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RESEARCH LETTER TO THE EDITOR

Sulphurous mud-bath therapy for treatment of chronic low back pain caused by lumbar spine osteoarthritis

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Dear Editor,

Chronic low back pain (CLBP) is one of the most important causes of workplace absenteeism with deleterious social and economic consequences.

Several factors are involved in CLBP development, such as lumbar spine osteoarthritis that is a degenerative process characterized by functional limitations, and significant psychological distress with a negative effect on Quality of Life (QOL) [1].

There is the literature that reports that mood disorders, such as anxiety and depression, are often associated with CLBP caused by lumbar spine osteoarthritis [2], which, in turn, might cause insomnia [3].

Given the very high prevalence of CLBP, physicians are interested in testing feasible therapeutic interventions, including those representing complementary medicine, such as sulphurous mud-bath therapy, a salus per aquam (spa) treatment, commonly prescribed to contrast CLBP caused by lumbar spine osteoarthritis [4].

This technique includes mud made up by a combination of clay and sulphurous mineral water, leaving on 6–8 months until maturation.

Nowadays, data on the efficacy of such approach on psychological discomfort and insomnia, often present in the patients suffering from CLBP caused by lumbar spine osteoarthritis, are very scarce.

Starting from this evidence, the aim of the present study was to investigate whether sulphurous mud-bath therapy modifies the components of the CLBP, including pain perception and tuning, disability function, depression, and insomnia that all together affect the QOL of patients suffering from CLBP associated with lumbar spine osteoarthritis.

A prospective, longitudinal, observational study was conducted at the Telese spa (Telese Terme—Benevento, Italy) on 47 Caucasian patients (40% male, mean age 63 ± 9 years and BMI range 21.6–41) with CLBP treated with one cycle of 12 applications of sulphurous mud packs (with 5 cm height of the mud layer), one a day, in the morning, preferably in fasting condition, applied to the lumbo-sacral region of the spine for 15 min. at 44 °C, followed by a cleansing shower and a thermal bath in sulphurous mineral water at 38 °C for 10 min. The control group was represented by 10 patients (30% male, mean age 58 ± 9 years and BMI range 20–35) who had tap water baths only, at 38 °C for 10 min. one a day for 2 weeks.

All the recruited subjects were referred to the center as outpatients. Nobody underwent any other pharmacological or instrumental treatment beyond those foreseen by the protocol (mud therapy or bath in tap water for the control group).

The study was conducted in accordance with the guidelines of the Declaration of Helsinki and its amendments and all participants provided their informed consent. Moreover, it was compliant with the standards for the reporting of interventional trials assessing spa therapy, and was written according to the SPAC checklist developed using the Delphi consensus method [5].

All enrolled patients received a diagnosis of lumbar spine osteoarthritis, assessed by clinical and radiological

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examination, in the presence of CLBP for at least 12 weeks. The exclusion criteria were acute low back pain or radicular pain, intra-articular injections of steroids in the previous 3 months, recent surgical interventions, recent spa treatment, serious venous insufficiency, cancers, uncontrolled hypertension, diabetes, pregnancy, coronary heart disease, metal implants and cardiac pacemakers, and cognitive deficits.

The following parameters were evaluated, before and after spa treatment: *Low Back Pain* (LBP) using 100-cm Numerical Rating Scale (NRS: 0 = no pain to 100 = worst imaginable pain) with score 0–4 [6]; *Disability function of lumbar spine* by Fingertip-To-Floor test (FTF) [7] and Italian version of Oswestry Disability Index (ODI-I) (total scores range from 0 = no disability to 100 = maximum disability) [8]; *Psychological discomfort* by administering the Self-Rating Depression Scale (S.D.S. Zung test: score ≤ 20 = normal condition, a score between 21 and 80 identifies different grades of depression) [9]; *Sleep quality* by the self-administered Insomnia Severity Index (ISI) (score range from 0–7 = no clinically significant insomnia, a score to 8–28 described insomnia different levels) [10]. The occurrence of possible undesired or adverse events during the treatment was also considered and recorded in a Case Report Form.

