

# Dead Sea Mud Packs for Chronic Low Back Pain

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**ABSTRACT:** **Background:** Low back pain (LBP) is chronic disease without a curative therapy. Alternative and complementary therapies are widely used in the management of this condition.

**Objectives:** To evaluate the efficacy of home application of Dead Sea mud compresses to the back of patients with chronic LBP.

**Methods:** Forty-six consecutive patients suffering from chronic LBP were recruited. All patients were followed at the Soroka University Rheumatic Diseases Unit. The patients were randomized into two groups: one group was treated with mineral-rich mud compresses, and the other with mineral-depleted compresses. Mud compresses were applied five times a week for 3 consecutive weeks. The primary outcome was the patient's assessment of the overall back pain severity. The score of the Ronald & Morris questionnaire served as a secondary outcome.

**Results:** Forty-four patients completed the therapy and the follow-up assessments: 32 were treated with real mud packs and 12 used the mineral-depleted packs. A significant decrease in intensity of pain, as described by the patients, was observed only in the treatment group. In this group, clinical improvement was clearly seen at completion of therapy and was sustained a month later. Significant improvement in the scores of the Roland & Morris questionnaire was observed in both groups.

**Conclusions:** The data suggest that pain severity was reduced in patients treated with mineral-rich mud compresses compared with those treated with mineral-depleted compresses. Whether this modest effect is the result of a "true" mud effect or other causes cannot be determined in this study.

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**KEY WORDS:** Dead Sea, mud packs, low back pain (LBP), Ronald & Morris questionnaire, balneotherapy

The Dead Sea region is the major health resort area in Israel. Recently, the results obtained at this natural spa were evaluated in an exhaustive review [1]. The wide spectrum of therapies offered in the region includes use of the natural mud, whose composition is unique and reflects the magnesium and mineral-rich properties of the Dead Sea waters.

Mud pack therapy applied to the whole body, alone, or in combination with other modalities of balneotherapy has been shown to ameliorate symptoms of rheumatoid arthritis, psoriatic arthritis, fibromyalgia, osteoarthritis and ankylosing spondylitis [2-8]. This treatment, usually administered at a spa center in the health resort area, is relatively expensive and requires the assistance of a balneology staff member to apply the mud (warmed to 36–38°C) to the patient's body.

Ahava Laboratories Ltd., a company located in the Dead Sea area, recently developed mud compresses that can be used in patients' homes [5]. These Dead Sea mineral-rich compresses comprise three layers: the first consists of a porous fibrous cloth which allows the diffusion of certain liquids but almost completely prevents the migration of non-soluble solid matter. The second layer consists of an absorbent material on which the Dead Sea mud has been spread. The third layer is a non-permeable plastic sheath. During treatment the first layer of the mud compress is in contact with the target joints [5].

We recently showed that treatment with mud compresses temporarily relieves pain in patients with osteoarthritis of the knees and in patients with rheumatoid arthritis of the hands [5,6]. The aim of the present study was to assess the efficacy of home application of such mud compresses for patients with chronic low back pain.

## PATIENTS AND METHODS

Patients suffering from chronic LBP were enrolled in the study. All patients were above 18 years old and had LBP for more than a year. The pain was localized to the region below the 12th rib and above the gluteal line. Exclusion criteria included acute back pain, inflammatory LBP, malignant disease, disk herniation, patients under narcotics, sensitivity to mud, spa treatment in the last 6 months, scoliosis, pregnancy, infec-

This work is dedicated to the memory of Professor Shaul Sukenik, MD, who participated at the start of this study, but not at the final writing.

Prof. Sukenik succeeded in transmitting his exceptional way of behaving as a man, a physician, a scientist and a friend, through love for his family, his patients and the Dead Sea.

LBP = lower back pain

tions, heart failure, and osteoporosis. Patient enrollment was in accordance with the standards of the local ethics committee.

**RANDOMIZATION**

The patients were randomized into two groups: one group was treated with mineral-rich mud compresses, and the other, serving as a control, with mineral-depleted compresses. The study was double blinded: neither patients nor physicians were aware of the type of compresses a patient received.

**MUD PACKS**

The mineral-depleted compresses were obtained by repeated washing of the Dead Sea crude mud through a porous membrane, using fresh water. The rinsing process was repeated five times, and the remaining mud was tested for still-existing mineral content and then used for the production of mineral-depleted mud compresses. The appearance, size, weight and texture of both compress types were identical. The concentrations of major ions in the mud compresses and in the Dead Sea mud-filtered compresses have been described previously [4].

**TREATMENT PROTOCOL**

The patients, in their own homes, heated the compresses to 33–35°C in a microwave oven or in a pot of hot water and then applied them to the lower back. The mud compresses were applied 5 times a week (from Sunday to Thursday) for 3 consecutive weeks, totaling 15 treatments; the duration of each treatment was 20 minutes. Patients were instructed to apply the mud compresses in the evening. For religious reasons, mud compresses were not applied during the weekend as observant Jews cannot use electrical appliances on the Sabbath.

