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Investigation of the Effect of Radial Nerve Mobilization on Pain, Function, and Grip Strength in Patients with Thumb Osteoarthritis: A Randomized Controlled Trial

Ethics Approval: The study was conducted with the approval of the Ethics Review Board of Gazi University, Ankara, Turkey. (approval number 2022 - 1117).

Clinical trials ID: NCT05650970

MATERIALS AND METHODS

The design of this prospective, randomized controlled, single-blinded parallel study was approved by the Gazi University Ethics Committee (Date: 04.10.2022, Research Code No: 2022 - 1117).

This study was conducted with patients who applied to the Hand Surgery Outpatient Clinic of X hospital between November 2022 and February 2023 and were referred to hand therapy with the diagnosis of TMC OA in Ankara. The patients included in the study were divided into two groups: mobilization and control groups according to the order in which they applied to the clinic.

The treatment and evaluation of all patients were carried out by two different hand therapists at X University Hand Rehabilitation Unit. The evaluations were made twice, before treatment and after four weeks of the treatment. The patients in both groups received treatment 2 sessions per week for 4 weeks. All patients were called for a second evaluation on a separate day after the completion of their treatment to avoid an acute effect of the treatment session on the results.

Participants

The inclusion criteria of the participants were the diagnosis of OA in the TMC joint and the presence of pain. It was planned to exclude patients who had a history of surgery (trigger finger, carpal tunnel, Dupuytren's contracture, tenosynovitis, etc.) in the last 6 months, using a splint for thumb during the previous 3 months, and who had lack of cooperation, which could be an obstacle to completing the questionnaires. In addition, patients who were found to have any extra pathologies of the upper extremity (epicondylitis, neck hernia, nerve compression, bone cyst, etc.) that could cause pain during the study period and who started to use splinting, pain relieving treatments such as medications or injection were excluded from the study. Evaluation and treatment of patients with bilateral involvement were done for both hands and each hand's results were recorded separately. Among the data of these patients, clinical status (symptomatic hand, stage, and symptom duration), pain (at rest, activity, and night), strength (gross grip, lateral, and double pinch), and performance in the Nine-Hole Peg Test (9HPT) were included in the analysis for both hands separately; demographic information (age, height, weight, gender) and scores of Michigan Hand Outcomes Questionnaires (MHOQ) and Functional Index of Hand Osteoarthritis (FIHOA) were included as single data for each patient.

The entire flow data of the patient enrollment is given in Figure 3 as a flowchart according to the CONSORT guide.

The patients were informed about the study on the first day they came to the hand rehabilitation unit for treatment, and their written consent was obtained. The patient's age, gender, height, body weight, dominant and affected hand, surgical history, previous

47 treatments, disease stage, and duration of symptoms were recorded. Afterward, physical
48 assessments were performed.

49

50 **Outcome measures**

51 In this study, our primary outcome measure was the improvement in pain level; secondary
52 outcome measures were the improvement in thumb function and grip strength.

53 The pain level of the participants was evaluated with the Visual Analog Scale (VAS) in 3
54 different conditions including rest, activity, and night. The assessment was made with a 10-cm
55 straight line with endpoints describing the intensity of the pain. All patients were asked to mark
56 the pain level corresponding to the intensity of the pain on the line between "0" representing
57 "no pain" and "10" representing "the most/extremely unbearable pain". The distance between
58 "0" and the mark made by the patients was measured and recorded in cm.

59 A hydraulic hand dynamometer (Jamar ®) was used for grip strength assessment, and a pinch
60 meter was used for bipod and lateral pinch strength. These measurements were made in the
61 standard sitting position as determined by the American Association of Hand Therapists. The
62 participant holds the elbow at 90 degrees flexion and the wrist in a neutral position at the side
63 of the trunk. During the assessment, the patient sits in a chair with a backrest. During the grip
64 strength measurements, the patient was asked to squeeze as hard as possible, and the
65 measurements were repeated three times consecutively for both hands. The mean value of the
66 measurement results was taken and recorded in kilograms (kg).

67 9HPT was used in the evaluation of the functionality and fine dexterity level of each hand.
68 During this evaluation, the patient sits in a comfortable position. The patient was taught the
69 test to be performed and allowed to make a trial. Starting from the position where the pegs
70 were inserted into the holes, the patient was asked to remove all the pegs as fast as he/she

could with the evaluated hand, remove the last one, and then quickly insert the pegs into the holes. The total removal and insertion times were recorded in seconds for both hands separately.

