Arch Rheumatol 2021;36(x):i-ix
doi: 10.46497/ArchRheumatol.2021.8123

ORIGINAL ARTICLE

Comparison of Efficacy of Fluidotherapy and Paraffin Bath in Hand Osteoarthritis: A Randomized Controlled Trial

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ABSTRACT

Objectives: This study aims to compare the efficacy of paraffin bath therapy and fluidotherapy on pain, hand muscle strength, functional status, and quality of life (QoL) in patients with hand osteoarthritis (OA).

Patients and methods: This prospective randomized controlled study included 77 patients (8 males, 69 females; mean age 63.1±10.3 years; range 39 to 88 years) with primary hand OA who applied between July 2017 and March 2018. The patients were randomized into two groups with the sealed envelope method: Paraffin bath therapy (20 min, one session per day, for two weeks) was applied for 36 patients whereas 41 patients received fluidotherapy for the same period. The pain severity of the patients, both at rest and during activities of daily living (ADL) within the last 48 hours was questioned and scored using Visual Analog Scale. Duruöz Hand Index (DHI) was used to evaluate hand functions. Gross grip strength was measured using Jamar dynamometer whereas fine grip strength was measured using pinch meter in three different positions (lateral pinch, tip pinch, and palmar pinch). The 36-Item Short Form (SF-36) was used to analyze the QoL. All measurements were performed before, immediately after, and three months after treatment.

Results: Improvement was observed in pain score at rest and during ADL, DHI scores, gross and fine grip strengths, and SF-36 subscores in both groups after treatment. However, no significant difference was observed between the groups.

Conclusion: Both fluidotherapy and paraffin bath therapy have been found to have positive effects on pain, hand muscle strength, functional status, and QoL in the treatment of hand OA. However, no superiority was observed between the two treatment modalities.

Keywords: Fluidotherapy, grip strength, hand functions, hand osteoarthritis, paraffin.

Hand osteoarthritis (OA) is a chronic disease causing decreased quality of life (QoL) due to decreased hand function, loss of hand muscle strength, and pain.[1]

The role of pharmacological treatments in the treatment of OA is limited. The side effects of medical treatments limit their use in the treatment of OA since OA is frequently seen in the elderly population, has a chronic course, and its treatment takes a longer time.[2-4] Non-pharmacological treatments include patient education, self-management programs, joint protection techniques, exercises, assistive devices, orthoses, and thermal modalities.[5-9]

Hand OA is a blurred area in evaluating the efficacy of treatment modalities. There are few

Received: March 23, 2020 ***Accepted:*** August 09, 2020 ***Published online:*** September 28, 2020

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Citation:
Öncel A, Küçükşen S, Ecesoy H, Sodalı E, Yalçın Ş. Comparison of Efficacy of Fluidotherapy and Paraffin Bath in Hand Osteoarthritis: A Randomized Controlled Trial. Arch Rheumatol 2021;36(x):i-ix.

randomized controlled trials evaluating the efficacy of different non-pharmacological treatments on hand OA, and most of them are of poor quality. It is difficult to perform a meta-analysis because of the heterogeneous approaches and the absence of standard outcome measures.[10-12]

Although physical therapy modalities are widely used in the treatment of hand OA in clinical practice, there is no evidence-based data about which modality should be preferred in the treatment of hand OA. Despite the fact that the number of randomized controlled trials investigating the efficacy of non-pharmacological treatments in hand OA cases has increased in recent years, the number of studies investigating physical therapy modalities is very small. These studies have generally investigated the efficacy of the following treatment modalities: exercises,[13-15] laser treatments,[16,17] infrared therapy,[18] different mobilization techniques,[19,20] magnetotherapy,[21] and balneotherapy.[22,23]

American College of Rheumatology (ACR) recommends the use of thermal modalities in the treatment of hand OA.[5,8] In 2007, The European League Against Rheumatism (EULAR) recommended the use of heaters such as paraffin and hot pack and ultrasound therapy in the treatment of hand OA, particularly before exercise.[7] However, the recommendation was deleted in 2018 stating that the use of these treatment modalities was based on expert opinion and extrapolated from hip or knee OA studies.[24]

