of alternative therapies poses several significant problems, some of which are demonstrated by our study. *Balneotherapy* is a term that includes many modalities of treatment, and many methods of applying these modalities. Studies performed at health resort sites need to take numerous possible effects into account, and almost preclude the use of randomized placebo controls. Another significant problem is choosing appropriates placebo controls, when the objective is to evaluate specific effects. Comparing studies and repeating them in different settings can be very difficult. We have tried to address these issues by performing the study at patients' homes and by studying one specific component of the variety of treatment modalities available at the Dead Sea area, the use of mud packs. Our choice of using mineral-depleted mud compresses for the control group patients still does not enable us to evaluate other possible effects of mud pack treatment, such as the effects of local heat.

We have demonstrated that treatment with natural mud com-

presses temporarily relieves pain better than mineral-depleted mud compresses in patients with OA of the knees. This study did not compare treatment with mud compresses to conventional therapy, but it is our conclusion that mud compresses are one alternative that can augment conventional medical therapy in these patients.

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