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Comparative effects of mud therapy versus a mud-like substance in the rehabilitation of patients with knee osteoarthritis

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Abstract: The aim of this non-randomized controlled study was to assess the impact of mud therapy on pain and functional capacity in patients with knee osteoarthritis, by comparing a group treated with mud therapy to a control group that received treatment with a placebo substance similar to mud. Fifty patients patients diagnosed with knee osteoarthritis were enrolled in the study. The intervention group (n=25) received local mud therapy, while the control group (n=25) underwent local treatment with a placebo substance mimicking mud therapy. Pain intensity was evaluated using the Visual Analogue Scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index and the Lequesne Index. Functional performance was assessed through standardized physical performance tests: the 30-Seconds Chair Stand Test (30-s CST) and Stair Climb Test (SCT). At baseline, no significant differences were observed between groups regarding pain and functional outcomes ($p > 0.05$). Following treatment, the intervention group showed a significant reduction in pain compared to the control group, with a difference of -3 points in VAS scores ($p < 0.001$), and an improvement in functional performance, reflected by an increase in the 30s-CST ($p = 0.023$). No significant between-group differences were observed for WOMAC, Lequesne Index or SCT outcomes. A higher proportion of patients in the control group received anti-inflammatory medication, which may represent a potential cofounding factor. These findings support the effectiveness of mud therapy in reducing pain and improving physical performance in patients with knee osteoarthritis.

Keywords: mud therapy, knee osteoarthritis, balneotherapy, pain management, functional performance

1. Introduction

Knee osteoarthritis is one of the most common degenerative osteoarticular pathologies, having a significant impact on patients' quality of life [1,2]. The main clinical manifestations of this condition include chronic pain, limited mobility, and reduced functional capacity. The prevalence of knee osteoarthritis increases with advancing age and is influenced by factors such as obesity, joint overuse, trauma, and genetic predisposition [3]. Recent epidemiological data indicate a continuous rise in the global burden of knee osteoarthritis, with substantial increases in prevalence and disability projected in the coming decades, particularly in aging populations [4]. Consequently, knee osteoarthritis represents a major public health concern, generating considerable medical and socioeconomic costs worldwide.

The management of knee osteoarthritis is complex and primarily aims to alleviate symptoms, slow disease progression, and preserve joint function. In addition to pharmacological therapies and surgical interventions, balneotherapy represents an alternative treatment option for managing the symptoms of this condition. The use of natural therapeutic factors has attracted considerable research interest due to their anti-inflammatory, analgesic, and muscle-relaxant effects [5-8]. Among these natural therapeutic factors is sapropelic mud from the Techirghiol area, which is recognized for its thermal, mechanical, and chemical properties [9,10].

Despite the growing use of mud therapy in clinical practice, evidence regarding its specific therapeutic effects remains heterogeneous, and outcomes may be influenced by non-specific factors such as patient expectations and contextual effects associated with physical therapies. For this reason, placebo-controlled design are essential to distinguish the specific effects of mud therapy from placebo-related responses and to provide a more rigorous assessment of its clinical efficacy. Therefore, the present study aims to evaluate the impact of treatment with Techirghiol mud on pain and functional capacity in patients with knee osteoarthritis, compared with a control group receiving a mud-like placebo substance.

2. Materials and Methods

1.1 Study Design

A controlled, non-randomized clinical study was conducted to evaluate the impact of balneotherapy on pain and functional capacity. The study included a total of 50 patients, who were divided into two groups. Group A, intervention group consisted of 25 participants who underwent local mud therapy at the Techirghiol Balneary and Rehabilitation Sanatorium and group B, control group also comprising 25 participants, received local treatment with a mud-like substance at the Physical Medicine and Rehabilitation Department of the Constanța County Emergency Clinical Hospital. Group allocation was performed based on treatment availability at the participating centers. The therapist applying the treatment was aware of group allocation due to the nature of the intervention and was therefore not blinded. Patients were blinded to treatment allocation. The therapist delivering the intervention could not be blinded. No formal assessment of blinding success was performed.

Patients were allowed to continue their usual analgesic and anti-inflammatory medication throughout the study. No changes in medication regimens were required or enforced during the intervention period. Medication use was recorded at baseline and considered in the interpretation of results.