In *in vivo* studies, paraffin therapy induces local relaxation of smooth muscles in the arterioles by causing an increase in the temperature up to 7.5°C in the joint capsule and muscles. It shows its efficacy by providing vasodilation in peripheral blood vessels, increasing hyperemia and tissue fluid conduction, and accelerating the lymph flow and absorption of the exudate. A limited number of randomized controlled trials have shown its efficacy in patients with hand OA.[25,26]

Fluidotherapy, which provides dry heating, conducts heat to the soft tissues through convection. Heating is provided by synthetic cellulose parts in dry air. Fluidotherapy has been reported to be the most preferred thermal modality after paraffin and ultrasound in the treatment of hand OA cases.[27] Although it is widely preferred in patients with OA, there is a limited number of studies in the literature showing the efficacy of fluidotherapy in OA patients. Therefore, in this study, we aimed to compare the efficacy of paraffin bath therapy and fluidotherapy on pain, hand muscle strength, functional status, and QoL in patients with hand OA.

PATIENTS AND METHODS

In this prospective randomized controlled study, 98 patients who applied to Necmettin Erbakan University, Meram Faculty of Medicine, Physical Medicine and Rehabilitation between July 2017 and March 2018 with the complaint of bilateral hand pain were assessed for eligibility. All patients were examined by the same researcher for the diagnosis of primary hand OA according to the ACR criteria.[28]

Exclusion criteria included secondary hand OA due to various diseases such as gout, hemochromatosis, or calcium pyrophosphate deposition disease, rheumatoid arthritis or psoriatic arthritis, malignancy, entrapment neuropathy, diabetic neuropathy or other neurological diseases of the upper extremity, open wound of the hand, chronic infection, palmar tenosynovitis, severe hand injury or surgical operation within the last six months, intraarticular steroid or hyaluronic acid injection into the hand joint within the last six months, or balneotherapy within last six months.

A total of 16 patients were excluded from the study based on the exclusion criteria (nine patients had another rheumatic disease that affected hand functions, four had received balneotherapy in the last six months, and three were diagnosed with neuropathy). Remaining 82 patients were randomly assigned into fluidotherapy or paraffin groups via the sealed envelope method. However, in paraffin group, at the first month control, one patient left the study due to moving out of the city, two patients discontinued the treatment without giving any reason, and at the third month follow-up, two patients developed a local or systemic disease affecting hand function. Finally, a total of 77 patients (8 males, 69 females; mean age 63.1±10.3 years; range 39 to 88 years) (36 in paraffin group, 41 in fluidotherapy group) completed the study (Figure 1). The study protocol was approved by the Necmettin Erbakan University, Meram Faculty of Medicine

