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The Efficacy of the Combined Ultrasound Therapy with 5% Lidocaine Medicated Patch for the Management of Plantar Fascia Tendinopathy

G Panoutsopoulos[1*], A Mitseas[2], D Panidis[1], K Tzirogiannis[1], Maria Polikandrioti[3], Ariadni M Dede[4], Danai A Mitsea[5], V Dedes[6]

[1]*Department of Nutritional Science and Dietetics, University of Peloponnese, Kalamata Greece*

[2]*Department of Orthopaedic, City Hospital, Pindarou , Kalamata, Greece*

[3]*Department of Nursing, University of West Attica, Athens, Greece*

[4]*Physiotherapy Department, Saxion University, Enschede, Netherlands*

[5]*Department of Biology, University of Patras, Patras , Greece*

[6]*Department of Nursing, University of Peloponnese, Tripoli, Greece*

Abstract

Therapeutic ultrasound has been routinely used to treat tendinopathies, including plantar fascia tendinopathy. The 5% lidocaine patch is designed as a targeted peripheral analgesic to treat postherpetic neuralgia, osteoarthritis, low back pain, myofascial pain syndrome, and diabetic polyneuropathy. The present study aimed to investigate if the addition of 5% lidocaine patches between the therapeutic ultrasound sessions could improve analgesia in people suffering from plantar fascia tendinopathy. Eighty-two patients with plantar fascia tendinopathy received therapeutic ultrasound combined with 5% lidocaine patches between sessions, and fifty-six patients received therapeutic ultrasound alone. The pain intensity and functional and quality of life impairments were evaluated by the self-administered "UoP-PFQ" questionnaire pre-treatment, post-treatment, and at the 4-week follow-up. Pain intensity, functionality and quality of life impairments were significantly reduced in both the combined group with therapeutic ultrasound and 5% lidocaine patches and the ultrasound group. However, the reduction was more pronounced in the combined group in all parameters pre-treatment, post-treatment, and at the 4-week follow-up. Although both ultrasound and combined therapies were effective in patients with plantar fascia tendinopathy, the statistical analysis showed that the addition of 5%lidocaine patches between the ultrasound treatments could cause a further reduction in pain intensity and improve the functionality and quality of life.

Keywords: Ultrasound therapy • Rehabilitation • Plantar fascia tendinopathy • Lidocaine patch

Introduction

Plantar fascia tendinopathy is a degenerative syndrome due to the irritation or partial rupture of the plantar fascia caused by excessive loading. The main symptom of plantar fascia tendinopathy is a stubbing pain in the calcaneus' medial tuberosity [1]. The pain is initiated with the first steps in the morning or when first standing after a resting period. Once the patient starts walking, the pain gets better, but it is never fully resolved during the day. However, the pain is exacerbated by prolonged walking, exercises, or prolonged standing, especially on hard surfaces. The disorder can last for a long time making everyday activities difficult to perform. The first approach for treating plantar fascia tendinopathy includes strapping the foot, using therapeutic orthotic insoles and prefabricated orthotic devices, plantar fascia stretching exercises, night splints, cast immobilizations, analgesics, and the use of physiotherapy methods such as laser therapy, ultrasound therapy, and extracorporeal shockwave therapy. Other treatment options include cortisone injections, botulinum toxin injections, and platelet-rich plasma injections. Finally, surgery can be used as a last resort and only when other conservative treatment methods have failed. The 5% lidocaine patch is a peripheral analgesic with proven efficacy for pain relief of various peripheral neuropathic pain conditions, including postherpetic neuralgia, diabetic polyneuropathy, and postoperative neuropathic pain. This efficacy led clinicians to explore its usefulness in other clinical conditions that cause pain, such as myofascial pain,

***Address to correspondence:** G Panoutsopoulos, Department of Nutritional Science and Dietetics, University of Peloponnese, Kalamata Greece; Email: gpanouts@uop.gr*

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low-back pain, and osteoarthritis. Furthermore, neuropathic pain conditions can be debilitating, negatively impacting patients' functionality in daily activities and quality of life [2]. The present study aimed to assess pain effectiveness by adding medicated 5% lidocaine patches during ultrasound therapy to patients suffering from plantar fascia tendinopathy. Additionally, it wished to evaluate if there is an additional improvement in the functionality and quality of life when used in combination with therapeutic ultrasound post-treatment and at the 4-week follow-up.

