

Original article

Clinical effectiveness of mud pack therapy in knee osteoarthritis

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Abstract

Objective. The main objective of this study was to systematically review all the scientific studies that analyse the effectiveness of mud pack therapy on patients diagnosed with knee OA.

Methods. One hundred and fifteen publications were identified through an electronic and manual search and 20 of those studies were chosen based on the inclusion criteria: randomized clinical trials, systematic reviews or meta-analyses whose objective was to analyse the effect of mud pack therapy on perceived pain, function and quality of life, with a sample size of ≥ 20 subjects, published since 2000 and showing conclusive results.

Results. In the studies that met the inclusion criteria, 12 analyse functionality, 17 perceived pain, 5 quality of life and all showed a significant improvement in the three analysed variables. The methodological quality of the studies had a moderate risk of bias.

Conclusion. Mud pack therapy is considered an alternative and effective therapy in the clinical management of knee OA. Studies with better methodology are needed to prove its scope.

Key words: knee osteoarthritis, rheumatic diseases, mud therapy, quality of life, review, randomized clinical trial.

Introduction

Mud pack therapy has been used to treat rheumatic conditions since time immemorial, representing an unquestionable reality [1]. However, there are only a few review articles that evaluate the therapeutic effect of its application in knee OA [2], which is defined as a chronic illness characterized by progressive deterioration of the articular cartilage [3].

Mud pack is defined as a natural product that consists of a mixture of mineral or mineral-medicinal water (including seawater or saltwater from lakes) with organic or inorganic material produced from biological and/or geological processes and used as a therapeutic treatment in the form of a mud wrap or bath [4]. The main use of the

treatment is to relieve rheumatic musculoskeletal pain [5]. Its effects on neuralgias and skin problems are also known for the successful results obtained [6]. Although the main mechanical action of the mud pack is thermal therapeutic, its systemic action allows it to act on molecular and chemical processes in degenerative conditions like OA [7]. However, this fact continues to be mentioned alongside hydrotherapy and spa treatments despite the differences in its action mechanisms [8].

According to the last National Health Survey (ENS, 2006) [9], arthritis represents the illness with the second highest impact on the quality of life and the third on functional ability in the Spanish population, mainly affecting the knee joint. Recently, a study by Batlle-Gualda *et al.* [10] assessed the generated costs of symptomatic management in OA, concluding that it was one of the illnesses where more resources were consumed.

Bearing in mind balneotherapy as an intervention procedure in the management of rheumatism [11] and the need for scientific evidence of the therapeutic scope of the different techniques used in this discipline [12], the main objective of this study was to systematically review scientific studies that analyse the therapeutic effects of

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mud pack application on functional capacity, perceived pain and quality of life in patients diagnosed with OA.

Materials and methods

The bibliographical search was carried out between November 2010 and December 2011. The strategy to select the studies was done in three phases. Phase 1 was the detailed search in scientific databases PubMed, PEDro, Scopus, Cochrane Library, EMBASE, Cinahl and Science Direct. The keywords were knee osteoarthritis, arthralgia, rheumatic diseases, mud therapy, and quality of life obtained from Medical Subject Headings (MeSH) using Boolean operators AND and OR. Phase 2 involved analysing references from the selected articles from the first phase. Phase 3 involved analysing scientific documents in paper format on mud pack therapy studies. The inclusion criteria for the selection of articles were the following: (i) articles on experimental studies, quasi-experimental and clinical trials whose main objectives were to analyse the effect of mud pack therapy on patients diagnosed with knee OA as well as doctoral thesis and systematic reviews that evaluated the effects of mud pack therapy; (ii) articles whose sample size was ≥ 20 individuals; (iii) studies published from 2000 to the present that show conclusive results in English, French, Italian, Portuguese and Spanish.

The studies that were excluded from the review were the following: those that analysed the effects of mud pack therapy in body regions other than the knee joint; studies that analysed the effects of mud packs on a pathology other than OA and those that did not study perceived pain, functional capacity and quality of life (Fig. 1).

