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The Effectiveness of Polarized Polychromatic Noncoherent Light (Bioptron Light) In Patients with Chronic Rotator Cuff Tendinopathy. A Clinical sTrial

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Abstract

The aim of the present clinical trial was to compare the clinical results of the use of an exercise program with those of an exercise program and polarized polychromatic noncoherent light (Bioptron light) in patients with chronic rotator cuff tendinopathy. Patients were allocated to two groups by drawing lots. Pain, function and strength were measured. An exercise program and polarized polychromatic noncoherent light (Bioptron light), had reduced the pain and improved function and strength in patients with chronic rotator cuff tendinopathy at the end of the treatment and at the follow-ups. Future well-designed randomized controlled clinical trials are needed to establish the effectiveness of polarized polychromatic noncoherent light (Bioptron light) in the management of chronic rotator cuff tendinopathy.

Keywords: Bioptron light; Polychromatic; Chronic rotator cuff; Tendinopathy; Supraspinatus; Lateral epicondylitis; Physiotherapy treatments; Electrotherapeutic modalities; Exercise programs, Soft tissue manipulation; Manual techniques; Bioptron light; Bioptron, Wollerau

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. 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)). Rotator cuff tendinopathy (RCT) is the most common tendinopathy in the shoulder area and one of the two most common tendinopathies of the upper limb. Pain and decreased function are the main symptoms of RCT. Diagnosis is simple. The symptoms are reproduced by overhead activities; palpation on the site of pain; clinical tests such as Hawkins & Neer [1]. Many clinicians advocate a conservative approach as the choice of treatment for chronic RCT. Chronic RCT is degenerative or failed healing tendon response rather than inflammatory. Physiotherapy is a conservative treatment that is usually recommended. A wide array of physiotherapy treatments has been recommended for the management of chronic RCT such as electrotherapeutic modalities, exercise programs, soft tissue manipulation, and manual techniques. These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function. 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 program. One consisting of strengthening and static stretching exercises has shown good clinical results in tendinopathies such as chronic RCT.

Although an exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is the

polarized polychromatic noncoherent light (Bioptron light), a new modality of light therapy for the management of tendinopathies such as chronic RCT. Manufacturers of polarized polychromatic non-coherent light devices (Bioptron light; Bioptron, Wollerau, Switzerland) claim that the waves of this light move in parallel planes (i.e., are polarized), cover a wide range of wavelengths (480-3400nm) including visible light and part of the infrared range (polychromy), and are not synchronized (incoherent) [1]. To our knowledge, there have been no studies to investigate the effectiveness of Bioptron light as a supplement to an exercise program in the management of chronic RCT. Therefore, the aim of the present study was to compare the clinical results of the use of an exercise program with those of an exercise program and Bioptron light in patients with chronic RCT.

Methods

A monocenter trial was conducted in a research center over 16 months to assess the effectiveness of a protocol that was constituted from an exercise program in comparison to another protocol constituted by an exercise program and Bioptron light in patients with chronic RCT. Patients over 18 years old with shoulder pain were examined and evaluated in the Cyprus Musculoskeletal and Sports Trauma Research Centre located in Nicosia between May 2018 and October 2019. All patients lived in Nicosia, Cyprus, 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 RCT 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 epty can position test [2]. Patients were excluded if they:

a) had a history of rotator cuff surgery.

b) reported a history of glenohumeral dislocation, or other traumatic injury to the shoulder.

c) reported only periscapular or cervical pain during arm elevation; or

d) 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 exercise program and exercise program and Bioptron light by drawing lots. All patients were instructed to use their arm during 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.

All treatments were administered at the center by a qualified physiotherapist with about 20 years' experience in the management of tendinopathies. Communication and interaction (verbal and non-verbal) between the therapist and patient were kept to a minimum and behaviors 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. Patients received Bioptron light therapy, via the BIOPTRON Pro optical device (BIOPTRON AG, Wollerau, Switzerland;) [1] for 10min once daily for 4 weeks, totally 20 treatments. The equipment used was noninvasive. The physical parameters of the light output from this optical medical device were as follows: wavelength 480-3400nm, light spot size 254cm^2, and specific power density 40mW/cm2. During active light exposure, the energy output of the device (energy density) was 2.4J/cm^2/min (that is, 24J/cm^2/10min session). During each light exposure the patient was seated and fitted with darkened eye wear, the treatment area (shoulder area) was exposed, carefully cleaned (by wiping with a sterile gauze soaked in clean water) and dried, then the optical medical device was powered up and used to 'paint' the exposed area with Bioptron light for 10min. During light exposure, the optical medical device was positioned via a support floor stand to be approximately at right angles to the skin surface, and at approximately 10cm from the treatment area. A ''beep'' signified the end of the 10min treatment.

