A pilot trial to study the effectiveness of an exercise programme in the treatment of rotator cuff tendinopathy

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ABSTRACT

The aim of this pilot trial was to study the effectiveness of an exercise programme in the treatment of chronic rotator cuff tendinopathy. Patients were allocated to two groups by sequential allocation. The patients in group A (n=10) received an exercise programme consisted of slow progressive isotonic, including eccentric, strengthening exercises and static stretching exercises. The exercise programme was given daily (apart from weekends) for 4 weeks. The patients in the group B (placebo group, n=10) received placebo tablets (unmarked vitamin C) twice daily for four weeks. Patients’ pain was evaluated using a visual analogue scale (VAS) at the end of the four-week course of treatment (week 4) and three months after the end of treatment (week 16). Differences between groups were determined using the independent t test. The difference within groups between baseline and end of treatment was analysed with a paired t test. At the end of treatment there was a decline in visual analogue scale of about 7 units in the exercise programme group compared with baseline (p<0.0005, paired t test). There were significant differences in the magnitude of reduction between the groups at the end of treatment and at the three month follow up (p >0.0005, independent t test) in favour of the exercise programme group. Although the pain reduced in patients with shoulder tendinopathy at the end of the treatment using an exercise programme, future controlled studies are needed to establish the effectiveness of an exercise programme in the treatment of rotator cuff tendinopathy.

Key Words: Rotator cuff tendinopathy, Exercise programme, Eccentric, Stretching
INTRODUCTION

Tendinopathies are not only common among professional and recreational sports players but also among people in general, especially those in jobs that involve manual labour (9). Tendinopathies may affect a variety of tendons including Achilles, patellar, rotator cuff (mainly supraspinatus) and extensor carpi radialis brevis (ECRB, commonly referred to as tennis elbow and/or lateral epicondylitis (LE)). Many clinicians advocate a conservative approach as the choice of treatment for tendinopathy (22). Physiotherapy is a conservative treatment that is usually recommended (32). A wide array of physiotherapy treatments has been recommended for the management of tendinopathy such as electrotherapeutic modalities, exercise programmes, soft tissue manipulation, and manual techniques (4, 22, 32). These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function (13). Such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to discover the most effective treatment in patients with tendinopathy. One of the most common physiotherapy treatments for tendinopathy is an exercise programme (25, 26). One consisting of strengthening, especially eccentric, and static stretching exercises has shown good clinical results in LE (15, 28), patellar (8, 21, 27, 33) and Achilles tendinopathy (2, 14, 16, 17, 23, 24). Such an exercise programme is used as the first treatment option for our patients with tendinopathy (29). To our knowledge, there have been no studies to investigate the effectiveness of such an exercise programme in patients with rotator cuff tendinopathy (12). Therefore, the aim of this pilot study was to investigate the effects of an exercise programme in patients with chronic rotator cuff tendinopathy.

METHODS

A monocentre pilot trial was conducted in a clinical setting over 5 months to assess the effectiveness of an exercise programme in patients with rotator cuff tendinopathy. Three investigators were involved in the study: (1) the primary investigator who administered the treatments (DS); (2) a specialized rheumatologist (IS), who had over 25 years’ experience and who evaluated the patients to confirm the rotator cuff tendinopathy diagnosis; and (3) a medical student (KS), who performed all baseline and follow-up assessments, and gained informed consent. All assessments were conducted by KS who was blind to the patients’ therapy group. KS interviewed each patient to ascertain baseline demographic and clinical characteristics, including patient name, sex, age, duration of symptoms, previous treatment, occupation, affected arm and dominant arm.
Patients over 18 years old with shoulder pain were examined and evaluated in the rheumatology and rehabilitation centre located in Athens between October 2005 and February 2006. All patients lived in Athens, Greece, were native speakers of Greek, and were either self-referred or referred by their physician or physiotherapist.

Patients were included in the study if, at the time of presentation, they had been evaluated as having clinically diagnosed rotator cuff tendinopathy for at least four weeks. Patients were included in the trial if they reported pain on palpation (upper aspect of the head of the humerus), positive Hawkins, Neer and epyt can position test (5). Patients were excluded if they: (1) had a history of rotator cuff surgery; (2) reported a history of glenohumeral dislocation, or other traumatic injury to the shoulder; (3) reported only periscapular or cervical pain during arm elevation; or (4) had shoulder symptoms reproduced by a cervical assessment. In addition, an x-ray was performed to detect calcifications and whether there were signs of arthrosis in the acromio-clavicular joint. Patients with signs of arthrosis in the acromioclavicular joint and/or calcifications in the rotator cuff were also not included in this pilot study.

