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ORIGINAL ARTICLE

Efficacy of Paraffin Bath Therapy in Hand Osteoarthritis: A Single-Blinded Randomized Controlled Trial

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Abstract

Objective: To evaluate the efficacy of paraffin bath therapy on pain, function, and muscle strength in patients with hand osteoarthritis.

Design: Prospective single-blinded randomized controlled trial.

Setting: Department of physical medicine and rehabilitation in a university hospital.

Participants: Patients with bilateral hand osteoarthritis (N=56).

Interventions: Patients were randomized into 2 groups with a random number table by using block randomization with 4 patients in a block. Group 1 (n=29) had paraffin bath therapy (5 times per week, for 3-week duration) for both hands. Group 2 (n=27) was the control group. All patients were informed about joint-protection techniques, and paracetamol intake was recorded.

Main Outcome Measures: The primary outcome measures were pain (at last 48h) at rest and during activities of daily living (ADL), assessed with a visual analog scale (0−10cm) at 12 weeks. The secondary outcome measures were the Australian Canadian Osteoarthritis Hand Index (AUSCAN) and the Dreiser Functional Index (DFI), used for subjective functional evaluation, loss of range of motion (ROM), grip and pinch strength, painful and tender joint counts, and paracetamol intake. A researcher blind to group allocation recorded the measures for both hands at baseline, 3 weeks, and 12 weeks at the hospital setting.

Results: At baseline, there were no significant differences between groups in any of the parameters ($P>.05$). After treatment, the paraffin group exhibited significant improvement in pain at rest and during ADL, ROM of the right hand, and pain and stiffness dimensions of the AUSCAN ($P<.05$). There was no significant improvement in functional dimension of the AUSCAN and the DFI ($P>.05$). The control group showed a significant deterioration in right hand grip and bilateral lateral pinch and right chuck pinch strength ($P<.05$), but there was no significant change in the other outcome measures. When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of painful and tender joints at 12 weeks significantly decreased in the paraffin group ($P<.05$). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks ($P<.05$).

Conclusions: Paraffin bath therapy seemed to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. It may be regarded as a beneficial short-term therapy option, which is effective for a 12-week period.

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Hand osteoarthritis is the most common cause of pain in hand joints and can lead to loss of function, as well as pain, swelling, stiffness, and deformity in the affected joints. Hand osteoarthritis especially affects older adults and postmenopausal women, with population-based studies reporting that this prevalence is 30% to 52%.[1] Clinically, hand osteoarthritis can be classified as nodular, thumb-based, generalized, or erosive.[2] Major factors influencing the development of hand osteoarthritis are age, joint location, genetic predisposition, joint deformity, joint hypermobility, obesity, trauma, and sex.[2,3] Treatment guidelines recommended by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) include a range of conservative (pharmacologic and nonpharmacologic) and surgical treatments for hand osteoarthritis, as well as a general approach for osteoarthritis treatment.[4,5] Local application of heat, such as paraffin baths, hot packs, and ultrasound are recommended for the

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treatment of hand osteoarthritis by EULAR.[4] But because research evidence for the benefit of the local application of heat or ultrasound for hand osteoarthritis is lacking, this recommendation is currently based solely on expert opinion. EULAR suggests that the future agenda for research on hand osteoarthritis should include a thorough evaluation of physical treatments, such as ultrasound, laser, transcutaneous electrical nerve stimulation, and local application of heat.[4] Although evidence of the benefit of paraffin is lacking in the literature, in vivo studies have shown that paraffin bath therapy causes temperature increases of 7.5°C in the joint capsule and 4.5°C in muscle.[6] Paraffin bath therapies have a local effect of relaxing the smooth muscle fibers in arterioles, which in turn results in the vasodilatation of the peripheral blood vessels. This produces hyperemia, increased transduction of tissue fluid, increased lymph flow, and the absorption of exudates.[7,8] To our knowledge, despite the common use of paraffin baths in clinical practice, no randomized controlled trial (RCT) of the efficacy of paraffin bath therapy in the treatment of hand osteoarthritis has been previously reported in the literature.

The aim of this study was to evaluate the efficacy of paraffin bath therapy on pain, functional status, and muscle strength in patients with hand osteoarthritis.