The results, expressed as mean ± standard deviation (SD), were analyzed with Student's "*t*" test paired and unpaired for normally distributed data, and with the Wilcoxon's signed rank test and Mann–Whitney test for variables with non-normal distribution. The sample size was calculated using an estimated standard deviation of 0.5 and the two-tailed alpha set at 0.05. A $n = 8$ per group was determined to provide sufficient power at 0.9 in order to detect a significant difference between the groups.

A p values < 0.05 was considered statistically significant. Data were collected and analyzed using the SPSS 23.0 statistics package.

All enrolled patients completed the study, and no side effects or undesirable events were found.

At the end of sulphurous mud-bath cycle, a significant decrease of low back pain compared with baseline ($p < 0.01$) was observed in the treated patients but not in the control group (Table 1a), with also a significant improvement of the painful symptomatology assessed by 4° NRS-pain scores in spa group (Table 1b) but not in the control group.

At the end of the treatment, significant decreases of FTF ($p < 0.05$) (Table 2a), total ODI-I ($p < 0.01$) (Table 2b), total S.D.S. Zung test ($p = 0.013$) (Table 2c) and total ISI ($p < 0.01$) (Table 2d) score were observed without significant changes in the control group.

The analysis of ISI categories also shows that 62% of the spa-treated patients and 70% of the controls had no clinically significant insomnia both before and after 2-week observation. On the contrary, in the remaining 38% of the subjects, who had referred slight or moderate sleep disorders before the spa treatment, a significant reduction of the ISI score (11.2 ± 3 vs 7.8 ± 3, $p < 0.020$) was found at the end of the spa therapy. In 30% of the control patients with sub-threshold insomnia, no significant modification were observed after the study period (Table 3).

Furthermore, we investigated the possible relationship between insomnia and depression, finding that the patients (62%) who regularly slept before sulphurous mud-bath treatment also demonstrated a S.D.S. Zung test score corresponding to a low-level of depressive status. Conversely, in the remaining 38%, who had sub-threshold insomnia, the score of S.D.S. Zung test corresponded to a low–medium depressive status (38 ± 6 vs 35 ± 7, $p < 0.05$). This finding highlights the presence of a link between insomnia and depressive mood. This association is also confirmed by the absence of changes in the control group (Table 3).

Table 1 Total score (*A*) and Percentage variation of subjects divided by NRS-pain score (*B*) in the mud-bath therapy ($N = 47$) and control ($N = 10$) groups. In the panel B the delta was referred to the variation in % of subjects between "After" and "Before" sulphurous mud-bath treatment

(A)	Total score NRS—pain (mean ± SD)		*p* value
	Before	After	
Mud-bath therapy group	2.0 ± 0.9	1.1 ± 0.9*	< 0.01
Control group	1.9 ± 1.0	1.9 ± 1.0	NS
(B)	Delta after–before spa treatment (%)		
Score NRS-pain	Mud-bath therapy		
Score 0 (absent)	+ 17.01		
Score 1 (mild)	+ 21.28		
Score 2 (moderate)	− 10.21		
Score 3 (severe)	− 27.66		

*$p < 0.01$, after mud-bath therapy group vs control group

Table 2 Flexibility of the lumbar spine using FTF test (*A*), total ODI-I score (*B*), total S.D.S. Zung-test score (*C*) and total ISI score (*D*) in the mud-bath therapy ($N=47$) and control ($N=10$) groups

(*A*)	Total score FTF–test (mean ± SD)		*p* value
	Before	After	
Mud-bath therapy group	15.4 ± 10	13.6 ± 9*	< 0.05
Control group	22 ± 10	23 ± 12	NS
(*B*)	Total ODI-I score (mean ± SD)		*p* value
	Before	After	
Mud-bath therapy group	17 ± 0.1	11 ± 0.1	< 0.01
Control group	14.6 ± 0.1	14.8 ± 0.1	NS
(*C*)	Total S.D.S. Zung-test score (mean ± SD)		*p* value
	Before	After	
Mud-bath therapy group	33.5 ± 7.8	31.9 ± 7.5	<0.05
Control group	35.3 ± 8.0	35.4 ± 8.0	NS
(*D*)	Total ISI score (mean ± SD)		*p* value
	Before	After	
Mud-bath therapy group	5.7 ± 5	4.0 ± 3.7	< 0.01
Control group	5.4 ± 5.0	5.6 ± 5.0	NS