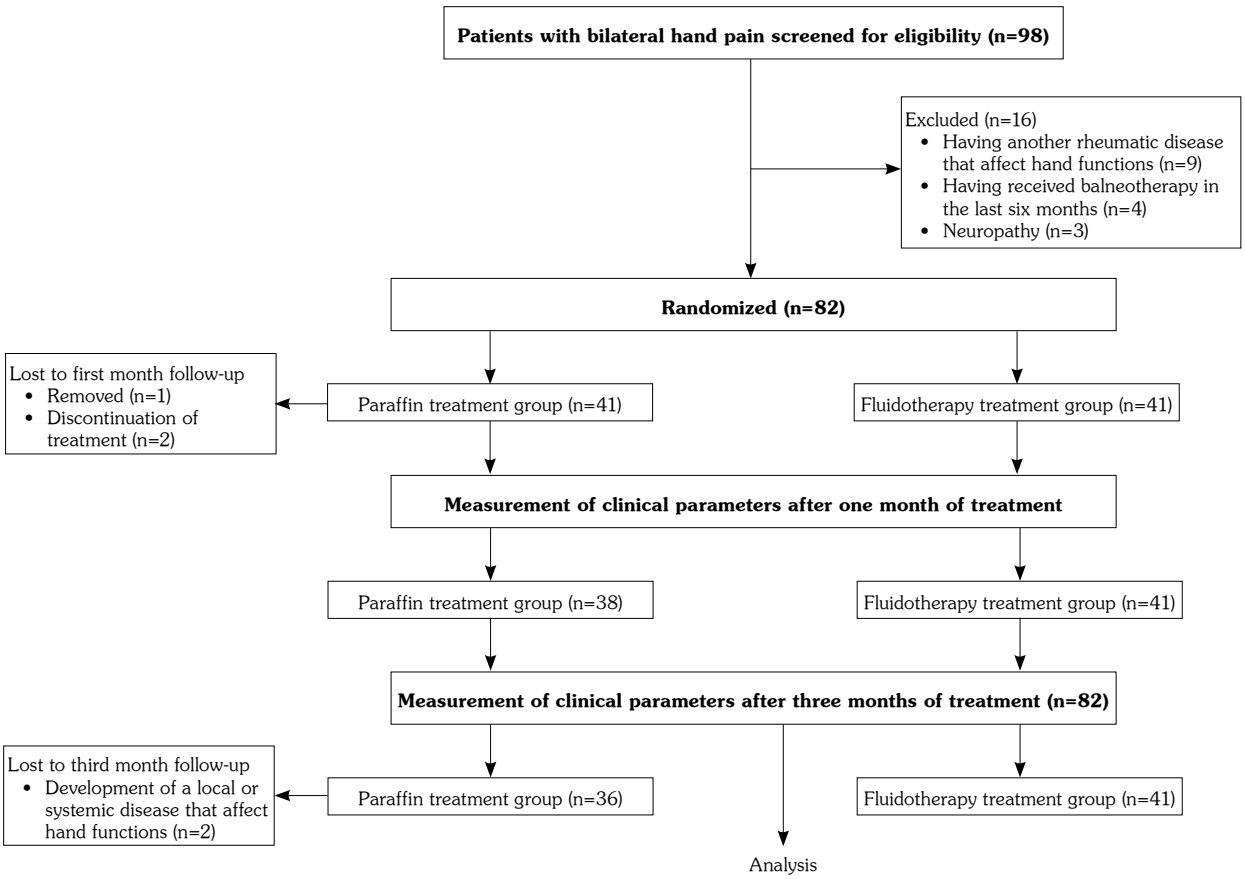

Figure 1. Study design and flow of participants through trial.

Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Sociodemographic and clinical characteristics of the patients including age, sex, body mass index (BMI), occupation, educational level, duration of disease, frequency of menopause, and duration of menopause were recorded. A researcher blinded to groups evaluated the patients in terms of outcome measures before treatment, immediately after treatment, and three months after treatment. The primary evaluation criteria were pain, hand functions, and QoL. Pain at rest and pain during activities of daily living (ADL) within the last 48 hours was assessed via a 10-cm Visual Analog Scale (VAS). Hand functions were evaluated with Duruöz Hand Index (DHI)[29] whereas gross grip strength was assessed via Jamar dynamometer (J A Preston Corp., New York, USA) and fine grip strength was measured using pinch meter in three different positions (lateral pinch, tip pinch, and palmar pinch). The 36-Item Short Form (SF-36)[30] was used to analyze the QoL.

The patients in the paraffin group received paraffin treatment for 14 days, one session per day. During the application, patients dipped their hands into the paraffin bath for 10 times. Their hands were covered with a towel and waited for 20 minutes to preserve the heat. For the treatment, a standard paraffin boiler of 28 L with an automatic thermostat and a temperature of 53°C was used. In the fluidotherapy group, the distal part of the forearm was completely placed inside the device when the patients were in a seated position. This procedure was performed for 14 days, a session (20 min) per day. Chattanooga® FLU115 (Chattanooga Group, Inc., Hixson, TN, USA) was used for fluidotherapy.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA). Descriptive statistics were expressed as number, percentage, mean and standard deviation, median. Visual (histogram and probability plots) and analytical techniques (Kolmogorov-Smirnov, Shapiro-Wilk tests) were used to evaluate whether the variables showed a normal distribution. Dependent t-test and independent t-test were used for the intra- and intergroup comparison of the normally distributed numerical variables, respectively. Wilcoxon signed-rank test and Mann-Whitney U test were used for the intra- and intergroup comparison of the not-normally distributed numerical variables, respectively. Chi-square analysis was preferred to compare the nominal data. A *p* value of <0.05 was considered statistically significant in all statistical analyses.