Methods

Participants

Patients with bilateral hand osteoarthritis were recruited consecutively from the outpatient clinic of the Department of Physical Medicine and Rehabilitation at the Dokuz Eylül University Hospital in Izmir, Turkey. The study was planned and conducted over a 30-month period. There was no suitable comparable study in the literature to use in the calculation of the sample size. We decided to use a medium effect size to determine the decrease in pain, both at rest and during activities of daily living (ADL). When the sample size was calculated according to the medium effect size ($d = .50$, $\alpha = .05$, with a power of 80%), the result was 64 patients in each group. The study was conducted from September 2008 to March 2011. The study protocol was approved by the ethics committee at the same institution. During the study, the inclusion criteria were provided to the outpatient physicians in order to assess eligible patients. Patients who met the inclusion criteria during their routine outpatient physical and radiologic examinations were reassessed by the researchers (B.D., M.B.) to determine eligibility and to then obtain written informed consent. After reviewing inclusion and exclusion criteria, patients who submitted written informed consent were included in the trial. The inclusion criterion was the fulfillment of the ACR criteria for bilateral hand osteoarthritis. Exclusion criteria included: acute inflammation, trauma or open wounds, steroid or nonsteroidal anti-inflammatory drugs intake, glucosamine drug intake, sensory deficits (polyneuropathy and diabetic neuropathy), muscle weakness (cervical disk hernia, nerve damage), malignancy, Raynaud disease and phenomenon, atrophic skin, palmar tenosynovitis, trigger finger, Dupuytren contracture, or collagen diseases, inflammatory arthritic diseases (rheumatoid arthritis, psoriatic arthritis, lupus, gout, etc), high acute phase reactants, steroid or hyaluronan injection to joints, history of physical therapy, and coagulation disorders.

List of abbreviations:

ACR	**American College of Rheumatology**
ADL	**activities of daily living**
AUSCAN	**Australian Canadian Osteoarthritis Hand Index**
DFI	**Dreiser Functional Index**
EULAR	**European League Against Rheumatism**
RCT	**randomized controlled trial**
ROM	**range of motion**

Research design

The study was designed as a prospective, single-blinded RCT. For this RCT, an independent researcher (G.E.) provided a randomization scheme from a random number table by using block randomization with 4 patients in a block, prior to the start of the study. The eligible patients who had submitted a written informed consent were then referred to another researcher (Ö.E.) who was not involved in the selection and consent process. This researcher used the randomization scheme to assign patients into intervention or control groups. This process thus ensured allocation concealment.

Setting and intervention

Demographic data including age, sex, education, occupation, body mass index, dominant extremity, symptom duration, systemic diseases, Heberden and Bouchard nodules, and drug use were recorded for both groups by a researcher (M.G.) blind to group allocation at the outpatient clinic of the Department of Physical Medicine and Rehabilitation. Another researcher (E.S.) provided written and verbal information about the disease and joint protection techniques to both groups. Group 1 (n = 29) was treated with dip-wrap paraffin bath therapy. The temperature of the paraffin bath was 50°C. Patients dipped both hands into the paraffin, removed them, and waited for the layer of paraffin to harden and become opaque. Then they redipped both hands. These steps were repeated 10 times. When the last layer hardened, their hands were wrapped within a plastic bag and covered with a towel. They then waited for 15 minutes until the paraffin cooled. A physiotherapist in the Department of Physical Medicine and Rehabilitation in the university hospital conducted these treatments 5 days per week for a period of 3 weeks. Group 2 (n = 27) was the control group. Only paracetamol intake was permitted during the study, and the patients were asked to keep a drug diary.

Outcome

The primary outcome measures were pain (during last 48h) at rest and pain during ADL, assessed with a 0 to 10cm visual analog scale at 12 weeks.

The secondary outcome measures were the Australian Canadian Osteoarthritis Hand Index (AUSCAN) and the Dreiser Functional Index (DFI), which were used for subjective functional evaluation, loss of range of motion (ROM), grip and pinch strength, painful and tender joint counts, and paracetamol intake both at 3 and 12 weeks. Loss of ROM was assessed by measuring the distance between fingertips and the distal palmar crease of the hand. The validity and reliability of this procedure was reported in healthy joints and in patients with systemic sclerosis.[9,10] The standard finger-to-palm measurement was obtained for both hands by using a ruler to measure the distance (in centimeters) between the tip of the pulp of the 4 fingers and the distal palmar crease, while the patient attempted to clench his/her fist (maximal finger flexion at all