All patients received a written explanation of the trial before entry into the study and then gave signed consent to participate. They were allocated to two groups by sequential allocation. For example, the first patient with rotator cuff tendinopathy was assigned to the exercise programme group, the second patient with rotator cuff tendinopathy to the placebo group, and so on.

All patients were instructed to use their arm during the course of the study but to avoid activities that irritated the shoulder such as full elevation of the shoulder, sleep on the affected shoulder and quick movements of the shoulder. They were also told to refrain from taking anti-inflammatory drugs throughout the course of study. Patient compliance with this request was monitored using a treatment diary. Access to patients was authorized by the manager (IS) of the rheumatology and rehabilitation centre, who approved the study.

All treatments were administered at the centre by a qualified physiotherapist (DS) with about 8 years’ experience in the management of tendinopathies. Communication and interaction (verbal and non-verbal) between the therapist and patient was kept to a minimum and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided. For example, patients were given no indication of the potentially beneficial effects of the treatments or any feedback on their performance in the pre- and post-application measurements.

The exercise programme was given daily (apart from weekends) for 4 weeks. The exercise programme consisted of slow progressive isotonic, including eccentric, strengthening exercises and static stretching exercises. The strengthening exercises including (i) shoulder medial and lateral rotation with the elbow in 0 and 90 degrees of abduction; (ii) shoulder abduction to 90 degrees with elbow in flexion: (iii) scaption-the arm was kept at 30 degrees of horizontal abduction with the thumb
pointing downwards; and (iv) diagonal pattern from full flexion to extension. Each exercise was performed twice at each treatment session with 12 repetitions in each set and 1 min rest interval between each set. Patients were told to continue with the exercise even if they experienced mild pain. However, they were told to stop the exercise if the pain became disabling. When patients were able to perform the strengthening exercises without experiencing any minor pain or discomfort, the load was increased using free weights or therabands. Static stretching exercises including (i) posterior and inferior capsule stretch according to Prentice (1999) (20) and (ii) external rotators. Static stretching exercises were repeated three times at each treatment session, after the strengthening exercises with a 30-s rest interval between each repetition. Each stretching was held for 30-45 s each time and then released. The exercise programme treatment was individualized one the basis of the patient’s description of pain experienced during the procedure.

Patients were given placebo tablets (unmarked vitamin C) twice daily for four weeks in the placebo group. Standard advice was given to take the tablets with food and about potential side effects.

Pain and dropout rate were measured in this study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4) and three months (week 16) after the end of treatment in order to see the intermediate effects of the treatments. Pain was measured on a visual analogue scale (VAS), where 0 (cm) was “least pain imaginable” and 10 (cm) was “worst pain imaginable”. The pain VAS was used to measure the patient’s worst level of pain over the 24 hours before each evaluation. The dropout rate was also used as an indicator of treatment outcome. Dropouts were categorised as follows: (a) withdrawal without reason; (b) did not return for follow up; (c) request for an alternative treatment.

The change from baseline was calculated for each follow up. Differences between groups were determined using the independent t test. The difference within groups between baseline and end of treatment was analysed with a paired t test. A 5% level of probability was adopted as the level for statistical significance. SPSS 20 statistical software was used for the statistical analysis.

RESULTS

27 patients eligible for inclusion visited the clinic within the trial period. 3 were unwilling to participate in the study, and 4 did not meet the inclusion criteria described above. The other 20 patients, who all completed the trial (including follow-ups), were sequentially allocated to one of the two possible groups: (a) exercise programme (n=10; 4 men, 6 women; mean (SD) age 48.14 (6.15) years); (b) placebo (n=10; 5 men, 5 women; mean (SD) age 47.87 (6.31) years).
At baseline there were more women in the groups (2 more in total). The mean age of the patients was about 48 years, and the duration of rotator cuff tendinopathy was about 3.5 months. Rotator cuff tendinopathy was in the dominant arm in 85% of patients. There were no significant differences in mean age ($p > 0.0005$, independent t test) or the mean duration of symptoms ($p > 0.0005$, independent t test) between the groups. All patients were manual workers.

Baseline pain on VAS was 8.55 (95% confidence interval 8.32 to 8.87) for the whole sample ($n = 20$). There were no significant differences between the groups for baseline pain ($p > 0.05$ independent t test). At week 4 there was a decline in VAS of about 7 units in the exercise programme group compared with the baseline ($p < 0.0005$, paired t test) and only 2 units in the placebo group ($p > 0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at week 4 and week 16 ($p < 0.0005$ independent t test) in favour of exercise programme.