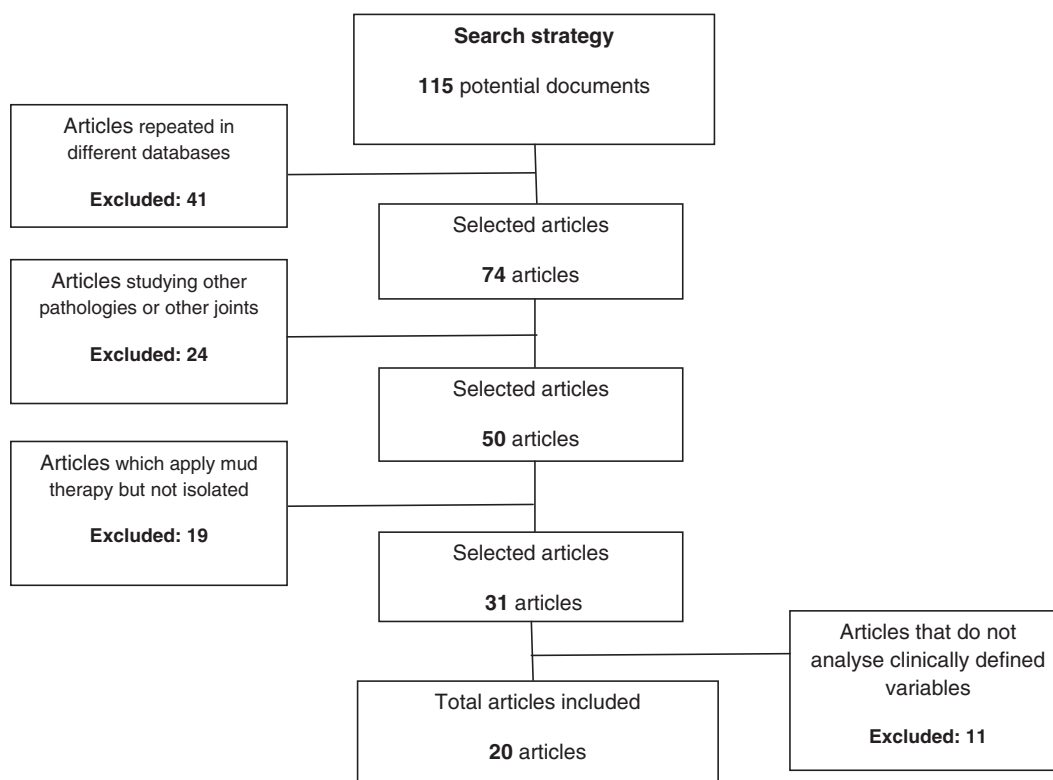
Evaluating the methodological quality of the studies

To avoid any possible variation caused by systematic errors in the design or execution of the study, the authors independently assigned each study to quality levels as described in *Cochrane's Handbook for Systematic Revisions on Interventions* [13]. Any doubts or disagreements were resolved through discussion among the authors and consensus.

The following criteria were used: blinded researcher and patient, hidden assignment, evaluation of results, co-intervention and dropouts during the follow-up. The evidence classification system used is the one recommended by the Cochrane group on musculoskeletal conditions, as it was considered the most appropriate for the present study.

The selected studies were organized in descriptive tables (Tables 1, 2 and 3), registering the most relevant elements such as author, year, applied treatment, sample size, duration and frequency of treatment, accomplished effects, measuring tools used and if there were any controls on medication intake.

Fig. 1 Flow diagram of the selection process for included studies.



Results

After carrying out the three search phases, 115 documents were chosen and 20 of those studies were selected as they met the inclusion criteria. Only two review studies [14, 15] were found and therefore our study could be considered to be the first review focusing on knee OA. Regarding the revised variables, we found that perceived pain was analysed in 17 studies, function in 13 and quality of life in only 5.

The majority of the studies included in the review were published in the past 5 years, as we can observe a notable increase in scientific production in this area. The average sample size is 81.76 subjects, ranging from 20 [16] to 349 diagnosed with OA [17].