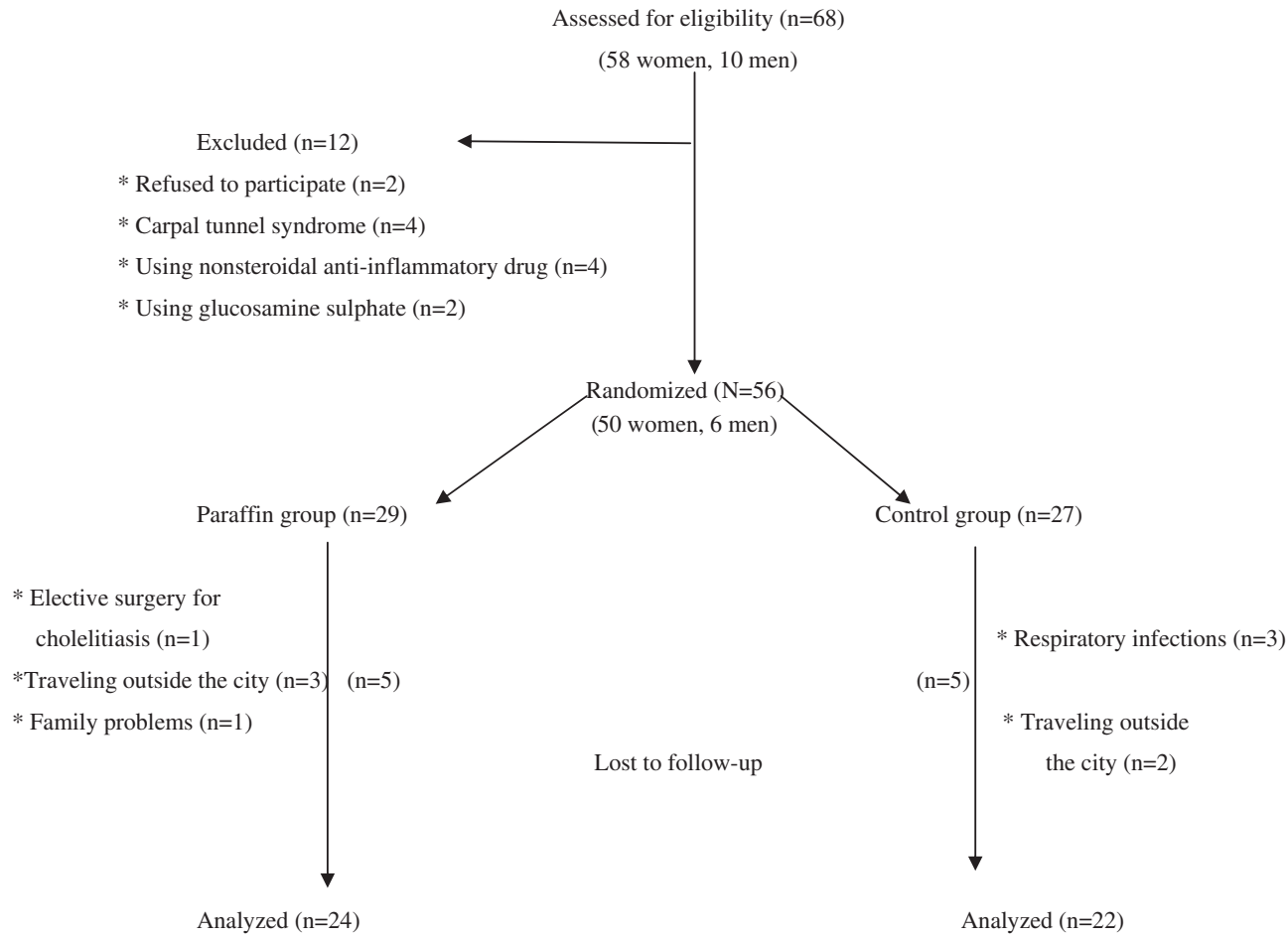

Fig 1 Flowchart of patients.

3 finger joints: metacarpophalangeal, proximal interphalangeal, and distal interphalangeal). The sums of finger-to-palm measurements of the fingers of both hands were recorded separately. Handgrip strength was measured with a JAMAR dynamometer,[a] and a pinchmeter[b] was used to determine the pinch strength of fingers in 3 different positions (lateral, chuck, and pulp-to-pulp pinch) of each hand. For grip and pinch strength measurements, 3 trials were conducted, and the average value was calculated. Patients were given a 1-minute rest period between each test. Both hands were assessed for painful and tender joints. A total number of painful and tender joint counts were recorded. Translated forms of the DFI and the AUSCAN were used for functional evaluation.[11-13] At weeks 3 and 12, total paracetamol intake (in grams) was calculated according to the patients' drug diaries.

All measures were recorded for both groups at baseline, 3 weeks, and 12 weeks by a researcher (M.G.) blind to group allocation.