The FIHOA questionnaire developed specifically for hand osteoarthritis was used to assess the level of disability. The questionnaire consists of 10 items containing statements about the use of hands in daily life, and each item is scored from 0 to 3 points according to the difficulty level: "0: possible without difficulty", "1: possible with slight difficulty", "2: possible with importance difficulty", “3: impossible’’. The total score varies from 0 to 30 points. As a result of this questionnaire, a low score represents a better function, while a high score represents a worse function. The adapted version of the Turkish language was used.

The Michigan Hand Outcomes Questionnaires (MHOQ) were used in the functionality and general evaluation of hand use bilaterally and right-left separately in daily life. The MHOQ is reliable, valid, and responsive in patients with TMC joint osteoarthritis. The questionnaire evaluates pain, function, aesthetic appearance, and satisfaction as sub-parameters. Since the MHOQ measures function/satisfaction, the higher the score on the questionnaire, the higher the reported functionality/satisfaction. The adapted version to the Turkish language was used.

Interventions

The study consisted of two groups: mobilization and control group. The only difference between the mobilization group from the control group was the addition of radial nerve mobilization exercises to the treatment program in this group. The remaining treatment program was the same in both groups. Both groups in the study were included in the treatment program twice per week for 4 weeks in the clinic. Patients were also instructed to repeat the

exercises and interventions at home 3 times per day. The treatment program for the patients consists of the interventions below:

• Patient education: During the treatment period, patients were told not to use their hands for heavy work and not to perform any application other than the treatment. Patients were assessed about how much they use the hand during the day in daily life, during the recreation and hobby times and they were educated about the correct grip positions as explained below.

• Teaching correct grip techniques: Patients were taught correct gripping techniques with objects of different sizes and shapes and were informed about maintaining this position during their daily activities (Figures 1 and 2).

• Massage: Massage was applied on the superficial branch of the radial nerve trace and the thumb. Relaxation in the tissue, pain relief with mechanical stimulation, and edema reduction were aimed.

• Nerve mobilization exercise: Radial nerve mobilization exercises were performed in two consecutive ways: isolated wrist (ulnar-radial deviation with the thumb grasped in the palm in a fist) and combined wrist-elbow (wrist in ulnar deviation with the elbow in extension and wrist in radial deviation with the elbow in flexion, starting in anatomical posture). These exercises were only given to the mobilization group.

• Ice therapy: It was applied on the dermatome of the superficial branch of the radial nerve for 10-12 minutes at the end of the treatment.

Data analysis

SPSS 26.0 program was used for statistical analysis of the data. The measured data were expressed as percentages (%) and numbers (n) for qualitative variables and mean ± standard

deviations for quantitative variables. The Pearson Chi-Square test was used for the comparison of the categorical variables (gender, dominant hand, affected hand, bilateral involvement, and history of surgery for the disease). All participants with available baseline data were included in the analyses. Missing outcomes were imputed based on baseline values. No participant was excluded from the final analysis because of missing data. The Mann-Whitney U test was used to compare the differences (delta) before and after the treatment. The magnitude of effect sizes of differences between groups was calculated using Monte Carlo defining clinically meaningful effect sizes with 95% Confidence level. P value <0.05 was accepted for statistical significance.

RESULTS

Sixty-four patients were invited to the study. A total of 6 patients were excluded because 2 of these patients did not meet the inclusion criteria (concomitant bone cyst in one patient and diagnosis of entrapment neuropathy in one patient) and 4 patients refused to participate in the study. After exclusion, 58 patients were included in the study. At the end of the 4-week treatment program, the data of 51 patients who completed the treatment program. Missing data of the 7 patients who discontinued were also included in the analysis after multiply imputation by maximum-likelihood-based regression methods. As a result, data from a total of 58 patients were analyzed. The remaining 58 patients were included in the mobilization (n=28) or control group (n=30). The patients did not know which group they belonged to. One patient in the mobilization group was excluded after the start of the study as she received an additional treatment. One another patient in this group discontinued the treatment program. Five patients in the control group discontinued the treatment. All participants with available baseline data were included in the analyses. Missing outcomes were imputed based on baseline values. No participant was excluded from the final analysis because of missing data.

Finally, the data of 58 patients in total, 28 in the mobilization group and 30 in the control group were compared. Since 3 patients in the mobilization group and 1 patient in the control group had bilateral involvement, the evaluation and treatment of these patients were performed separately for both hands. Therefore, the data from 58 patients (mobilization: 28, control: 30) and 62 hands (mobilization: 31, control: 31 hands) were analyzed. (Figure 3).