In relation to the source of the selected studies, Italy published the most scientific studies (60.80%) followed by Turkey (17.30%), Serbia and Poland with 8.70% and lastly France with 4.3%. Spain is experiencing a period of growth in scientific production, with research groups dedicated to the characterization of biochemical and thermophysical properties of mud packs in national thermal spa centres, including five doctoral studies researching different aspects related to mud pack therapy [18–22].

The results obtained regarding temperature and length of mud application indicates a lack of homogeneity in this criteria. The studies range from an application of treatment at a temperature of 47°C for 20 min [23] to an application of 46°C for 15–20 min [24], 45°C for 30 min [12, 25] or 42°C for 15–20 min [16, 26, 27].

Studies that analyse the effects of mud therapy on function

Twelve studies that analyse the effect of mud therapy on functional capacity of the joint [8, 16, 17, 23–27, 30–33] were found (Table 1). The measurement tools used are the WOMAC [28] questionnaire and the Lequesne Algofunctional Index, which are recommended by the European League Against Rheumatism (EULAR) [29]. At least one of these measurement tools is used in each study. Of those that use WOMAC, we highlight the work done by Odabasi *et al.* [25], whose objective was to assess the effectiveness of mud therapy on patients diagnosed with knee OA. They divided the study population into a control group that followed daily pharmacological treatment and an experimental group ($n=32$) to which a 45°C mud pack was applied for 30 min for five sessions a week for 3 weeks. The results indicated a 60% improvement in functional capacity maintained for 4 weeks after the end of the treatment; however, the methodological quality of the study indicates a moderate risk bias, as it did not use a randomized sample or controls and it did not indicate the possible dropouts during the follow-up of the study. Similar to this are the recent studies by Fraioli *et al.* [23] and Forestier *et al.* [17]. Both established a comparison between an experimental group that received mud pack therapy and a control group that continued with daily pharmacological treatment for knee OA. The Lequesne Algofunctional Index was used as the measurement tool for the first and the WOMAC questionnaire for

the second. The results showed a significantly favourable improvement for the group that received mud therapy in comparison with the control group.

Fioravanti *et al.* [24], Cantarini *et al.* [30] and Mika *et al.* [16] carried out comparative studies on the effectiveness and tolerance of mud therapy in contrast to short wave therapy [24, 30] and physical exercise [16] with the objective of establishing a comparison of the effects gained with mud therapy and other frequently used techniques in physiotherapy. Fioravanti *et al.* [24] studied a sample of 72 subjects randomly divided into two groups: group 1 ($n=48$), which had mud treatment, and group 2 ($n=24$), which received short wave cycles. The results were satisfactory in both groups. Cantarini *et al.* [30] divided their sample into three randomly assigned groups ($n=74$). The first group ($n=30$) received mud treatment, the second group ($n=24$) was treated with diathermia and the third group ($n=20$) constituted a control group. Functional capacity was measured with the Lequesne Algofunctional Index and there were better results in group 1. Both studies presented quality methods with a low risk of bias, randomization, control of the subjects as well as a blinded researcher.

Of the studies that establish comparisons between different balneotherapy techniques and frequency of treatment, we highlight those by Cutovik *et al.* [31] and Evcik *et al.* [26]. Evcik *et al.* [26] divided a sample of 80 subjects into three groups. The first group took baths in thermal pools, the second received mud therapy and the third received 10 sessions of hot packs with a frequency of five sessions a week. The results showed a significant improvement regarding function for the three applied techniques; however, the group treated with mud therapy showed the greatest improvement. The necessary treatment period to obtain positive effects was the objective of the Vath *et al.* [27] study. The subjects ($n=296$) were divided into two groups: both received the same treatment of mud therapy and thermal baths, but one group had treatment for 6 days and the other for 12 days. The results obtained were similar in both groups.