Statistical analysis

Statistical evaluation was performed using SPSS 15.0.[c] Data were analyzed using Shapiro-Wilk tests to establish whether there was a normative distribution. Normally distributed data were expressed as means and SDs. For data that were not normally distributed, the median was used as the measure of central tendency, with variability expressed as the interquartile range. Analysis of variance in repeated measures and the Bonferroni test for pair-wise comparisons were used for normally distributed parameters (function and pain dimensions of the AUSCAN). The Friedman test was used for nonnormally distributed parameters (pain at rest and during ADL, distance between tip of fingers and the distal palmar crease of hand, pinch and grip-strength measurements, stiffness dimension of the AUSCAN, and DFI scores). Groups were compared for differences using the Mann-Whitney *U* test, and within-group differences were analyzed using the Wilcoxon signed-rank test for differences between baseline, 3 weeks, and 12 weeks. Comparisons of the measures were assessed with the Bonferroni correction in the Wilcoxon signed-rank test, and the significance level was set at $P<.016$ for these measures. For all other measures, the significance level was accepted as $P<.05$. All analyses were carried out by intention-to-treat analysis and per protocol. Both results are provided separately in the Results section. Per protocol analysis was conducted to demonstrate the effects of the intervention on those who adhered to the treatment. In the intention-to-treat analysis, the last observation carried forward method was used, in which the last observation obtained from a patient was substituted for all subsequent observations that were either missing or obtained after the patient was no longer considered to be evaluable.

A retrospective power analysis was also implemented. In the post hoc power analysis, performed using sample sizes, means, and SD values for the significance level (alpha) of .05, the power was calculated by statistical software, PASS.[d]

Table 1 Demographics of the groups

Demographics	Paraffin (n=24)	Control (n=22)	*P*
Age	58.87±9.47	59.95±8.71	.50
Body mass index (kg/m^2)	26.70±3.59	26.92±3.96	.84
Sex (female/male)	20/4	20/2	.44
Education level	11/13*	15/7*	.12
Symptom duration (mo)	64.42±57.19	67.60±55.85	.54
Heberden nodules (no.)	4.50±2.51	4.00±2.55	.41
Bouchard nodules (no.)	0.00±1.25	0.00±2.16	.19

NOTE. Values are mean ± SD or as otherwise indicated.
* Primary school and preprimary school/postprimary school.

Results

Sixty-eight patients met the inclusion criteria during their routine outpatient physical and radiologic examinations for hand osteoarthritis. After reviewing inclusion and exclusion criteria, 56 patients (50 women, 6 men) with bilateral hand osteoarthritis, and who had submitted written informed consent, were included in the trial. These patients were randomly allocated into intervention (n=29) or control (n=27) groups. Five patients in each group were lost at follow-up. Therefore, 46 patients completed the study (fig 1). During treatment, no complications were observed in the study groups.

Per protocol

The mean age ± SD was 58.9±9.4 years in the paraffin group and 59.9±8.7 years in the control group. Demographic characteristics of the groups are presented in table 1. There were no significant differences between groups in terms of age, body mass index, sex, symptom duration, education level, or Heberden and Bouchard nodules (see table 1). There were also no significant between-group differences at baseline in terms of pain at rest and during ADL, number of painful and tender joints, loss of ROM, grip and pinch strength, stiffness, function, and pain dimensions of the AUSCAN (tables 2–7) and the DFI ($P=1.00$). There were no significant differences between groups in terms of drug intake at 3 weeks ($P=.73$) and 12 weeks ($P=.42$). The dominant hand of all patients was right; therefore, dominant and nondominant hand differences were not compared.

Within-group differences in the paraffin group were significant in terms of the primary outcomes, pain at rest and pain during ADL ($P<.001$ and $P<.001$, respectively) (see table 2) at 12 weeks. However, within-group differences in the control group were not significant in terms of the primary outcomes, pain at rest and pain during ADL ($P=.74$ and $P=.06$, respectively) (see table 2). As for secondary outcomes, there was a significant decrease in terms of the pain ($P<.001$) and stiffness ($P=.002$) dimensions of the AUSCAN and loss of ROM of the right hand ($P=.03$) in the paraffin group (see tables 3–4). There were no significant differences in terms of the DFI ($P=.84$) and the functional dimension of the AUSCAN ($P=.13$). In addition, there were no significant differences in terms of hand-grip (see table 5) and pinch strength (see table 6) in the paraffin group. Within-group differences in the control group were only significant at 12-weeks follow-up when there was deterioration in right hand grip (see table 5), bilateral lateral pinch, and right chuck pinch strength (see table 6).