Both groups were similar regarding their demographic and clinical characteristics ($p>0.05$). The two groups differed only in the number of participants with a history of surgery for TMC OA. The number of patients who had surgery in the control group was 6 (20%) and 1 (3.57%) in the mobilization group ($p=0.045$) (Table 1). Moreover, both groups were at similar clinical levels in terms of the results of the pre-treatment evaluations in all parameters ($p>0.05$) (Table 2).

Comparison of the differences between the two groups before and after the treatment showed that the improvement in pain level in rest ($p=0.002$), in activity ($p=0.008$), at night ($p=0.053$); and gross grip ($p=0.013$) and lateral pinch strength ($p=0.003$); FIHOA score ($p=0.001$); and MHOQ overall score ($p=0.005$) in the mobilization group were significantly superior to the control group (Table 3).

Figure 1: Gripping position before patient education

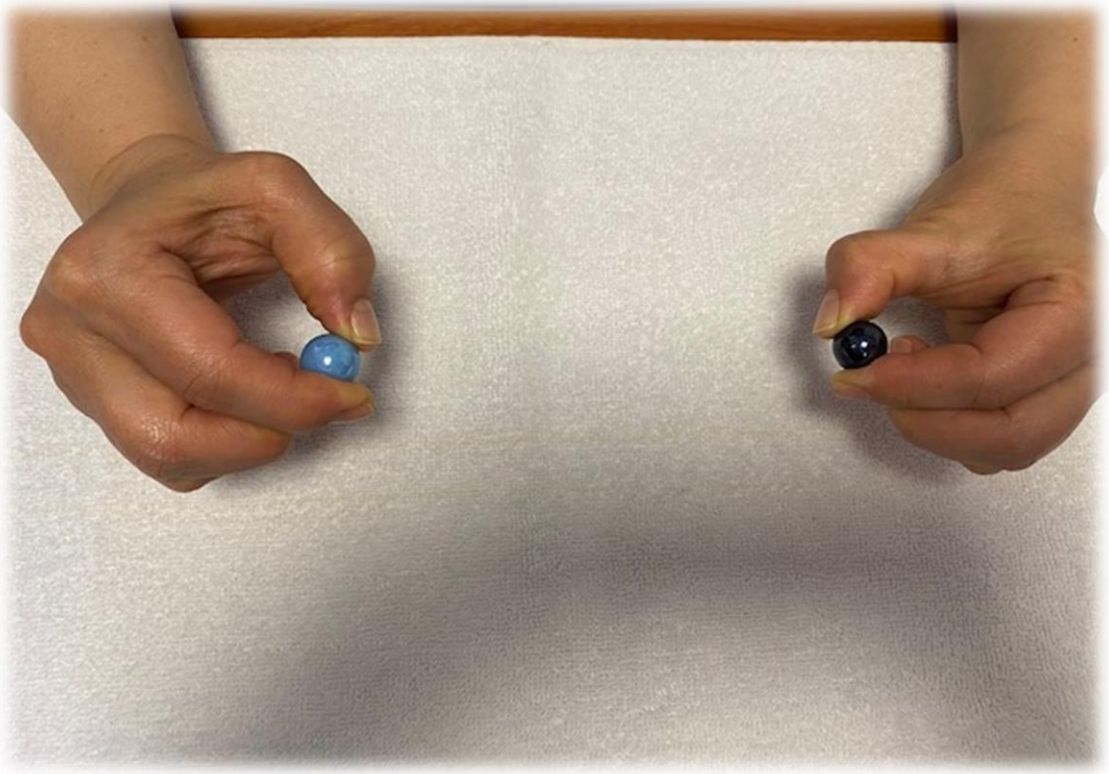
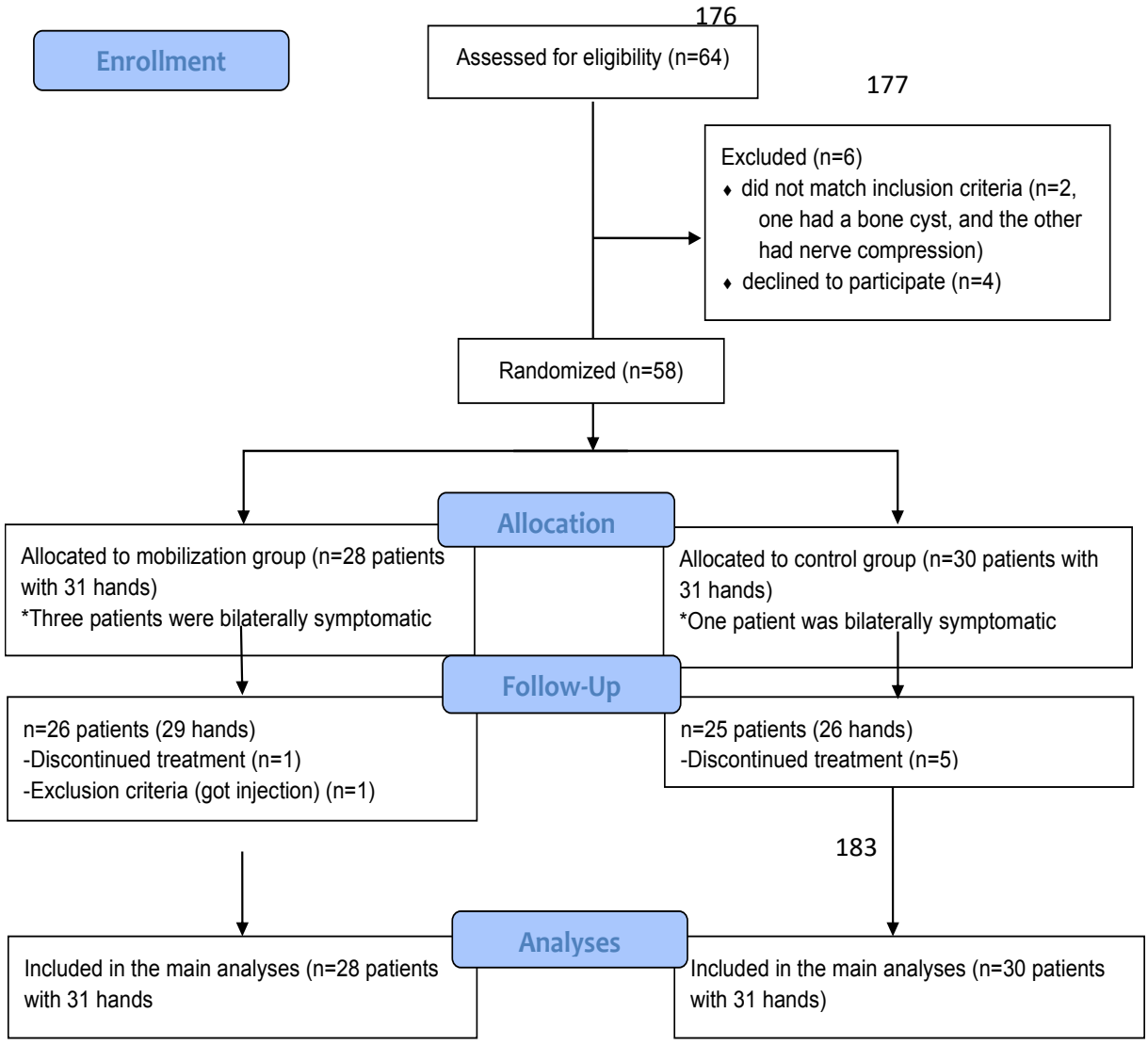