Finally, there were studies that showed the importance of the organic components of mud therapy to the improvement in functional capacity and pain. These studies applied the same intervention methodology in individuals with knee OA using enriched and impoverished mineral components in mud packs. The only limitations found were the lack of homogeneity in the distribution of the sample and its size.

Studies that analyse the effects of mud therapy on pain

There were 16 studies [8, 16, 17, 23–27, 30–37] that analysed the effects of mud pack therapy on perceived pain while also assessing the effect on function, and in some cases the influence on the need for medication [15, 38]. All the reviewed studies used a visual analogue scale (VAS) assessment of pain as the measurement tool (Table 2). The duration of the intervention ranged from 2 to 3 weeks. The studies' main objective was to analyse the

TABLE 1 Studies that analyse the effects of mud therapy on function in knee OA

Author	Year	Techniques	Size	Length	Frequency	Effects	Measurement tools	Control med
Cantarini <i>et al.</i> [30]	2007	Mud therapy SW therapy Control	30 24 20	3 weeks	Five times a week	> Functionality ($P \leq 0.0001$)	LAI	Yes
Fraioli <i>et al.</i> [23]	2010	Mud therapy	61	1 year	Three cycles/year, 12 sessions/cycle	> Functionality (38.3%)	LAI	Yes
Odabasi <i>et al.</i> [25]	2009	Control group Mud therapy	40 32	3 weeks	Five times a week	> Functionality (60%)	WOMAC	Yes
Evciik <i>et al.</i> [26]	2007	Control Mud therapy Hot packs	40 29 26	2 weeks	Five times a week	> Functionality (30%) > Functionality (21%)	WOMAC	Yes
Bostan <i>et al.</i> [8]	2010	Therapy with thermal bath Mud therapy HA injection	26 12 11	12 days	Daily interval	> Functionality (25%) > Functionality (26%) > Functionality (14%)	WOMAC	No
Floravanti <i>et al.</i> [33]	2010	Mud therapy	40	2 weeks	daily	> Functionality WOMAC (39.3%) > Functionality LAI (22.5%)	WOMAC, LAI	Yes
Floravanti <i>et al.</i> [24]	2000	Control group (usual drug therapy) Mud therapy	40 48	2 weeks	Six times a week	> Functionality at medium term ($P \leq 0.0001$)	LAI	Yes
Forestier <i>et al.</i> [17]	2010	SW therapy Spa therapy (including mud + thermal bath)	24 174 175	2 weeks 3 weeks	Five times a week Six times a week	> Functionality ($P \leq 0.001$)	WOMAC	Yes
Cutovic <i>et al.</i> [31]	2006	Control group (e.g. HEP + drug therapy)	30			> Functionality (44%)	LAI	No
Vath <i>et al.</i> [27]	2008	Balneoherapy + mud therapy	28 235	6 days	Daily	> Functionality (31%)	LAI	No
Mika <i>et al.</i> [16]	2006	Balneoherapy + mud therapy	61	12 days	Daily	> Functionality (36%)	WOMAC	No
Flusser <i>et al.</i> [32]	2002	Mud therapy + exercises + physical agent	10 40	2 weeks 3 weeks	Daily Five times a week	> Functionality (5.75%) > Functionality (7.90%) > Functionality (12.78%) > Functionality (7.83%)	LAI	No
Espejo-Antúnez [22]	2010	Mud therapy with impoverished minerals Natural mud therapy	18 61	3 weeks 2 weeks	Daily	> Functionality (38%)	WOMAC, LAI	Yes

Control med: medication control; SW: short wave; LAI: Lequesne Algofunctional Index; P: statistical significance index; HEP: home exercise programme.