When the 2 groups were compared, pain at rest at 3 and 12 weeks significantly improved in the paraffin group ($P=.01$ and $P=.003$, respectively), while there was no difference in pain during ADL ($P=.07$ and $P=.09$, respectively) (see table 2). In addition, when compared with the control group, the numbers of painful and tender joints at 12 weeks decreased significantly in the paraffin group ($P=.01$ and $P=.02$, respectively) (see table 7). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks (see tables 5–6). Differences between the paraffin and control groups in other parameters, such as the dimensions of the AUSCAN, loss of ROM (see tables 3–4), and the DFI ($P=.29$ and $P=.05$, respectively), were not significant. Although there were no statistically significant differences between the 2 groups as regards hand function, pain during ADL, and loss of ROM measurements, there was a tendency toward improvement in the paraffin group.

Intention to treat

In the intention-to-treat analysis, the significance of the results did not differ from the per protocol analysis for the primary outcomes. The *P* values are provided in tables 2 through 7.

Table 2 Pain scores of groups

Pain (VAS)	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa* Int
At rest					
Beginning	5.00 (4.00–5.00)	*Pd*<.001†	4.00 (3.00–8.00)	*Pd*=.74	.703/.740
3wk	2.00 (0.00–4.00) *Pb**, *Pb*-int*	*Pd*-int<.001†	4.00 (3.00–5.00)	*Pd*-int=.98	.010‡/.010‡
12wk	0.00 (0.00–3.00) *Pc**, *Pc*-int*		5.00 (1.00–6.00)		.003‡/<.001‡
During ADL					
Beginning	7.00 (7.00–9.00)	*Pd*<.001†	8.00 (6.00–8.00)	*Pd*=.06	.880/.840
3wk	5.00 (3.00–6.00) *Pb**, *Pb*-int*	*Pd*-int<.001†	7.00 (5.00–8.00)	*Pd*-int=.07	.070/.030‡
12wk	5.00 (3.00–6.50) *Pc**, *Pc*-int*		7.00 (5.00–8.00)		.090/.050

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pb*, within-group difference between baseline and 3 weeks; *Pc*, within-group difference between baseline and 12 weeks; *Pd*, the differences of measurements within groups.
* In the *Pb* and *Pc* groups, Wilcoxon signed rank test, $P<.016$, significant value.
† In the *Pd* group, Friedman test, $P<.05$, significant value.
‡ In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value.

Table 3 AUSCAN scores in groups

Dimensions of AUSCAN	Paraffin Group (n=24)		Control Group (n=22)		*Pa*/*Pa*-Int
Stiffness	Median (25%–75%)		Median (25%–75%)		
Beginning	2.00 (1.00–2.00)	*Pd*=.002†	2.00 (0.00–3.00)	*Pd*=.58	.82/.95
3wk	1.00 (1.00–2.00) *Pb**, *Pb*-int*	*Pd*-int=.001†	1.00 (0.00–2.00)	*Pd*-int=.28	.78/.58
12wk	1.00 (0.00–2.00) *Pc**, *Pc*-int*		1.00 (0.00–2.00)		.50/.34
Pain	Mean ± SD		Mean ± SD		
Beginning	10.65±3.25	*Pe*<.001†	9.78±5.69	*Pe*=.64	.42/.47
3wk	7.73±4.66 *Pb**, *Pb*-int*	*Pe*-int<.001†	8.89±5.11	*Pe*-int=.57	.53/.57
12wk	6.47±3.98 *Pc**, *Pc*-int*		9.52±4.97		.05/.07
Function					*Pf*/*Pf*-int
Beginning	16.17±6.69		17.10±9.21	*Pe*=.13	.37/.50
3wk	14.52±7.05		15.44±7.99	*Pe*-int=.07	
12wk	13.82±7.04		17.84±8.44		

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups (Mann-Whitney *U* test); *Pb*, within-group difference between baseline and 3 weeks; *Pc*, within-group difference between baseline and 12 weeks; *Pd*, differences of measurements within groups; *Pe*, differences of measurements within groups; *Pf*, difference between groups (analysis of variance).

* In the *Pb* and *Pc* groups, Wilcoxon signed rank test, $P<.016$, significant value.

† In the *Pd* group, Friedman test, $P<.05$, significant value. In the *Pe* group, analysis of variance, $P<.05$, significant value.