The study protocol was approved by the Ethics Committees of both participating centers and was conducted in accordance with established ethical standards and relevant institutional guidelines. All participants received detailed information regarding the study objectives and procedures, and written informed consent was obtained prior to study participation.

The enrollment process of participants is summarized in the flowchart presented in Figure 1.

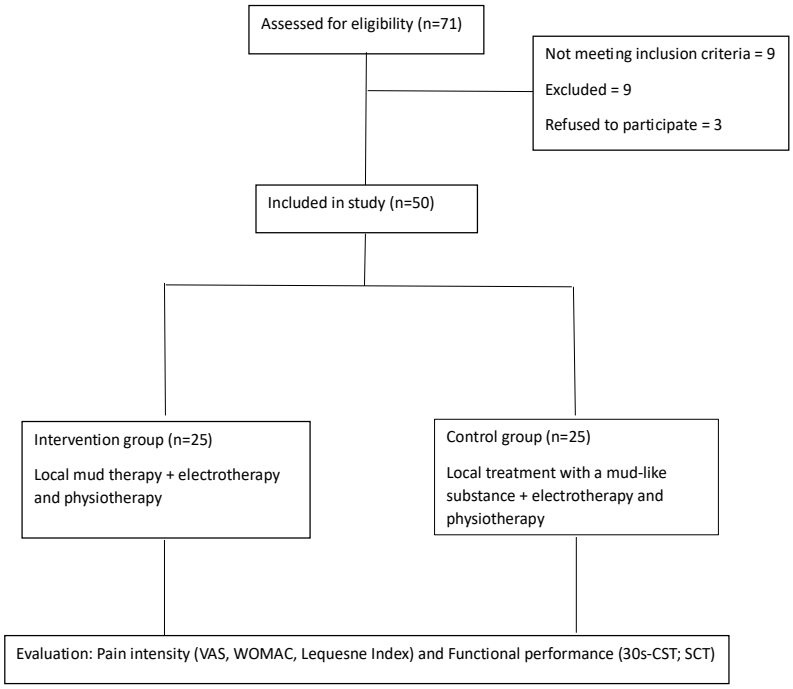

Figure 1. Flow diagram of the study

1.2 Eligibility Criteria

Inclusion criteria consisted of patients aged over 50 years with a diagnosis of primary knee osteoarthritis established according to the American College of Rheumatology (ACR) criteria. Eligible participants presented radiographic knee osteoarthritis grades I-III based on the Kellgren-Lawrence (KL) classification and were physically and cognitively able to participate in regular treatment sessions. Patients with unilateral or bilateral knee osteoarthritis were included and in case of bilateral involvement, the more symptomatic knee at baseline was selected as the index knee for analysis.

Exclusion criteria included the presence of other inflammatory joint diseases, a history of knee surgery within the previous six months and the presence of a knee either total or partial. Patients who had received intra-articular injections within the previous three months were also excluded, as were those with epidermal lesions at the knee joint or medical conditions that contraindicated balneotherapy.

1.3 *Treatment procedure*

All participants underwent a ten sessions of treatment protocol consisting of balneotherapy combined with electrotherapy and kinesiotherapy procedures over a period of two weeks. Electrotherapy consisted of a combination of low, medium or high frequency electrical currents, selected according to the treating physician's clinical indications. Kinesiotherapy comprised structured and supervised therapeutic exercise programs focused on improving knee joint mobility, enhancing periarticular muscle strength, increasing functional stability and reducing pain. Natural therapeutic mud or placebo substance was applied as a local wrap directly to the skin in a thick layer measuring approximately 1–2 cm. The treated area was subsequently covered with plastic foil and a blanket in order to maintain local heat. The duration of each application was 20 minutes.

The placebo material (artificial mud) was prepared under controlled laboratory conditions to mimic the physical properties of sapropelic mud. The base formulation consisted of starch glycerin ointment. Briefly, starch was placed in a pre-weighed and pre-heated porcelain capsule, followed by the addition of water heated to 70 °C, and the mixture was triturated until homogeneous. After a 10 minutes resting period, glycerin preheated to 90°C was added in a water bath. The mixture was further heated on a wire gauze with continuous stirring until gelification occurred. Warm water (approximately 70 °C) was then added to adjust the final weight to 100 g, and the mixture was stirred continuously until cooling. The resulting product was a homogeneous, translucent, odorless, and hygroscopic ointment. To reproduce the characteristic dark color of therapeutic mud, activated charcoal powder was incorporated at a concentration of 500 mg per 100 g of ointment using gradual addition with continuous mixing. Subsequently, sulfur was added at a concentration of 1 g per 100 g of ointment, following the same gradual incorporation procedure. Finally, after all components were uniformly mixed, distilled water was added until the desired consistency was obtained. The final product was a black, viscous, semisolid material closely resembling the physical appearance and texture of natural sapropelic mud.