RESULTS

There was no significant difference between the groups in terms of age, sex, BMI, occupation, and educational status (Table 1). Similarly, there was no significant difference between the groups in terms of VAS score at rest, VAS score during ADL, hand muscle strength, DHI scores, and SF-36 scores before treatment (Table 2).

Findings obtained before, immediately after, and three months after treatment were examined in each group. In the paraffin group, a significant decrease was observed in the VAS scores both at rest and during ADL after treatment compared to the baseline (p<0.001). However, an increase was observed in the VAS score in the third month compared to the VAS score measured immediately after treatment. Despite this, third-month scores were lower than those measured before treatment (p<0.001).

In the fluidotherapy group, a significant decrease was observed in the VAS scores both at rest and during ADL after treatment compared to the baseline (p<0.001). However, an increase was observed in the VAS score at rest in the third month compared to the VAS score measured immediately after treatment (p=0.020). There was no change in VAS score during ADL in the third month compared to VAS score during ADL measured immediately after treatment (p=0.538). Despite this, third-month VAS scores at rest and

Table 1. Sociodemographic characteristics of patients

	Total			Paraffin			Fluidotherapy			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p**
Age (year)			63.1±10.3			61.9±10.3			64.2±10.3	0.323
Sex										0.015
Male	8	10.4		7	19.4		1	2.4		
Female	69	89.6		29	80.6		40	97.6		
Body mass index (kg/m^2)			32.0±5.4			31.2±5.9			32.7±4.9	0.251
Occupation										0.159
Unemployed	64	83.1		27	75.0		37	90.2		
Retired	10	13.0		7	19.4		3	7.3		
Worker	2	2.6		2	5.6		0	0		
Civil servant	1	1.3		0	0		1	2.4		
Education										0.574
Illiterate	26	33.8		11	30.6		15	36.6		
Primary school	41	53.2		20	55.6		21	51.2		
High school	4	5.2		1	2.8		3	7.3		
University	6	7.8		4	11.1		2	4.9		
Disease duration (year)			4.7±4.6			4.6±5.0			4.8±4.4	0.822
Menopause	65	84.4		27	75.0		38	92.7		0.056
Duration of menopause (year)			18.8±11.5			18.0±12.5			19.3±10.8	0.674

SD: Standard deviation; * Chi-square test, independent t-test.

Table 2. Clinical parameters of groups

	Paraffin group			Fluidotherapy group			
	Mean±SD			Mean±SD			*p**
VAS-rest							
Before treatment		4.3±2.3			3.8±1.7		0.311
After treatment		1.0±1.4			1.0±1.1		0.620
Third month		1.6±1.6			1.6±1.4		0.903
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.040	<0.001	<0.001	0.020	<0.001	
VAS-act							
Before treatment		8.3±1.4			8.1±1.4		0.631
After treatment		3.0±1.7			3.2±1.5		0.246
Third month		3.8±2.0			3.4±2.2		0.508
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.014	<0.001	<0.001	0.538	<0.001	
Hand grip							
Before treatment		12.8±8.6			11.3±5.0		0.717
After treatment		16.8±8.0			14.8±4.5		0.191
Third month		17.2±8.4			15.3±5.8		0.222
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.561	<0.001	<0.001	0.223	<0.001	
Palmar pinch							
Before treatment		4.4±1.9			4.2±1.3		0.810
After treatment		5.9±1.8			5.4±1.3		0.084
Third month		5.9±2.0			5.4±1.5		0.131
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.771	<0.001	<0.001	0.727	<0.001	
Three point tip pinch							
Before treatment		4.2±1.8			3.9±1.6		0.504
After treatment		5.6±1.9			4.6±1.3		0.009
Third month		5.6±1.9			4.9±1.4		0.059
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.915	<0.001	<0.001	0.116	<0.001	
Lateral pinch							
Before treatment		4.2±1.7			4.0±1.4		0.717
After treatment		5.6±1.8			5.2±1.4		0.315
Third month		6.0±2.0			5.5±1.3		0.232
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.020	<0.001	<0.001	0.029	<0.001	
Duruöz Hand Index							
Before treatment		26.6±18.7			25.7±14.7		0.862
After treatment		11.6±11.6			10.6±7.2		0.516
Third month		12.7±13.4			10.4±7.8		0.783
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.269	<0.001	<0.001	0.273	<0.001	

SD: Standard deviation; VAS-rest: Visual Analog Scale score at rest; VAS-act: Visual Analog Scale score during activity; BT: Before treatment; AT: After treatment; * Mann-Whitney U test-intergroup analysis; ** Wilcoxon test-intragroup analysis.

during ADL were lower than those measured before treatment (p<0.001).