In the post hoc power analysis, performed using sample sizes, means, and SD values for the significance level (alpha) .05, the power was found to be 89.7% for pain at rest. However, the power was below 50% for the functional dimension of the AUSCAN, the DFI, and pain during ADL.

Discussion

In this study, paraffin bath therapy reduced pain and tenderness and alleviated the pain and stiffness dimensions based on the AUSCAN in patients with hand osteoarthritis at 12 weeks, but it had no statistically significant effect on function. Local heat applications are frequently used in therapy for hand osteoarthritis and are often combined with other treatments.[4] This study is the first, to the best of our knowledge, single-blinded RCT evaluating the efficacy of paraffin bath therapy in hand osteoarthritis.

Most available therapeutic heating modalities demonstrate their effectiveness by producing analgesia, hyperemia, changes in local or systemic temperature, and reduced muscle tone. The therapeutic effects derived from these physiological responses are relief of pain, reduction of muscle spasm, and increased metabolism.[7,8,14] A pilot study[15] of the use of paraffin bath therapy in patients with systemic sclerosis showed that hand exercises in combination with paraffin baths seemed to improve mobility, perceived stiffness, and skin elasticity. In addition, even though the symptoms of hand osteoarthritis are not as severe as in systemic sclerosis, on the completion of the paraffin bath therapy in our study, we observed significant improvement regarding the regaining of motion, reduction of pain, and tenderness of hand joints. The loss of ROM in left hands in both groups was less than in right hands. This may be attributed to hand dominancy. In general, right hands are used more than left, and this may therefore cause more pain and loss of ROM in the right hand. Similarly, Dellhag et al[16] reported that a combination of paraffin bath therapy and exercise was more effective than exercise alone for treating rheumatoid arthritis. They found better improvement of grip function and ROM in the group undergoing paraffin bath therapy followed by active hand exercise, but paraffin wax alone had no significant effect. The loss of function and loss of strength in rheumatoid arthritis are more prominent than in osteoarthritis.[2,17,18] Despite the fact that we observed improvements in the reduction of pain and the regaining of motion, we did not notice any statistically significant improvement of function in the paraffin group. This result could be attributed to the power of the study. Our study was not powerful enough to detect the differences in functional dimension of the AUSCAN and the DFI. Nevertheless, there was an obvious tendency toward improvement of hand function in the paraffin group. Further studies with

Table 4 Loss of ROM in groups*

Loss of ROM	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa*-Int
Right hand					
Beginning	60.00 (37.50–90.00)	*Pd*=.03†	45.00 (22.50–96.25)	*Pd*=.51	0.75/0.53
3wk	27.50 (12.50–38.75)	*Pd*-int=.01†	30.00 (7.50–87.50)	*Pd*-int=.36	0.53/0.45
12wk	25.00 (2.50–55.00)		20.00 (0.00–80.00)		1.00/0.44
Left hand					
Beginning	15.00 (2.50–35.00)	*Pd*=.20	20.00 (0.00–82.50)	*Pd*=.75	0.75/0.58
3wk	0.00 (0.00–7.50)	*Pd*-int=.09	10.00 (0.00–90.00)	*Pd*-int=.95	0.20/0.10
12wk	5.00 (0.00–40.00)		17.50 (0.00–50.00)		0.91/0.24

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pd*, differences of measurements within groups.

* Measured by the distance between tip of fingers and distal palmar crease (mm).

† In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value. In the *Pd* group, Friedman test, $P<.05$, significant value.

Table 5 Hand-grip strength of groups (kg)

Grip Strength (kg)	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		Pa/Pa-Int
Right hand					
Beginning	18.00 (14.66–24.66)	Pd=.34	16.66 (11.33–22.66)	Pd=.009†	.270/.380
3wk	18.00 (15.33–22.66)	Pd-int=.43	16.00 (12.60–20.66)	Pd-int=.004†	.070/.110
12wk	20.00 (14.66–23.33)		13.33 (10.00–18.66) Pc-int*		.010‡/.004‡
Left hand					
Beginning	18.00 (14.00–21.33)	Pd=.11	15.33 (12.66–21.00)	Pd=.050	.360/.460
3wk	17.33 (15.00–22.00)	Pd-int=.18	16.66 (12.00–20.66)	Pd-int=.080	.130/.190
12wk	18.00 (14.66–22.00)		12.00 (9.33–18.00)		.010‡/.010‡

Abbreviations: int, intention-to-treat analysis; Pa, difference between groups; Pc, within-group difference between baseline and 12 weeks; Pd, differences of measurements within groups.

* In the Pc group, Wilcoxon signed rank test, $P<.016$, significant value.