1.4 Evaluation parameters

The study population was characterized according to sociodemographic variables (age, sex, body mass index and area of residence), as well as clinical outcomes related to pain intensity and functional capacity. The patients were evaluated twice using clinical assessment scales, at baseline and after the treatment program.

Pain intensity was assessed using the Visual Analog Scale (VAS), a 10 cm horizontal scale ranging from 0 (no pain) to 10 (worst pain), on which patients indicated their perceived level of pain. The Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used to evaluate knee related pain, stiffness, and physical function. The questionnaire consists of 24 items divided into three subscales, with higher scores indicating greater symptom severity and functional impairment. The Lequesne Index was applied to assess the severity of knee osteoarthritis by evaluating pain, maximum walking distance and activities of daily living, with higher scores reflecting increased disease severity.

Functional capacity was assessed using standardized physical performance tests. 30 Seconds Chair Stand Test (30s-CST) was used to evaluate lower limb muscle strength and functional performance by recording the number of full stands completed from a seated position within 30 seconds. The Stair Climb Test (SCT) assessed functional mobility and lower extremity strength by measuring the time required to ascend and descend a standardized flight of stairs. For each outcome measure, the difference between discharge and admission scores was calculated to quantify treatment related improvement.

1.5 Data analysis

Data processing was performed using Microsoft Office Excel 2019 for spreadsheet calculations and IBM SPSS Statistics, version 26, for statistical analysis. Independent tests were used to compare baseline characteristics between groups at admission (Mann-Whitney U test for non-normally distributed variables and Student's t-test for normally distributed variables). Intragroup changes (admission vs. discharge) were analyzed using the Wilcoxon signed-rank test for variables with non-normal distribution. Between group comparisons of improvement were performed using the Mann-Whitney U test for non-normally distributed variables. Data are presented as medians [interquartile range, IQR] for non-normally distributed variables and as means ± standard deviation (SD) for normally distributed variables. Statistical significance was set at $p < 0.05$.

3. Results

The study included a total of 50 patients diagnosed with knee osteoarthritis, divided equally into the intervention group (n=25) and the control group (n=25). The majority of patients were female (78%) and came from an urban area (74%). The predominant radiological grade of damage was KL III (58%), followed by KL II (34%). There were no statistically significant differences between the intervention and control groups in terms of demographic, anthropometric and clinical baseline charcateristics ($p > 0.05$), except for the use of anti-inflammatory medication, ehich was more common in the control group ($p < 0.01$). The demographic, antropometric and clinical characteristics of the patients are presented in Table 1.

Table 1. Demographic and behavioral characteristics of the 2 groups

Variable	Category	Intervention group	Control group	p
Gender	Male	4 (16%)	7 (28%)	0.32
	Female	21 (84%)	18 (72%)	
Environment	Urban	20 (80%)	17 (68%)	0.36
	Rural	5 (20%)	8 (32%)	
BMI (kg/m²)		29.22 ± 5.99*	30.39 ± 5.89*	0.48
KL knee	I	-	4 (16%)	0.18
	II	10 (40%)	7 (28%)	
	III	15 (60%)	14 (56%)	
Anti-inflammatory medication	Yes	4 (16%)	14 (56%)	0.01
	No	21 (84%)	11 (44%)	

* mean values ± SD; BMI – Body mass index; KL - Kellgren-Lawrence

At the time of admission, there were no statistically significant differences between the intervention group and the control group in terms of pain scores (VAS), joint function and discomfort (WOMAC, Lequesne Index) and functional tests (30s-CST, SCT) ($p > 0.05$ for all comparisons). These results indicate good baseline comparability of the two groups (Table 2). The analysis of the intragroup evolution at the level of the entire study group revealed a statistically significant improvement in all the evaluated parameters between admission and discharge. There were significant decreases in pain and dysfunction scores (VAS, WOMAC, Lequesne Index), as well as improvements in functional performance (30s CST, SCT), with p values < 0.001 for all variables analyzed (Table 3).