TABLE 2 Studies that analyse the effects of mud therapy on pain in knee OA

Author	Year	Employed techniques	Size	Length	Frequency	Effects	Measurement tools	Control med
Fiorevanti <i>et al.</i> [24]	2000	Mud pack therapy	48	2 weeks	Six times/week	<Mid-term pain ($P \leq 0.001$)	VAS	Yes
		SW therapy	24	2 weeks	Five times/week			
Odabasi <i>et al.</i> [25]	2009	Mud pack therapy	32	3 weeks	Five times/week	>Pain (43%)	VAS	Yes
		Control	40	3 weeks				
Evciik <i>et al.</i> [26]	2007	Mud pack therapy	29	2 weeks	Five times/week	<Pain (20%)	VAS	Yes
		Hot packs	26			<Pain (5%)		
		Therapy with thermal bath	25			<Pain (33%)		
Bostan <i>et al.</i> [8]	2010	Mud pack therapy	12	12 days	Daily	<Pain (48.3%)	VAS	No
		HA injection	11	Interval		<Pain (45.4%)		
Cantarini <i>et al.</i> [30]	2007	Mud pack therapy	30	3 weeks	Five times/week	<Pain ($P < 0.01$)	VAS	Yes
		SW therapy	24					
		Control	20					
Fraioli <i>et al.</i> [23]	2010	Mud pack therapy	61	1 year	Three cycles/year, 12 sessions/cycle	<Pain (52.9%)	VAS	Yes
		Control group						
Fiorevanti <i>et al.</i> [33]	2010	Mud pack therapy	40	2 weeks	Daily	<Pain ($P \leq 0.001$)	VAS	Yes
		Control group (usual drug therapy)	40					
Jokic <i>et al.</i> [34]	2010	Mud pack therapy	31	3 weeks	Six times/week	<Pain ($P \leq 0.001$)	VAS	No
		Control group	31					
Benedetti <i>et al.</i> [35]	2010	Mud therapy + thermal bath	30	2 weeks	Six times/week	<Pain (44%)	VAS	Yes
		Control	15			<Pain (37%)		
Forestier <i>et al.</i> [17]	2010	Spa therapy (including mud + thermal bath)	174	3 weeks	Six times/week	<Pain ($P < 0.003$)	VAS	Yes
		Control group (e.g. HEP + drug therapy)	175					
Cutovic <i>et al.</i> [31]	2006	Balneotherapy + mud therapy	30	2 weeks	Daily	<Pain (38%)	VAS	No
		Balneotherapy	28		Two times/day	<Pain (31%)		
Costantino [36]	2006	Mud pack therapy	51	12 days	Daily	<Pain ($P \leq 0.05$)	VAS	No
Flusser <i>et al.</i> [32]	2002	Natural mud therapy	40	3 weeks	Five times/week	<Pain (11.07%)	VAS	No
		Mud therapy with impoverished minerals	18	3 weeks		<Pain (2.61%)		
Vath <i>et al.</i> [27]	2008	Balneotherapy + mud therapy	235	6 days	Daily	<Pain (62.2%)	VAS	No
			61	12 days	Daily	<Pain (72.7%)		
Mustur <i>et al.</i> [37]	2007	Mud therapy + hydrokinesitherapy + analgesic electrotherapy	109	4 weeks	Six times/week	<Pain ($P \leq 0.05$)	VAS	No
Mika <i>et al.</i> [16]	2006	Mud pack therapy + exercises + physical agent	10	2 weeks	Daily	<Pain (16.6%)	VAS	No
		Exercises + physical agent	10					
Espejo-Antúñez [22]	2010	Natural mud therapy	61	2 weeks	Daily	<Pain (41.6%)	VAS	Yes
						<Pain (43.7%)		

Control med: medication control; SW: short wave; VAS: visual analogue scale assessment of pain; HEP: home exercise programme.

