08.03.2017

Kinesiotaping in Lateral Epicondylitis

(NCT03074500)

(Unique Protocol ID: 09.2017.004)

STUDY PROTOCOL

Participants

Eligible patients with lateral epicondylitis (LE) who were admitted to Physical Medicine and Rehabilitation outpatient clinic at a tertiary university hospital were enrolled to study according to inclusion criteria.

Patients who had lateral elbow pain less than 12 weeks, clinically diagnosed with LE in our outpatient clinic were given NSAID treatment (Naproxen Sodium 75 mg 2x1 p.o.) for 2 weeks if not contraindicated. Patients who did not benefit from NSAIDs were enrolled in the study after informed consent was obtained.

The inclusion criteria were: (1) having had symptoms less than 12 weeks, (2) tenderness and pain over lateral epicondylitis, (3) Provocation of the lateral elbow pain with at least one of the following tests - resisted middle finger extension (Maudley's test), resisted wrist extension or passive stretch of wrist extensors (Mill's test).

The exclusion criteria were: (1) cervical spondylosis or radiculopathy, (2) diabetes mellitus, (3) neuropathy, (4) arthritis in the upper extremities, (5) history of injection and physical therapy for lateral epicondylitis within the last three months, (6) pregnancy, (7) history of surgery or acute trauma in the elbow, (8) allergy to tape.

The study was conducted after approval from the the institutional Human Research Ethics Committee in accordance with the Declaration of Helsinki. Informed consent was obtained from all patients. Reporting was conducted in accordance with CONSORT14 and recommendations for pilot studies.

Study design

The study was designed as prospective, single-blinded, randomized, controlled trial. Patients with LE were randomized to either of three groups: Group 1 (exercise + KT), Group 2 (exercise + sham-taping) and Group 3 (control - only exercise group) (GA) which the assessors were blinded to (EG, DKB). To ensure group concealment, randomization was done using sealed opaque envelopes which were sequencely numbered in advance, including the

information about which group the patient would have been allocated to. The practitioner (EG) opened the envelopes and started the interventions according to group allocation.

Sample size

It was found out that 8 individuals for each group must had been recruited to have 90% power with 5% type 1 error level according to change in Patient Rated Tennis Elbow Evaluation (PRTEE) Questionnaire based on the previous research conducted by Dilek et al evaluating the effects of kinesiology taping on LE.

Intervention

All patients received home exercise program including stretching exercises of wrist (three repetitions of 10 manual stretches with a gentle sustained force for 30 seconds and a rest period of 30 seconds), twice a day and strengthening exercises 10 repetitions in 2 or 3 series. Control group received exercises only.

In KT and sham-taping (ST) groups, tapings were performed by a trained and certified physician (EG) and changed every 3-4 days for two weeks. Therefore each patient had 4 tapings in total. KT was applied by using muscle inhibition and fascia correction techniques on forearm as described by Kase et Al.

An X shaped strip from wrist to lateral epicondyle of the humerus and an approximately 10 cm Y shaped strip was prepared before application. Short tails of the X-strip were applied to dorsal side of hand without any tension, crossing part was applied to dorsal wrist with maximum tension and long tails were fixed along extensor carpi radialis and extensor carpi ulnaris to lateral epicondyle without tension. On the other hand SH was performed with 2 narrow I-shaped strips from the same taping material, applied to forearm avoiding muscle origo and insertio points and without applying tension.

All subjects were informed to remove tape if any adverse effect (such as skin irritation) occurred.

During the study period, oral or topical NSAIDs were not prescribed or allowed to the patients however they were allowed to take occasional analgesics (such as paracetamol) if

needed. Home exercise program and restriction of NSAIDs was regularly reviewed by phone calls twice a week in only-exercise group and during tapings in the KT and ST groups.

Outcome Measures

Demographic parameters such as age, gender, affected side, duration of symptoms, occupation and Nirschl's Scale for grading LE via symptom severity and duration were recorded initially.

All evaluations were performed in the beginning, after taping (2. week) and 4 weeks after taping (6.week). In addition VAS at rest, VAS at daily activity and grip strengths were also assessed in KT and ST groups to evaluate immediate effect, after initial tape application. Evaluations were made by a blinded investigator (DKB).

Primary Outcome Measure

Patients were asked to estimate their forearm pain and disability using "Patient rated tennis elbow evaluation (PRTEE)" questionnaire as primary outcome measurement.

The PRTEE is a 15-item questionnaire designed to measure forearm pain and disability in patients with lateral epicondylitis. The PRTEE allows patients to rate their levels of tennis elbow pain and disability from 0 to 10, and consists of 2 subscales; pain and function. Scores were calculated ranging from 0 to 100, in which higher scores indicating more forearmpain and disability.

Secondary Outcome Measures

The secondary outcome measurements were (1) The Disabilities of the Arm, Shoulder and Hand Score (QuickDash) scale, (2) painless grip strength, (3) and maximum grip strength (4) visual analogue scale (VAS) on a 10-cm scale at rest, (5) VAS at daily activity and (5) VAS at night.

QuickDASH is an 11-item scale for any or multiple disorders of the upper limb evaluating physical function during acitivities of daily living. To calculate a *Quick*DASH score at least 10 of the 11 items must be completed. Each item has 5 response options; much better,

somewhat better, unchanged, somewhat worse, much worse. Scale scores were calculated, ranging from 0 (no disability) to 100 (most severe disability).

Grip strengths were measured by using a handheld dynamometer (JAMAR, Sammons Preston, Inc., Bolingbrook, IL), with a rest period of 20 seconds 3 trials were performed and mean values (kg) were recorded.