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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