† In the Pd group, Friedman test, $P<.05$, significant value.

‡ In the Pa group, Mann Whitney U test, $P<.05$, significant value.

a larger sample size are needed to analyze the effect of paraffin bath therapy on function.

The severity of functional impairment in hand osteoarthritis reported in the literature is equivocal. One controlled study pinpointed only minor global impairment of ADL in patients with erosive osteoarthritis compared with patients with nodular osteoarthritis.[19] In another study of 522 subjects, hand osteoarthritis accounted for only 5% to 7% of the variation in function, grip strength, and pain, and the association with function and grip strength seemed to be mediated by pain.[20] In the present study, we found significant deterioration in terms of right hand grip, bilateral lateral pinch, and right chuck pinch strength in our control group, whereas these strengths were maintained in the paraffin group. Both groups were provided information not only concerning the disease, but also about joint protection techniques to be used during daily activities. They were also asked to avoid forceful gripping activities that caused pain. The strength decrease in the control group may be related to limited use of

Table 6 Pinch strength of groups (kg)

Pinch Strength (kg)		Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		Pa/Pa-Int
Right hand	Pulp-to-pulp pinch					
	Beginning	3.33 (2.33–4.00)	Pd= .23	3.50 (3.16–4.66)	Pd=.160	.32/.36
	3wk	3.66 (2.66–4.50)	Pd-int=.15	3.66 (2.33–4.33)	Pd-int=.120	.20/.23
	12wk	3.33 (2.83–4.50)		3.33 (2.33–4.16)		.82/.43
	Chuck pinch					
	Beginning	4.33 (3.50–5.50)	Pd=.62	5.16 (3.83–6.33)	Pd=.003†	.54/.68
	3wk	4.50 (3.66–6.00)	Pd-int=.48	4.33 (3.00–5.83) Pb-int*	Pd-int=.003†	.20/.23
	12wk	5.33 (3.33–6.33)		3.66 (2.66–5.33) Pc-int*		.10/.03‡
	Lateral pinch					
	Beginning	5.00 (4.50–6.16)	Pd=.76	6.00 (5.16–6.83)	Pd=.010†	.44/.48
	3wk	5.66 (4.83–7.00)	Pd-int=.63	5.33 (3.83–7.00)	Pd-int=.003†	.09/.10
	12wk	6.00 (4.66–7.00)		4.33 (3.83–6.16) Pc-int*		.07/.01‡
Left hand	Pulp-to-pulp pinch					
	Beginning	3.50 (2.66–4.00)	Pd=.09	3.66 (2.66–4.33)	Pd=.230	.99/.99
	3wk	3.16 (2.66–4.16)	Pd-int=.09	3.16 (2.33–4.33)	Pd-int=.090	.34/.40
	12wk	3.66 (2.66–4.50)		3.00 (2.50–3.66)		.11/.08
	Chuck pinch					
	Beginning	4.66 (3.33–6.00)	Pd=.61	4.83 (3.50–5.16)	Pd=.120	.69/.63
	3wk	4.33 (3.83–5.50)	Pd-int=.47	4.50 (3.00–5.66)	Pd-int=.030†	.24/.20
	12wk	4.83 (3.50–6.16)		3.66 (2.60–5.00) Pc-int*		.03‡/.01‡
	Lateral pinch					
	Beginning	5.00 (4.66–5.83)	Pd=.59	5.66 (4.50–6.33)	Pd=.020†	.75/.42
	3wk	5.33 (4.50–7.16)	Pd-int=.46	5.50 (3.83–6.33)	Pd-int=.010†	.27/.56
	12wk	5.16 (4.83–6.33)		4.33 (3.50–5.66) Pc-int*		.02‡/.05

Abbreviations: int, intention-to-treat analysis; Pa, difference between groups; Pb, within-group difference between baseline and 3 weeks; Pc, within-group difference between baseline and 12 weeks; Pd, differences of measurements within groups.

* In the Pb and Pc groups, Wilcoxon signed rank test, $P<.016$, significant value.

† In the Pd group, Friedman test, $P<.05$, significant value.

‡ In the Pa group, Mann Whitney U test, $P<.05$, significant value.