TABLE 3 Studies that analyse the effects on quality of life in knee OA

Author	Year	Treatment	Size	Length	Frequency	Effects	Measurement tools	Control med
Fioravanti <i>et al.</i> [33]	2010	Mud therapy + thermal bath Control group (usual drug therapy)	40 40	2 weeks	Daily	>QLRH AIMS (29.1%)	AIMS	Yes
Evcik <i>et al.</i> [26]	2007	Mud therapy Hot packs Thermal bath (T: 36°C, 20 min)	29 26 25	2 weeks	Five times/week	>QLRH sleep dimension (31%) >QLRH pain (20%) >QLRH sleep dimension (19%) >QLRH pain (5%) >QLRH sleep dimension (23%) >QLRH pain (33%) >QLRH (54.4%)	NHP	Yes
Forestier <i>et al.</i> [17]	2010	Spa therapy (including mud + thermal bath) Control group (HEP + drug therapy)	174 175	3 weeks	Six times/week	>QLRH (29.7%) >QLRH fitness (15%) Physical role (16%) Body pain (12%) General health (10%) Vitality (18%) Emotional role (13%) Mental health (25%)	SF-36	Yes
Yilmaz <i>et al.</i> [39]	2004	Balneotherapy	46	3 weeks	Daily	>QLRH fitness (2.4%) Physical role (41%) Body pain (38.8%) General health (4%) Vitality (34.8%) Social function (11.4%) Emotional role (14.8%) Mental health (49.2%)	SF-36	Yes
Espejo-Antúnez [22]	2012	Natural mud therapy	61	2 weeks	Daily		SF-36	Yes

Control med: medication control; SW: short wave; HEP: home exercise programme; QLRH: quality of life related to health; AIMS: arthritis impact measurement scales; NHP: Nottingham Health Profile; SF-36: short form health survey; T: temperature.

effects of mud therapy on pain, basing the methodological design on the establishment of a comparison of the benefits of a physiotherapy and balneotherapy treatment and where the previous therapy was applied but mud therapy was added [16, 31]. Others analysed perceived pain through a mud-based therapy and an invasive approach such as HA IA injection [8], through an association of mud therapy and drug therapy [36] or simply through a control group [17].

The study of Flusser *et al.* [32] showed an 11.07% improvement with the application of natural mud pack therapy compared with a 2.61% improvement obtained with the use of impoverished mud packs. The improvement was maintained during a 3-month follow-up period. On the other hand, Vath *et al.* [27] concluded that the duration of the intervention influences pain intensity. The perceived pain was less in individuals to whom the treatment was applied for 12 days than in those who received a 6-day application. This improvement has been related to specific changes found in biochemical markers that are involved in articular cartilage degeneration [33, 34].

Studies that analyse the effects on quality of life

We only found four articles that studied the impact of mud pack therapy on the quality of life of patients with knee OA [17, 26, 33, 39]. Unlike the previous reviewed variables, the measurement tools used were heterogeneous (Table 3). In a study of 349 subjects diagnosed with knee OA, Forestier *et al.* [17] estimated an improvement of 54.4% for the experimental group after 3 weeks of treatment compared with an improvement of 29.7% obtained by the control group according to the outcomes of the SF-36 (short form health survey) questionnaire that was used. Yilmaz *et al.* [39] studied a smaller group of subjects ($n=46$) during a similar intervention period and using the same assessment scale. The improvements obtained were at least 10% in each dimension that constitutes the questionnaire. Fioravanti *et al.* [33] analysed in one of their studies the perceived quality of life for a subject with knee OA who receives mud pack therapy treatment. The subjects of the study ($n=80$) were randomly divided into two groups (experimental and control) and the first received daily treatment for a total of 2 weeks. The results showed an improvement in the quality of life close to 30%. Finally, Evcik *et al.* [26] applied the Nottingham Health Profile (NHP) questionnaire to three study groups and obtained an improvement in pain and sleep dimensions in all the groups, showing better results in the group of subjects who received a treatment of mud pack therapy and thermal baths.

Discussion

The objective of this study was to systematically review all the literature that analyse the different therapeutic effects of mud pack therapy. The results show that this therapy achieves significant improvements in function, quality of life and perceived pain for subjects with OA. However, the evidence-based treatment protocols and guidelines do not include balneotherapy as an effective intervention [11, 40].

These results agree with those obtained by Bartels *et al.* [41] on the need to carry out randomized controlled trials that reflect the potential effects of specific techniques. In this way, studies like those of Fraioli *et al.* [23] and Evcik *et al.* [26] were classified as having a high risk of bias, as neither article specified the presence of a blinded researcher, blinded patient or randomization. The first of these studies also showed an uncertain intervention for the control group and the second had a small sample size and did not establish dropouts during follow-up.