There was a significant decrease in the post-treatment DHI scores of both groups compared to the baseline (p<0.001). Statistically significant improvement in DHI scores after the treatment also continued in the third month (p<0.001). However, DHI scores measured immediately after treatment and those measured in the third month were similar.

Table 3. Intra- and intergroup analysis of 36-item Short Form scores

SF-36		Paraffin group Mean±SD			Fluidotherapy group Mean±SD		*p**
Physical functioning							
Before treatment		26.3±26.2			22.3±17.5		0.797
After treatment		35.2±23.8			27.4±14.3		0.254
Third month		35.1±24.1			26.8±17.9		0.142
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd Month	
	<0.001	0.859	<0.001	<0.001	0.572	0.004	
Role physical							
Before treatment		10.4±28.8			10.3±21.6		0.461
After treatment		18.0±29.6			19.8±21.9		0.216
Third month		22.2 ±30.3			20.1±23.1		0.838
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	0.005	0.201	0.002	0.001	1.000	0.001	
Role emotional							
Before treatment		9.2 ±28.2			12.9±25.6		0.124
After treatment		16.5±29.2			23.4±26.0		0.076
Third month		23.0±32.6			19.4±28.8		0.703
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	0.005	0.070	0.001	0.002	0.225	0.088	
Vitality							
Before treatment		28.8±19.8			28.7±16.4		0.663
After treatment		35.2±18.0			33.2 ±15.3		0.778
Third month		35.8±19.0			31.1±17.6		0.451
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.874	0.001	0.004	0.381	0.072	
Mental health							
Before treatment		45.6±19.7			43.8±18.0		0.850
After treatment		48.4±17.6			47.8±15.6		0.939
Third month		46.1±18.4			47.0±18.1		0.882
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	0.004	0.270	0.311	0.002	0.498	0.003	
Social functioning							
Before treatment		45.9±26.2			47.0±26.0		0.765
After treatment		55.7±21.5			57.6±19.9		0.593
Third month		61.6±18.4			55.3±21.6		0.167
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.035	<0.001	<0.001	0.191	0.011	
Bodily pain							
Before treatment		30.1±24.0			31.8±18.2		0.379
After treatment		52.1±20.1			55.8±17.9		0.355
Third month		61.6±22.2			55.2±19.3		0.256
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	<0.001	0.013	<0.001	<0.001	0.753	<0.001	
General health							
Before treatment		32.9±19.3			34.6±19.2		0.551
After treatment		33.4±18.9			36.8±19.2		0.304
Third month		34.0±18.0			37.0±19.0		0.564
*p***	BT-AT	AT-3rd month	BT-3rd month	BT-AT	AT-3rd month	BT-3rd month	
	0.046	0.552	0.191	0.001	0.746	0.042	

SF-36: 36-Item Short Form; SD: Standard deviation; BT: Before treatment; AT: After treatment; * Mann-Whitney U test-intergroup analysis; ** Wilcoxon test-intragroup analysis.

When the intragroup analysis of gross grip strength was examined, a significant improvement was observed in gross grip, palmar pinch, and tip pinch strengths in both groups after treatment ($p<0001$). This improvement also continued in the third month ($p<0.001$). Gross grip, palmar pinch, and tip pinch strengths in the third month were similar to those measured immediately after treatment.

A significant increase was observed in the lateral pinch strength in both groups after treatment compared to the baseline ($p<0.001$) and in the third month compared to the pinch strength measured immediately after treatment ($p=0.020$ in paraffin group and $p=0.029$ in fluidotherapy group).