*$p < 0.05$, after mud-bath therapy group vs control group

Table 3 Total score categories of ISI test and correlation with total score of S.D.S. Zung test in mud-bath therapy ($N=47$) and control ($N=10$) groups

Categories ISI test	ISI test, mean ± SD						SDS Zung test, mean ± SD					
	Before		*p*	After		*p*	Before		*p*	After		*p*
	Mud-bath	Control		Mud-bath	Control		Mud-bath	Control		Mud-bath	Control	
No clinically significant insomnia	2.3 ± 2	2.9 ± 3	NS	1.6 ± 1.5	3.0 ± 3.6	NS	30.6 ± 8	32 ± 5.8	NS	29.8 ± 7	32 ± 5.8	NS
Sub-threshold insomnia	11.2 ± 3	11 ± 3	NS	7.8 ± 3*	11 ± 3	NS	38 ± 6	42 ± 10	NS	35 ± 7*	42 ± 10	NS

*$p < 0.05$, before vs after in mud-bath therapy group

A significant difference ($p=0.008$) is found inter-groups in NRS-pain score with the lowest value in the group who underwent spa treatment. Similarly, a better flexibility of the lumbar spine is observed (using the FTF test) in the patients treated with sulphurous mud-bath therapy compared to the control group ($p=0.007$). No other differences are found inter-groups after the treatment.

This study demonstrates that a sulphurous mud-bath cycle might induce a reduction of pain and depressive status, also leading to a significant improvement of the insomnia in the subjects with sleep disorders.

The observed therapeutic effects of sulphurous mud-bath cycle are probably due to a combination of several properties attributed to the sulphurous mineral water.

Such properties are the *analgesic* (with increase in β-endorphine serum levels), *anti-inflammatory* (with reduction in circulation levels of Prostaglandin E2, Leuko-triene B4, Interleukin-1β, Tumour Necrosis Factor-α), *muscle relaxant* (with increase in the extensibility of collagen tissue, thereby counteracting ankylosis and fibrotic retraction with decreased stiffness), *antioxidant* (as demonstrated by decrease of reactive oxygen and reducing action of the sulfhydryl group effective against oxidative DNA damage associated with inflammatory respiratory diseases). Moreover, *trophic* and *vasodilatator* effects are due to the sulphurous mud-bath application able to break the vicious cycle: pain–muscular contracture–altered dynamic–pain, which characterize chronic arthropathies [11–13].

We [14] previously demonstrated on 99 subjects suffering from osteoarthritis, localized in cervical and lumbar back section, that sulphurous mud-bath therapy induces an improvement of physical function and psychosocial disability with reduction of pain at rest and during daily activities.

Fioravanti et al. [15] confirmed the clinical efficacy and persistence of the therapeutic effects over time of sulphurous mud-bath therapy administered for two consecutive years in patients with osteoarthritis, particularly in that localized in the cervical and lumbar spine, with a significant reduction in the recourse of additional treatments (hospital admissions, physical and pharmacological therapies) and workplace absenteeism.

In accordance with the literature, our results demonstrate that a sulphurous mud-bath cycle is effective and safe for treatment of patients suffering from CLBP due to lumbar spine osteoarthritis. Such spa treatment, through its beneficial effects on painful symptomatology and low back functionality, may favor a significant reduction of depression and insomnia with improvement of the patients QOL, a very important outcome taking into account the strong relationship between chronic pain, depression and insomnia.

Therefore, our data suggest that the mud-bath cycle with sulphurous mineral water should be included in the care course of the patients with CLBP associated to lumbar spine osteoarthritis. Nonetheless, an important limitation of this study is represented by the study design (observational) and the small sample size.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of human and animal rights The study was conducted in according to the guidelines of the Declaration of Helsinki and its amendments.

Informed consent All participants provided their informed consent.

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