Nevertheless, there are also studies with a high-quality methodology, like the one from Flusser *et al.* [32] that assessed functional capacity gained through the application of mud packs with different quantities of mineral components included in the mixture. The only limitation of the study was the lack of homogeneity in population distribution.

Regarding the studies that analysed the perceived pain variable, and despite the obtained improvements, some had a small sample size without any control on the drug therapy [8, 16, 31, 35, 36] (Table 2). Among those that analyse the quality of life, we highlight Forestier *et al.* [17] and Fioravanti *et al.* [33] for the quality of their studies that showed a low risk of bias.

There are also studies whose objective was to analyse the different enzymatic and molecular mechanisms of action of mud pack therapy application, highlighting the reduction in the levels of TNF- α , IL-1 β , PGE2 and LTB4 [7, 41, 42], the increase in the synthesis of noradrenalin, cortisol, beta endorphins and insulin growth factor [44] or stimulation of cartilage metabolism through diverse reactions [14, 44–47].

Currently, the effectiveness of mud pack therapy is supported by recent studies comparing its effects with those achieved by other thermotherapy techniques (Table 4) and those that analyse possible changes in molecular and enzymatic markers resulting from the intervention. Changes have been observed in the levels of TNF- α , IL-1 β , PGE2 and LTB4, which are responsible for the inflammatory mechanism and articular pain [8, 42, 43]. The reduction of reactive oxygen and nitrogen release, among other reactions, has been linked to metabolic stimulation of the cartilage [15, 44–48]. In relation to this, Bellometti *et al.* [49] showed an increase in pituitary hormones due to hypothalamic–pituitary axis activation as a response to the thermal stress produced by the high specific heat of the mud pack [15]. The influence on enzymatic activity has also been described [34, 35]. Jokic *et al.* [34] observed a significant decrease in superoxide dismutase and catalase activity after applying mud pack therapy at 42°C, establishing a direct relationship with pain relief. Future studies with an appropriate methodological design should continue to research the influence of mud pack therapy on biochemical markers, establishing follow-up periods [50] and analysing cost-effectiveness vs drug therapy.

In conclusion, we agree with Forestier and Françon [51] regarding the reported effects of mud packs on function, perceived pain and quality of life in knee OA patients, and

TABLE 4 Studies that compare the effects of mud pack therapy with those of other thermotherapy techniques

Author	Year	Techniques	Size	Length	Frequency
Cantarini <i>et al.</i> [30]	2007	Mud pack therapy	30	3 weeks	Five times/week
		SW therapy	24		
		Control	20		
Evcik <i>et al.</i> [26]	2007	Mud pack therapy	29	2 weeks	Five times/week
		Hot packs	26		
		Thermal bath therapy	26		
Fioravanti <i>et al.</i> [24]	2000	Mud pack therapy	48	2 weeks	Six times/week
		SW therapy	24	2 weeks	Five times/week
Cutovic <i>et al.</i> [31]	2006	Balneotherapy + mud pack therapy	30		
		Balneotherapy	28		
Vath <i>et al.</i> [27]	2008	Balneotherapy + mud pack therapy	235	6 days	Daily
		Balneotherapy + mud pack therapy	61	12 days	Daily
Mika <i>et al.</i> [16]	2006	Mud pack therapy + exercises + thermal agents	10	2 weeks	Daily
		Exercises + thermal agents	10		
Flusser <i>et al.</i> [32]	2002	Natural mud	40	3 weeks	Five times/week
		Mud with impoverished minerals	18	3 weeks	

SW: short wave.

that the therapy constitutes an effective alternative in the clinical management of this pathology. In spite of this, studies with a better methodological quality are needed to prove its real scope.

Rheumatology key messages

- Mud pack therapy is an effective alternative treatment in the management of knee OA.
- Studies with better methodological quality on mud pack therapy dealing with knee OA are needed.

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