Table 2. Functional and pain-related indices at admission in both groups. Values are expressed as mean [SD] for normally distributed variables and median [IQR] for asymmetrically distributed ones

Variable admission	Intervention group	Control group	p
VAS	6[3]	7[3]	0.539
WOMAC	39.24(17.82)	44.56(19.99)	0.326
Lequesne	10[5]	12[10]	0.432
30s-CST	9.48(2.36)	9.08 (2.76)	0.585
SCT	18[16]	18[9]	0.778

Table 3. The overall evolution between baseline and follow-up of the entire group

Variable admission	Hospitalization (median [IQR])	Discharge (median [IQR])	Δ (median [IQR])	p intragroup
VAS	6[2]	4[3]	−2 [3]	<0.001
WOMAC	42.5[32]	34[32]	−4 [5.25]	<0.001
Lequesne	12[9]	10.5[7]	−1 [2]	<0.001
30s-CST	9[4]	10[4]	+1 [2]	<0.001
SCT	18[10]	17[9]	−1 [1]	<0.001

(Δ = discharge – admission)

Both in the intervention group and the control group, a significant improvement was observed in most of the parameters evaluated between admission and discharge. In the intervention group, all the variables analyzed showed statistically significant improvements, including the 30s-CST ($p < 0.001$). in the control group, statistically significant improvements were observed for the VAS, WOMAC, Lequesne Index and SCT scores ($p < 0.01$). However, for the 30s-CST, the difference between admission and discharge did not reach statistical significance (Table 4).

Table 4. Intragroup improvement of parameters.

Lot	VAS admission	VAS discharge	Δ VAS	p intragroup
Intervention	6[3]	3[3]	-3[2]	<0.001
Control	7[3]	5[3]	0[2]	0.004
Lot	**WOMAC admission**	**WOMAC discharge**	**Δ WOMAC**	**p intragroup**
Intervention	39[23]	32[21]	-4[7]	0.001
Control	51[37]	46[38]	-4[5]	0.006
Lot	**Lequesne admission**	**Lequesne discharge**	**Δ Lequesne**	**p intragroup**
Intervention	10[5]	10[4]	-1[2]	0.002
Control	12[10]	12[11]	-2[1.5]	0.003
Lot	**30s-CST admission**	**30s-CST discharge**	**Δ 30s-CST**	**p intragroup**
Intervention	9[4]	10[4]	1[1]	<0.001
Control	9[5]	9[5]	0[1]	0.101
Lot	**SCT admission**	**SCT discharge**	**Δ SCT**	**p intragroup**
Intervention	18[16]	17[13]	-1[1]	<0.001
Control	18[9]	17[9]	-1[2.5]	0.001

(Δ = discharge – admission)

Comparison of the degree of improvement between the two groups revealed statistically significant differences in favor of the intervention group for the VAS score ($p < 0.001$) and for the 30s-CST ($p = 0.023$). these results suggest a superior effect of the intervention on pain and improvement in muscle strength and endurance. For the other parameters evaluated (WOMAC, Lequesne Index and SCT), although improvements were observed in both groups, the differences between the groups were not statistically significant ($p > 0.05$) (Table 5).

Table 5. Differences in evolution between groups

Variable	Intervention (Δ average ± DS / median [IQR])	Control (Δ average ± DS / median [IQR])	p between groups
Δ VAS	-3[2]	0[2]	<0.001
Δ WOMAC	-4[7]	-4[5]	0.392
Δ Lequesne	1[1]	-2[1.5]	0.637
Δ 30s-CST	1[1]	0[1]	0.023
Δ SCT	-3[2]	-1[2.5]	0.632

Comparison of changes between groups revealed a statistically significant improvement in the intervention group for pain (ΔVAS: -3 [IQR 2] vs. 0 [IQR 2], $p < 0.001$) and for the 30s-CST (Δ30s-CST: +1 [IQR 1] vs. 0 [IQR 1], $p= 0.023$). For the other functional parameters, the differences in improvement between groups did not reach statistical significance.

4. Discussion

The results of this study highlight a significant improvement in pain and joint function in patients with knee osteoarthritis during treatment, regardless of the type of treatment applied. However, the comparative analysis between groups suggests an additional benefit in the intervention group on pain reduction and functional performance, assessed by the VAS score and the 30s-CST.