Patients in both groups followed an exercise program that was given daily (apart from weekends) for 4 weeks [3]. The exercise program consisted of slow progressive isotonic, including eccentric, strengthening exercises and static stretching exercises [3]. The strengthening exercises including

a) shoulder medial and lateral rotation with the elbow in 0 and 90 degrees of abduction.

b) shoulder abduction to 90 degrees with elbow in flexion:

c) scaption-the arm was kept at 30 degrees of horizontal abduction with the thumb pointing downwards; and

d) 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

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weights or therabands. Static stretching exercises including

a) posterior and inferior capsule stretch according to prentice (1999) [4]

b) 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 30-45s each time and then released. The exercise program treatment was individualized one the basis of the patient's description of pain experienced during the procedure. Pain, Function, strength and dropout rate were measured in this study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4) three months (week 12) and six months (week 24) after the end of treatment in order to see the short, intermediate and long-term effects of the treatments. Pain and function were measured using the Greek version of Shoulder Pain and Disability Index (SPADI) which is a reliable and valid measure when administered to patients aged over 18 years old with shoulder pain for at least 4 weeks [5]. Strength was measured using the handheld dynamometer according to Savva et al. [6] which is a valid and reliable outcome measures for patients with RCT. The dropout rate was also used as an indicator of treatment outcome. Dropouts were categorized as follows:

a) withdrawal without reason

b) did not return for follow up

c) request for an alternative treatment

Based on methodology from a previous study using Bioptron light therapy from a BIOPTRON optical medical device in the treatment of lateral epicondylitis, [7] a sample size of 25 subjects per group was deemed sufficient to demonstrate statistical clinical significance for all outcome measures on musculoskeletal injuries, such as ankle sprains. Based on previous published data, clinical effects of 20% were reported as clinically meaningful in placebo or non-controlled studies measuring pain relief and functional outcomes in response to physiotherapeutic interventions. In this study, baseline variance for pain and functional outcomes was set at 25%, in line with previously published data in this field. Power calculations suggested that a sample size of 25 patients per group was sufficient to detect a 20% change in outcome measures, assuming variance was equivalent to 25%, with 80% power and a significance level of 5%. The formula that used to estimate the appropriate sample size was:

$$N=\frac{\phi 6^{2}}{d^{2}}$$

where σ2 the variability of the data and d2 the effect size. For example, in our trial σ=25&d=20. Therefore, the above formula is N =16(25^2)/ (20^2) =16X625/ 400=25. 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 of statistical significance. SPSS 20 statistical software was used for the statistical analysis (SPSS Inc., Chicago, IL).

Result

Sixty-five patients eligible for inclusion visited the CYPUSTREC within the trial period. Nine were unwilling to participate in the study, and 6 did not meet the inclusion criteria described above. The other 25 patients were allocated to one of the two possible groups:

a) exercise program [n=25; 18 men, 7 women; mean (SD) age 48.45 (6.67) y].

b) exercise program and Bioptron light [n=25;16 men, 9 women; mean (SD) age 48.06 (6.32) y].

At baseline there were more men than women in the study groups (18 more in total). The mean age of the patients was about 48y, and the duration of RCT was about 6months. RCT was in the dominant arm in 95% of patients. There were no significant differences in mean age (p>0.0005 by independent t-test) or the mean duration of symptoms (p>0.0005 on independent t-test) between the groups. The patients had received drug therapy as previous treatment. All patients were manual workers. Baseline SPADI was 90 (95% CI 85.1 - 93.4) for the entire sample. There were no significant differences between the groups for baseline SPADI (p>0.05 on independent t-test) At week 4, there was a decline in SPADI of about 82 units in the exercise program and bioptron light and 63units in the exercise program compared with the baseline (p<0.0005, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 12 and 24 (p>0.0005 independent t test).

Baseline grip strength was 28.6lb (95% CI 25.44-33.02) for the whole sample. There were no significant differences between the groups for baseline grip strength (p>0.05 independent t test). At week 4, there was a rise in pain-free grip strength of approximately 41 units in the exercise program and Bioptron light group and 23 units in the exercise program compared with the baseline (p<0.0005, paired t test). There were significant differences in the magnitude of improvement between the groups at weeks 12&24 (p>0.0005 independent t test). There were no dropouts, no adverse effects were referred, and all patients successfully completed the study.

Discussion

The aim of this study was not to explain how the Bioptron light acts but, rather to assess whether BIOPTRON light therapy was an effective form of intervention in patients with chronic RCT. Statistically significant improvements in efficacy outcomes were observed in participants who were exposed to exercise program plus Bioptron light therapy over the treatment period.