Throughout the treatment and follow-up period, patients in both groups continued to receive their regular medications.

**ASSESSMENTS**

All patients were examined and assessed by trained rheumatologists at three consecutive occasions: 3 days before beginning treatment (assessment 1); 3 weeks later, at the end of the treatment period (assessment 2); and 1 month after the end of the treatment period (assessment 3).

**OUTCOME MEASURES**

The primary outcome was the patient’s assessment of the overall back pain severity on a visual analog scale from 0 to 10 (where 0 signifies no pain and 10 maximal intractable pain). Secondary outcomes included: a) score of the Ronald & Morris questionnaire for assessment of functional disability [9] (the score ranges from 0 to 24, with 0 indicating no functional disability and 24 maximal severe functional disabilities; b) finger-to-floor distance (in centimeters); and c) Shober’s test.

**STATISTICAL ANALYSIS**

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 assessment in each group with the values at the baseline evaluation before initiation of treatment.

**RESULTS**

Forty-six patients were enrolled in the study. Two patients could not tolerate the local heat of the packs and withdrew from the study, leaving 44 patients who completed the therapy and the follow-up assessments. Thirty-two patients were treated with true mud packs and 12 patients used the mineral-depleted ones.

Table 1 presents the demographic data and the medications used by the treatment patients and the controls. There was no significant difference between the two groups in any of the demographic parameters or duration of LBP. All patients suffered from chronic low back pain secondary to degenerative disease.

Table 2 summarizes the measurements of the four outcome measures before, after completion of therapy, and 1 month later. A significant decrease in pain intensity, as described by the patients, was observed only in the treatment group. In this group, clinical improvement was clearly seen at completion of therapy and a month later. However, when comparing between the treatment and control groups, no significant improvement was observed in the three other outcome measures.

Significant improvement in the scores of the Roland & Morris questionnaire was observed in both groups. In the treatment group the improvement was noticed only a month after completion of therapy, while in the control group the significant improvement in scores was observed at completion of therapy and a month later.

**Table 1.** Demographic characteristics of patients who completed therapy, by group

	Treatment group (n=32)	Control group (n=12)	P value
<b>Age (yr)</b>			
Mean (range)	53.5 (31–74)	53 (34–69)	0.87
<b>Gender</b>			
Female (%)	24 (72)	10 (83.5)	0.7
Male (%)	9 (28)	2 (16.5)	
<b>Ethnic origin</b>			
Ashkenazi (%)	13 (40)	6 (50)	0.83
Non-Ashkenazi (%)	20 (60)	6 (50)	
<b>Duration of pain (yr)</b>			
Mean (range)	11.1 (1–40)	10.9 (1–25)	0.95
<b>Medication in use</b>			
Acetaminophen (%)	15 (47)	4 (33.3)	0.64
NSAIDs (%)	23 (72)	5 (42)	0.13
Surgical (%)	2 (6.5)	2 (16.5)	0.63

NSAIDs = non-steroidal anti-inflammatory drugs

**Table 2.** Clinical parameters for control and treatment groups before, after completion and 1 month after completion of therapy

Outcome (Mean ± SD)	Treatment group			Control group		
	Before	After	1 mo later	Before	After	1 mo later
Pain severity VAS	5.2 ± 2.5	3.7 ± 2.4**	4.2 ± 2.8*	5.5 ± 2.3	4.4 ± 3	3 ± 3.5
Ronald & Morris questionnaire	12.8 ± 4.9	8.3 ± 5	10 ± 6.2*	12 ± 5	8.8 ± 6.7*	6.3 ± 6.4**
Finger-to-floor test (cm)	26.6 ± 14.4	19.3 ± 14	21 ± 14	19.6 ± 14.5	20.4 ± 12.3	12.4 ± 10.5
Schober test (cm)	13.8 ± 1.8	14.2 ± 1.4	13.5 ± 1.7	13.3 ± 0.9	13.1 ± 1.6**	14 ± 1*

\**P* < 0.05\*\**P* < 0.001**Table 3.** Percentage of patients in treatment and control group with 20% improvement in outcome parameter after treatment and 1 month after completing treatment

20% outcome improvement	After treatment			1 month after treatment		
	Treatment group (%)	Control group (%)	<i>P</i> value	Treatment group (%)	Control group (%)	<i>P</i> value
Pain severity VAS	53	45.5	0.93	53.6	72.7	0.47
Ronald & Morris questionnaire	75	54.5	0.26	62	72.7	0.7
Finger-to-floor test	39.3	66.7	0.25	42.3	66.5	0.26
Schober test	3	0	1	10.7	0	0.55

A significant reduction in Schober test measurements was observed in the control group, at completion of therapy and 1 month after completion of therapy. No significant change in the scores of the Schober test was seen in the treatment group. However, when comparing differences at completion of therapy to 1 month later, we found a significant improvement in questionnaire scoring and Schober test in the treatment group.