Figure 2: Gripping position after patient education

Figure 3: CONSORT flow-diagram of participants throughout the study period



Note: All participants with available baseline data were included in the analyses. Missing outcomes were imputed on the basis of baseline values. No participant was excluded because of missing outcume values.

Tablo 1: Baseline characteristics of the study groups

Baseline characteristics	Mobilization group (n=28)	Control group (n=30)	P-value	Z-value	Effect size [CI]
Age (years) (Mean ± SD)	57.50 ± 11.30	61.67 ± 9.82	0.249	-1.153	0.45 [0.44;0.46]
Height (cm)	161.21 ± 9.41	160.83 ± 8.26	0.956	-0.055	1 [1]
Body weight (kg)	73.64 ± 12.94	74.90 ± 8.14	0.586	-0.545	0.40 [0.39;0.41]
Gender (n) (%) (female/male)	22/6 (78.5%)	25/5 (83%)	0.644		
Surgical history (n) (%) (operated/nonoperated)	1/27 (3.57%)	6/24 (20%)	0.045*		
Symptom duration (months)	15.46 ± 13	15.93 ± 13.99	0.994	-0.008	0.62 [0.61;063]
Dominant side (n) (%)					
Right	26 (92.85%)	29 (96.66%)	0.513		
Left	2 (7.15%)	1 (3.34%)			
Symptomatic side (n) (%)					
Right	14 (50%)	12 (40%)	0.305		
Left	11 (39.28%)	17 (56.66%)			
Bilateral	3 (10.72%)	1 (3.34%)			
Dominant hand symptomatic (n) (%)					
Yes	16 (57.14%)	13 (43.33%)	0.201		
No	9 (32.14%)	16 (53.33%)			
Bilateral	3 (10.72%)	1 (3.34%)			