There were no dropouts and all patients successfully completed the study.

**DISCUSSION**

The results obtained from this pilot trial are novel, as to date there have been no data to investigate the effectiveness of an exercise programme for the reduction of pain in shoulder tendinopathy.

Exercise programmes appear to reduce the pain and improve function, reversing the pathology, characterised by the increased presence of fibroblasts, vascular hyperplasia, increased amounts of proteoglycans and glycosaminoglycans, and disorganised collagen (11, 30), of tendinopathies (6, 9, 10, 18) as supported by experimental studies on animals (31). The way that an exercise programme achieves the goals remains uncertain as there is a lack of good quality evidence to confirm that physiological effects translate into clinically meaningful outcomes and vice versa.

There are two types of exercise programme: home exercise programmes and exercise programmes carried out in a clinical setting. A home exercise programme is commonly advocated for patients with tendinopathies because it can be performed any time during the day without requiring supervision from a physiotherapist. Home exercise programmes are rarely effective because patients fail to comply with the regimen (29). This problem can be solved by exercise programmes performed in a clinical setting under the supervision of a physiotherapist (13). For the purposes of this report, “supervised exercise programme” will refer to such programmes.

Standard eccentric exercises offer adequate rehabilitation for tendon disorders, but many patients with tendinopathies do not respond to this prescription alone (3). The load of eccentric exercises was increased according to the patients’ symptoms because the opposite has shown poor results (3). Eccentric exercises
were performed at a low speed in every treatment session because this allows tissue healing (2, 11).

Previous trials have found that a home exercise programme reduced the pain in patellar (8, 21, 33) lateral elbow (19) and Achilles tendinopathy (2, 14, 16, 17, 23, 24). However, it was performed for about three months in all previous studies. In contrast, in the present pilot clinical trial and the studies of Stasinopoulos and colleagues (15, 27, 28) a supervised exercise programme was administered for a month. Thus it seems that the supervised exercise programme may give good clinical results in a shorter period of time than the home exercise programme. The most likely explanation for this difference is that a supervised exercise programme achieves a higher degree of patient compliance. Studies to compare the effects of these two exercise programmes are required to confirm the findings of the present clinical trial.

The present findings suggest that an exercise programme consisting of isotonic strengthening, including eccentric and static stretching exercises is adequate treatment for patients with shoulder tendinopathy. However, this trial does have some shortcomings. Firstly, although this study was not a RCT, since no genuine randomization procedure was followed, the use of sequential allocation to allocate patients to treatment groups allowed for a true cause-and-effect relationship to be demonstrated. Secondly, a power analysis was not performed; this is required in order to estimate the magnitude of the effect of the proposed intervention, but research has showed that a sample size of twenty-five subjects was sufficient to demonstrate statistical significance of all outcome measures (1). Thirdly, the compliance of patients was not monitored when they were away from the clinic. Patients’ diaries suggested that patients were compliant to the study instructions, although patients may have given incorrect details to please the investigators. For example, it was possible that patients followed the treatment but took analgesic medications at the same time, and the improvement of symptoms may be due to those medications. Therefore, ways should be found to measure how other treatments such as analgesic medications contribute to the improvement of symptoms. Fourthly, outcome measures of unknown validity were used, as there are no studies to demonstrate which measures are variable and reliable in patients with shoulder tendinopathy. Finally, the lack of blinding of patients and therapists may be a reason for the effectiveness of the exercise programme. However, the blinding of patients and therapists would be problematic, if not impossible, because patients know if they are receiving the exercise programme treatment and therapists need to be aware of the treatment in order to administer it appropriately. In addition to the weaknesses discussed, structural changes in the tendon related to treatment interventions were not shown; improvement in shoulder strength after the treatment interventions was not measured, and long term effects (six months or more after the end of treatment) of these treatments were not investigated. Further research is needed to establish the effectiveness of an exercise programme in the management of shoulder tendinopathy.
CONCLUSION

This pilot trial showed that an exercise programme, consisting of isotonic strengthening, including eccentric, and static stretching exercises, had reduced the pain in patients with rotator cuff tendinopathy at the end of the treatment and three months after the end of treatment. However, future well-designed randomised controlled clinical trials are needed to establish the effects and the mechanism of action of such an exercise programme in rotator cuff tendinopathy. Furthermore, a cost effectiveness analysis should be incorporated into the analysis of the effectiveness of the exercise programme in a future trial, because reduced costs are important issues for the recommendation of a treatment. Such a trial is under progress.

REFERENCES


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