Table 3 shows the number of patients with a 20% improvement in the variable outcomes. Each group, treatment and control, had a 20% improvement; on comparison between groups no significance was observed.

## DISCUSSION

In this study we show an improvement in patients suffering from chronic LBP self-treated at home with natural mineral-rich mud packs. This improvement is demonstrated by two measures: self-assessment of pain severity based on a visual analog scale, and the score obtained by a functional questionnaire.

The degree of improvement in the various outcome measures was assessed by comparing the post-treatment scores with those at the beginning of therapy. These evaluations of improvement were possible within each group separately. Additionally, we compared the reduction of pain scores between the two groups.

In the treatment group, we found an improvement in pain severity and functional score, maintained 1 month after completing the therapy. In the control group, no improvement in the visual analog scale score was seen in any assessment; however, improvement in the Ronald & Morris score was observed both at completion and 1 month after completing the treatment.

No significant improvement in the Schober test was found in the treatment group; in the control group a reduction in the measurement was seen at completion of therapy and 1 month later. The significance of this finding is not clear. It may be related to the small sample size rather than to a clinically significant factor.

In addition, since the study did not include a true placebo group of patients (who did not receive any additional treatment), the improvement in the control group may be simply a placebo effect. Moreover, the local heat induced by the compresses on the lower back area may also have had a role in the parameter's improvement, and this applies to both groups.

Finally, we did not find a significantly higher number of patients in the treatment group with an improvement of more than 20% in outcome measures compared with patients treated with the mineral-depleted mud [Table 3].

In summary, the data presented here suggest better pain control in patients treated with mineral-rich mud compresses compared to those treated with mineral-depleted mud packs. Whether this modest effect is the result of a "true" mud effect or other causes could not be determined in this study.

Previous studies have shown that balneologic treatments are effective for LBP. A recent meta-analysis suggested that spa therapy and balneotherapy may be effective for treating patients with low back pain [10]. Constant et al. [11] evaluated the influence of spa treatment on LBP, including hot springs, mineral mud, high pressure baths and massages. After 6 months of treatment an improvement was seen in the treatment group compared to the control. The improvement was observed at the end of treatment in almost all variables except for the Schober test and consumption of medication, but the study was not double blinded. Another study [12] from the same group demonstrated a significant improvement in functional and movement ability, as well as reduced pain intensity after 3 weeks of treatment. The improvement was still seen after 9 months except for functional ability. Similar efficacy of mud packs and carbon dioxide baths in reducing chronic back pain was also reported by a group from Austria [13,14].

The side effects of balneotherapy and Dead Sea climato-therapy, which have been described previously, are scarce. In several studies the stay, as well as the descent to the lowest terrestrial point on earth, were described as safe, even in cardiac patients [15-17]. The beneficial effect of mud pack treatment has been ascribed mainly to heat and to the ability of mud to maintain heat for a relatively long period. Short-term thermal

stress is known to alleviate pain. Heat increases the secretion of noradrenaline, cortisol and growth hormone. In addition, the analgesic effect of heat can, at least partially, be attributed to increased concentrations of beta-endorphin [18,19]. We recently reviewed the possible physiologic mechanisms of mud packs or mud baths in alleviating pain [6], such as reduction in interleukin-1 levels, tissue necrosis factor-alpha, serum levels of prostaglandin E2 and leukotriene B4.

#### STUDY LIMITATIONS

The assessment of alternative therapies poses several 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 consider numerous possible effects, and almost preclude the use of randomized placebo controls. However, on the other hand, they can induce stronger results, which, in turn, can be related to several influencing factors. These issues are discussed in a recent publication on the effects on quality of life in patients treated at the Dead Sea [20]. Another problem is choosing appropriate placebo controls, when the objective is to evaluate specific effects.

Comparing studies and repeating studies in different settings can be challenging, and it may not be possible to draw conclusions about the same treatment performed at the Dead Sea simultaneously with other studies. We tried to address these issues by performing the study in patients' homes and by assessing only one specific component of the large variety of treatment modalities available at the Dead Sea area: namely, the use of mud packs. Moreover, despite our decision to use mineral-depleted mud compresses in the control group, we cannot evaluate other possible effects of mineral-rich mud pack treatment, such as the effects of local heat. A more sophisticated study – using isotopic markers and evaluating molecular mechanisms involved in pain – is needed to understand the true magnitude of the effects of Dead Sea mud treatment.

#### CONCLUSIONS

This study demonstrated that treatment with Dead Sea mud compresses can temporarily relieve pain in patients suffering from LBP. Since we did not compare mud compress therapy with conventional treatment, we can only recommend this option as a complement to the standard therapy and not as an alternative to the conventional medical treatment proposed to these patients.

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**“It is easier to fight for one’s principles than to live up to them”**

Alfred Adler (1870-1937), Austrian medical doctor, psychotherapist, and founder of the school of individual psychology. He was the first to emphasize the importance of the social element in the re-adjustment process of the individual, and the first to bring psychiatry into the community