There was a significant increase in the SF-36 subscale scores (physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, energy/vitality, mental health, social functioning, bodily pain, and general health perceptions) of both groups after treatment compared to the pretreatment scores. The increase in social functioning ($p=0.035$) and bodily pain ($p=0.013$) subscores in the paraffin group continued in the third month. However, there was no difference in other SF-36 subscale scores after treatment and in the third month. In the fluidotherapy group, there was no difference in the SF-36 subscale scores after treatment and in the third month. Mental health ($p=0.311$) and general health perception ($p=0.191$) scores in the paraffin group and role limitations due to emotional problems ($p=0.088$) and energy/vitality ($p=0.072$) scores in the fluidotherapy group returned to pretreatment values in the third month. Other SF-36 subscale scores remained higher than the pretreatment values in the third month.

There was no difference between the paraffin and fluidotherapy groups in terms of VAS scores at rest and during ADL, DHI scores, SF-36 subscales, gross grip strength, palmar pinch and lateral pinch strength measured before, immediately after, and three months after treatment. The tip pinch strengths of the treatment groups measured before treatment ($p=0.504$) were similar; however, tip pinch strength was higher in the paraffin group after treatment ($p=0.009$). Tip pinch strengths of the treatment groups were similar in the third month (Table 3).

DISCUSSION

In this study, positive outcomes have been obtained after treatment in both paraffin and fluidotherapy groups in terms of pain at rest and during activity, hand functions, hand muscle strength, and QoL. However, the treatment modalities were not found to be superior to each other.

In the literature, there is a limited number of randomized controlled trials on the treatment of hand OA. Most of these studies are weak in terms of methodology.[31,32] Although pain and function values have been reported in most of the studies in the relevant literature, other outcome measures have been reported in less than 50% of the studies.[10] In the present study, hand muscle strength and QoL were evaluated as well as pain and physical function.

The results of the present study are compatible with ACR and 2007 EULAR recommendations suggesting the use of heat application among non-pharmacological treatments in the treatment of hand OA.

Most of the studies have supported our finding that paraffin is effective in hand OA patients.[25,26,33] In a study by Myrer et al.,[26] the efficacy of paraffin in patients with hand OA was evaluated and patients were analyzed for pain and hand function. The authors reported improvement in pain and hand function after paraffin treatment. The present study has confirmed that the paraffin bath therapy has provided successful outcomes in patients with hand OA in terms of pain, hand functions, hand muscle strength, and QoL. In a randomized controlled trial carried out by Dilek et al.[25] in Turkey involving 56 patients with hand OA, the efficacy of paraffin was compared with the control group. Patients were compared with the control group in terms of pain at rest and during ADL, Australian Canadian Osteoarthritis Hand Index, the Dreiser Functional Index, range of motion, and hand muscle strength. The authors reported a significant improvement in terms of the reduction in pain during rest and ADL, gross

grip, lateral pinch, and tip pinch strengths in the paraffin group compared to the control group. The improvements achieved have been reported to continue until the third month.

In contrast to paraffin treatment, studies and evidence-based data on fluidotherapy are very limited. There are no randomized controlled trials evaluating the efficacy of fluidotherapy on pain, functionality, QoL, and hand muscle strength in patients with hand OA. Most of the data on fluidotherapy were obtained in non-OA diseases. Therefore, our study has provided important data about the efficacy of fluidotherapy in the treatment of hand OA.

Apart from OA, fluidotherapy has also been proven to be effective in reducing hand edema and examining the effect on nerve conduction velocities in carpal tunnel syndrome and stroke patients, and in warming the hypothermic patients.[34-36] In light of these findings, fluidotherapy may be preferred in patients with OA, while further studies are needed due to the limited number of studies in this field.

This study has some limitations. Firstly, a three-month follow-up period was selected and our results, therefore, reflect the short-term findings. However, a three-month follow-up period had been selected in the majority of prospective studies. Secondly, radiographic evaluation could not be performed due to the short follow-up period. Another limitation was that we did not specify the number and localization of the symptomatic joints. On the other hand, this is the first study in the literature comparing the efficacy of fluidotherapy and paraffin bath therapy in patients with hand OA. Therefore, this is a pilot study and there is a need for further studies to confirm our findings.

In conclusion, fluidotherapy is a good alternative to commonly performed paraffin therapy in terms of pain, hand functions, QoL, and hand muscle strength and it has the same level of efficacy as paraffin therapy in the treatment of hand OA. With these findings, we think that EULAR should reconsider its recommendation by including the paraffin bath therapy and fluidotherapy as a method for the management of hand OA.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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