The significant improvement observed in the entire group can be explained by the cumulative effect of standard medical treatment, electrotherapy, physiotherapy, and clinical supervision during the treatment period. The decrease in VAS, WOMAC and Lequesne scores indicates not only pain reduction, but also improvement in function and quality of life, essential aspects in the management of knee osteoarthritis. These results are consistent with data from the specialized literature, which support the effectiveness of mud therapy as part of non-pharmacological strategies for knee osteoarthritis. A recent meta-analysis of randomized clinical trials showed that local mud application has a significant effect on pain reduction in patients with knee osteoarthritis, suggesting a real benefit of mud therapy over control [5]. Similar results have been reported in several individual clinical trials, in which balneotherapy and mud application resulted in significant improvement in pain and functional parameters compared to simple thermal applications [11]. Another systematic review showed that mud therapy reduces pain, stiffness and improves joint function in knee osteoarthritis, underscoring the conclusion that peloid therapy is an effective and non-invasive therapeutic option for the symptomatic management of this condition [12]. These findings are consistent with recent evidence emphasizing the value of integrated rehabilitation approaches in musculoskeletal disorders. The implementation of complex rehabilitation protocols including balneal interventions has been associated with significant improvements in clinical and paraclinical parameters, supporting the role of such therapies in functional recovery [13]. In addition, previous evidence has emphasized the clinical relevance of biological factors, such as vitamin D status, in the pathophysiology and clinical progression of knee osteoarthritis [14].

Although the physiological mechanisms are not fully elucidated, the beneficial effects of mud application are attributed to both the thermal effect and the chemical properties of the peloids, minerals and organic compounds can modulate local inflammatory processes and influence connective tissue metabolism [15]. This could partly explain the differences observed between the mud treatment group and the control group in our study.

In our study, the differences between groups for VAS and 30s-CST score support the idea that mud-therapy may have an adjuvant effect on pain reduction and functional improvement, beyond the basic treatment applied to all patients. These findings are consistent with evidence from the existing literature, which shows beneficial effects on symptom severity and functional outcomes in patients with knee osteoarthritis undergoing mud-based treatment compared with placebo treatments or thermal treatments without active ingredients [5].

One methodological aspect to be considered when interpreting the present study is the non-randomized design. Group allocation was not randomized, as participants were assigned to intervention or control groups based on treatment availability and center specific clinical practice. An important limitation of the present study that should be considered when interpreting the results is the imbalance in concomitant anti-inflammatory medication use between the two groups. A higher proportion of

patients in the control group continued anti-inflammatory treatment during the intervention period. Given the well-known analgesic and anti-inflammatory effects of these medications, this imbalance would be expected to improve pain and functional outcomes in the control group. As a result, this factor may have biased the observed between- group differences toward the null hypothesis, potentially underestimating the true effect of mud therapy. The fact that significant differences in pain reduction and functional performance were still observed in favor of the intervention group supports the robustness of the therapeutic effect.

Although the evidence is generally favorable for mud therapy, the literature recognizes the heterogeneity of studies as a major limitation, differences in treatment durations, control types, and assessment scores influence the comparability of results [16,17]. Many of the meta-analyses also emphasize the need for better quality studies, with rigorous randomization and larger sample sizes to fully confirm the long-term benefits of mud therapy [5].

5. Limitation of the study

The actual study presents a number of limitations that should be taken into account. The relatively small sample size, each group consisted of 25 patients, which may limit statistical power and generalizability of the results. Random allocation was not feasible and selection bias cannot be completely excluded. Also, the short follow-up duration does not allow for the assessment of the maintenance of benefits in long-term duration. The use of subjective outcomes measures, sch as the VAS, WOMAC and Lequesne Index, may introduce a degree of assessment bias. Furthermore, the presence of uncontrolled factors, including comorbidities or concomitant medication, may influence the results.

6. Conclusions

The results of this study suggest that the additional use of mud therapy was associated with superior outcomes in pain reduction and functional performance, indicating its value in the treatment of knee osteoarthritis. From a clinical perspective, mud therapy may represent a safe and accessible complementary treatment option that alongside pharmacological management, electrotherapy and physiotherapy may enhance short-term symptom control and functional recovery.

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Data Availability Statement: The data presented in this study are not publicly available due to ethical and privacy restrictions involving patient data but are available from the corresponding author on reasonable request.

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