Table 7 Number of painful and tender joints in groups

Joint Counts	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa*-Int
Painful joint					
Beginning	8.00 (6.00–12.00)	*Pd*=.07	8.00 (8.00–16.00)	*Pd*=.36	.32/.88
3wk	4.00 (3.00–9.00) *Pb*-int*	*Pd*-int=.04†	8.00 (4.00–12.00)	*Pd*-int=.35	.05/.28
12wk	3.00 (2.00–9.00)		10.00 (6.00–16.00)		.01‡/.04‡
Tender joint					
Beginning	8.00 (4.00–13.00)	*Pd*=.49	7.00 (5.00–14.00)	*Pd*=.94	.62/.85
3wk	8.00 (3.00–10.00)	*Pd*-int=.65	8.00 (6.00–18.00)	*Pd*-int=.54	.12/.15
12wk	6.00 (4.00–9.00)		8.00 (6.00–14.00)		.02‡/.20

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pb*, within-group difference between baseline and 3 weeks; *Pd*, differences of measurements within groups.

* In the *Pb* group, Wilcoxon signed rank test, $P<.016$, significant value.

† In the *Pd* group, Friedman test, $P<.05$, significant value.

‡ In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value.

their hands because of pain. The fact that patients tended to protect their hands by decreasing muscle activity or avoiding forceful activities might have caused the strength loss in dynamometric assessment.

Recently, in a randomized study, Myrer et al[7] compared treatment with paraffin bath and paraffin bath combined with topical analgesic for patients with symptomatic hand osteoarthritis. Results indicated that both treatments produced immediate posttreatment relief of pain, albeit not to a great extent. After 12 treatments, the researchers concluded that the addition of topical analgesic to the paraffin bath produced significantly greater pain relief at rest and during movement and greater improved function than paraffin baths alone[7]; however, their study did not include a control group. In our RCT, we found that paraffin bath therapy, without the addition of topical analgesic, did reduce pain, but had no statistically significant effect on hand function when compared with the control group. We had anticipated a medium-sized effect, but we observed that the improvement was not as significant as we had initially expected.

Paraffin bath therapy is usually applied by an immersion or dipping method, with the latter being easier and more common.[14] In our study, we used dipping: both hands were slowly dipped 10 times into a 50°C wax bath, and were later wrapped in a plastic bag and then a towel, in which they were kept for 15 minutes. There are no existing data about the optimal number of treatment sessions or the application frequency of paraffin bath therapy. Paraffin applications may be applied 3 or 5 times a week.[8,15,16] In our daily practice, we applied this treatment 5 times a week; meanwhile, our patients attended outpatient physical therapy sessions and did their exercises diligently after applying superficial heat modalities, according to the recommendations of EULAR.[4]

Therefore, during the study, we conducted paraffin bath applications 5 times a week, just like we do in our normative daily practice. Other than the patients who we lost contact with at follow-up, all of the patients were compliant with the therapy sessions. Although this adherence to therapy is a definite strength of our study, such a high level of adherence may be unusual in the daily clinical practice of physical therapy. Future research may also establish the optimal number of treatment sessions for paraffin bath therapy.

There were not many patients lost at follow-up during the study period. Also, there was no remarkable difference between intention-to-treat and per protocol analyses, which suggests that those lost at follow-up were random in each group.

Study limitations

One of the major limitations of our study was the sample size. Although we calculated the sample size at the beginning of the study, we could not attain the estimated sample size within the time frame of the study because of changes in the Turkish health care system. As a result of the changes, fewer patients were referred to our hospital, and therefore the estimated sample size could not be attained. Another major limitation was the power of the study. Although our study seemed to be sufficiently powerful to detect the differences in our primary outcome, which was pain, it was not powerful enough to detect the differences in functional dimension of the AUSCAN and the DFI. The lack of a placebo or sham control group was another limitation. It is obvious that evaluating the efficacy of paraffin bath therapy is problematic in a double-blinded controlled design. In addition, the disproportional distribution of sex limited the generalization of the results. However, the fact that this was a single-blinded, randomized, controlled study with a low lost to follow-up rate enables this work to provide an ideal platform on which to build a larger scale trial. This study also provides some evidence for paraffin bath treatments, which are a routine procedure in many rehabilitation clinics.

Conclusions

Paraffin bath therapy seems to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. This method may be regarded as a beneficial short-term therapy option, which is effective for a 12-week duration. Further randomized studies with larger sample sizes are warranted to confirm the results and to evaluate the effects of paraffin bath therapy on function in hand osteoarthritis.

Suppliers

a. Sammons Preston, 1000 Remington Blvd, Bolingbrook, IL 60440.

b. Baseline, Trent Building, South Buckout St, Irvington, NY 10533.
c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.
d. NCSS LLC, 329 North 1000 East, Kaysville, UT 84037.

Keywords

Hand; Osteoarthritis; Pain; Rehabilitation

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