Grade (Eaton-Littler classification) (n) (%)					
Grade 1	1 (3.57%)	3 (10%)			
Grade 2	8 (28.57%)	14 (46.66%)	0.288		
Grade 3	17 (60.72%)	12 (40%)			
Grade 4	2 (7.14%)	1 (3.34%)			

n: Number of participants, SD: Standart Deviation, *p<0.05: statistically significant, CI: Confidence Interval

Table 2: Baseline values and between-group comparison results

Baseline Values	**Mobilization group (n=31) (Mean ± SD)**	**Control group (n=31) (Mean ± SD)**	**P value**	**Z value**	**Effect size [CI]**
Pain in Resting (cm)	3.34 ± 2.33	2.93 ± 2.61	0.373	-0.891	0.37 [0.36;0.38]

Pain in Activity (cm)	7.07 ± 2.14	6.70 ± 1.85	0.597	-0.529	0.59 [0.58;0.60]
Pain in Night (cm)	2.88 ± 2.83	2.74 ± 3.23	0.405	-0.833	0.41 [0.40;0.41]
Grip Strength (kg)	18.90 ± 9.05	19.85 ± 7.52	0.517	-0.648	0.51 [0.51;0.53]
Bipod Pinch Strength (kg)	3.16 ± 1.29	3.02 ± 1.35	0.582	-0.550	0.58 [0.57;059]
Lateral Pinch Strength (kg)	5.29 ± 2.04	5.40 ± 1.86	0.622	-0.493	0.62 [0.61;0.63]
9HPT Time (second)	23.62 ± 4.15	24.33 ± 5.29	0.598	-0.528	0.61 [0.60;0.62]
FIHOA Score	13.39 ± 6.06	10.61 ± 6.45	0.057	-1.906	0.055 [0.050;0.059]
MHOQ Overall Score	49.37 ± 13.20	53.04 ± 10.40	0.145	-1.457	0.14 [0.14;015]

SD: Standart Deviation, MHOQ: Michigan Hand Outcomes Questionnaires, FIHOA: Functional Index of Hand Osteoarthritis, 9HPT: 9 Holes Peg Test, *p<0.05: statistically significant, CI: Confidence Interval

Tablo 3: Result of comparing the differences between the pre- and post-treatment outcome measures between the groups

Outcome measures	Differences between Pre and post-treatment in mobilization group (Mean ± SD)	Differences between Pre and post-treatment in control group (Mean ± SD)	P value	Z value	Effect size [CI]
Pain (cm)					0.002 [0.001;0.002]
Resting	1.89 ± 2.10	-0.02 ± 2.43	0.002*	-3.055	
Activity	3.26 ± 2.34	1.64 ± 1.87	0.008*	-2.657	0.009 [0.007;0.011]
Night	2.19 ± 2.43	0.90 ± 1.44	0.053*	-1.935	0.055 [0.051;0.059]
Gross Grip Strength (kg)	4.31 ± 3.01	1.86 ± 4.68	0.013*	-2.487	0.009 [0.007;0.01]
Bipod Pinch Strength (kg)	0.68 ± 0.92	0.22 ± 1.33	0.074	-1.786	0.073 [0.068;0.078]
Lateral Pinch Strength (kg)	1.29 ± 1.65	0.05 ± 1.16	0.003*	-2.954	0.002 [0.001;0.002]
9HPT Time (second)	2.52 ± 3.35	1.48 ± 3.02	0.192	-1.303	0.198 [0.19;0.020]
FIHOA Score	5.54 ± 4.03	2.06 ± 4.20	0.001*	-3.237	0.001 [0.001;0.002]
MHOQ Overall Score	13.62 ± 9.49	5.91 ± 11.05	0.005*	-2.811	0.005 [0.003;0.006]

n: Number of participants, SD: Standart Deviation, MHOQ: Michigan Hand Outcomes Questionnaires, FIHOA: Functional Index of Hand Osteoarthritis, 9HPT: 9 Holes Peg Test, *p<0.05 statistically significant, CI: Confidence Interval