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These findings lend support to the use of Bioptron light therapy as an intervention for people with chronic RCT as an adjunct to cryotherapy. Exercise programs appear to reduce the pain and improve function, reversing the pathology of tendinopathy such as RCT, as supported by experimental studies on animals. The way that an exercise program achieves its 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 programs: home exercise programs and exercise programs carried out in a clinical setting. A home exercise program is commonly advocated for patients with tendinopathies such as RCT because it can be performed any time during the day without requiring supervision by a physiotherapist. Our clinical experience, however, has shown that patients fail to comply with the regimen of home exercise programs. This problem can be solved by exercise programs performed in a clinical setting under the supervision of a physiotherapist. For the purposes of this report, ''supervised exercise program'' will refer to such programs. Therefore, such a supervised exercise program was used in the present trial.

Although a supervised exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is the Bioptron light, which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. It is probable that BIOPTRON light accelerates the cellular mechanisms and improves the local blood supply, and exposure to both the visible and infrared parts of the electromagnetic spectrum of BIOPTRON light may explain its potential mechanism of action. Further research is needed to investigate exactly how this occurs [8]. Like laser therapy, Bioptron light is also a low-power light source but differs in that it is polychromatic and incoherent rather than monochromatic and coherent [1,8]. Moreover, Bioptron light combines visible light at a wavelength of 480–700nm and infrared light at a wavelength of 700-3400nm. In contrast, low power laser contains either visible or infrared light at one specific wavelength. Several drawbacks have impaired the usefulness of low-power laser light in comparison to Bioptron light, such as high cost, high risk, required user skills, and the small diameter of the laser beam, which allows only a limited area to be treated[1,8]. The BIOPTRON light therapy Instructions for use states that incorrect application of Bioptron light is not hazardous to a patient's health, [1,8] but that the effects of the Bioptron light therapy are reduced if any of the following conditions apply:

a) It is not applied to bare skin.

b) It is held at an operating distance more than of 10cm. (The appropriate distance is 5–10cm.)

c) It is not held at a 900 angle from the skin. (For the greater penetration depth, the device should be perpendicular to the treatment area.)

d) The light is not held steady relative to the skin.

e) The irradiation time is 56min. (The appropriate irradiation time is 6min: irradiation times46min do not produce better results.)

f) The period of treatment is at least 3 times per week for at least 1m.

It is important to mention that no side effects were reported during or after the treatment period. There is no UV light in the BIOPTRON light spectrum, so there is no tanning or heating effect on the skin. Furthermore, BIOPTRON light is not harmful to the eyes, and poses no danger to pregnant women. It is easy-to –use & can be used in the clinical setting or if required in the patient's home. Finally, BIOPTRON light is not associated with cancer: the unsafe range for cancer risk is UV light at 250nm, and the shortest wavelength in the Bioptron spectrum is 480nm.

Previous trials assessed the effectiveness of BIOPTRON medical light in chronic injuries, such as lateral epicondylitis [9-11] and carpal tunnel syndrome [12,13]. The most likely explanation for the lack of published research using BIOPTRON light for this application is that it has only recently become available for use in physiotherapy settings. Previously reported trials found that a course of BIOPTRON light treatment may improve patients' symptoms [9-13]. The findings of these published trials may also encourage the initiation of well-designed randomized controlled trials (RCTs) that might produce better evidence for the effectiveness of BIOPTRON light in acute and chronic injuries.

There were some limitations of the present trial. First, no placebo (sham) or no-treatment group was included in the present trial. The placebo (sham) or no-treatment group is important when the absolute effectiveness of a treatment is determined. Although, the absolute effectiveness of technique-based interventions such as BIOPTRON light is not difficult to investigate, absolute effectiveness does not provide the therapists with information as to which is the most appropriate treatment for the management of a condition, which in this case was an chronic RCT. Second, concomitant treatments, which patients might have been receiving outside of clinic visits were not monitored. Patients' diaries strongly suggested that patients were compliant to the study instructions, although it is possible that some patients may have given incorrect details to 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. Finally, the blinding of patients and therapists would be problematic in that case, if not impossible, because patients know which treatment they are receiving, and therapists need to be aware of the treatment to administer it appropriately. In addition to these weaknesses, structural changes

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in the tendond related to the treatment interventions were not shown. Pre- and post-therapeutic medical imaging studies, such as diagnostic ultrasound or magnetic resonance imaging (MRI) would shed further light on demonstrating such structural soft tissue changes. Further research is needed to establish the effectiveness of BIOPTRON light in the management of acute and chronic musculoskeletal injuries, the possible mechanism of action of this treatment approach, and the cost-effectiveness of such treatment, as reduced cost is an important issue for the recommendation of any given treatment.

Conclusion

Data from this study provide the evidence of the efficacy of exercise program plus Bioptron light therapy in the treatment of chronic RCT; however, a well-designed randomized controlled study conducted by a multidisciplinary team is necessary to confirm the efficacy of this form of phototherapy supplemented with exercise program in patients with chronic RCT and to objectively evaluate recommendations for its routine use in clinical practice.

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