Materials and Methods

Research population

A power sample analysis test was performed using the Sample Power 3 extension of the IBM SPSS v.25 programs to determine the minimum number of patients in each group. It was estimated that 19 patients are the minimum number for each group to obtain 95% power for the study. The total sample consisted of 138 individuals suffering from plantar fascia tendinopathy, who attended the orthopaedic clinic between June 2019 and May 2020, and the physician considered their need for the particular treatment. The individuals were randomly divided into two groups, with a ratio of 1.5:1. Thus, eighty-two patients received a combined therapeutic ultrasound treatment and 5% lidocaine patches from the total sample, and 56 patients received therapeutic ultrasound alone. Patients that met any of the following criteria were excluded from this study: a) patients with malignant diseases, b) patients who had undergone surgery of the plantar fascia tendinopathy, c) patients with a systemic infection or inflammatory rheumatic disease, d) patients under the age of 18.

Research tools

The pain, functionality, and quality of life were assessed by the self-administered questionnaire 'University of Peloponnese Pain, Functionality and Quality of Life Questionnaire - UoP-PFQ' on a 5-point Likert scale (0= no pain and 4= extreme pain) for the lower limbs (Table 1).The Cronbach alpha of the questionnaire is 0.88. The patients compiled the questionnaire pre-treatment, post-treatment, and at the 4-week follow-up as described by Dedes et al. Patients of the therapeutic ultrasound group received ultrasound using a Gymna Pulson 200 device and a model 204 transducer (4 cm2), in pulse mode, using coupling gel. The treatment parameters were set at 3 MHz of frequency for lesions of a depth below 2 cm. The effective radiating area was 4 cm2 and the intensity at 2 W/cm2, meaning that the intensity in situ was approximately 1 W/cm2 . Although there are no definitive rules on intensity selection, increasing the intensity intensifies the biophysical effects and their magnitude. Each session lasted twelve min, three sessions per week, and ten sessions in total [3]. The physiotherapist effectuated the treatment by moving the transducer's head along the affected area.

Pain	Functional Impairment	Quality of Life Impairment
Walking	Walking	Going for a walk
Standing up	Standing up	Standing in a queue
Going up and down the stairs	Going up and down the stairs	Getting on/off a bus
Squatting	Squatting	Sitting down/ standing up
Getting in and out of the car	Getting in and out of the car	Stooping by bending the knees to pick up an object from the floor
Getting up from a chair	Getting up from a chair	Getting in or out of the bathtub

Table 1: Pain, functionality and quality of life impairments of the lower limbs as evaluated by 'University of Peloponnese Pain, Functionality and Quality of Life Questionnaire' pre-treatment, post-treatment, and at the 4-week follow-up.

The patients in the combined therapy group received therapeutic ultrasound and applied a 5% lidocaine patch after each ultrasound treatment for 12 hours, after which it was removed, leaving the area patch free for 12 hours before the application of the next one (12 hours on - 12 hours off) until the next ultrasound session. The 5% lidocaine patch used in this study measured 10 X 14 cm, and the lidocaine dose totalled 700 mg.

Statistical analysis

The results of the present study were analyzed by using the IBM SPSS v. 25 programs. The frequencies, the means, and the standard deviations were calculated from all six questions of each parameter (pain, functionality, and quality of life) that constituted the questionnaire. Then comparisons were performed on the mean and standard deviations in each group, before the treatment, after the treatment, and at the 4-week follow-up by paired samples T-test. An independent samples T-test was then carried out on the mean and standard deviations between groups, pre-treatment, post-treatment, and at the 4-week follow-up [4]. The statistical significance was set to 0.05.

Ethical considerations

The present research met all the ethical principles that govern the conduct of research, such as participants' full confidentiality, the safety of the material, and anonymity of the participants. Finally, the study protocol complied with the Helsinki Declaration and was approved by the University of Peloponnese Ethical Committee.

Results

In both the combined therapy group and the ultrasound groups, the mean of the reported pain was significantly decreased after the completion of the therapy ($p<0.001$), and this decrease remained at the 4-week follow-up ($p<0.001$). However, the reduction was not as pronounced as in the combined therapy group, both post-treatment and at the 4-week follow-up ($p<0.001$). The functional impairment also showed a reduction in both groups post-treatment ($p<0.001$) and at 4-week follow-up ($p<0.001$), and this decrease was more evident in the combined therapy group ($p<0.001$). Accordingly, the same pattern of reduction was observed in the quality of life, with patients of the combined therapy group showing a more significant reduction than the ultrasound group ($p<0.001$).

Discussion

Therapeutic ultrasound has been routinely used to treat various tendinopathies, including plantar fascia tendinopathy [5]. The pulsed mode of action in therapeutic ultrasound is primarily attributed to the non-thermal effects of better tissue healing. The non-thermal effects initially cause cavitation, which then aids acoustic micro streaming. Cavitation is the formation, oscillation, and finally, the destruction of gas-filled bubbles formed by pulsed ultrasound. Consequently, this cavitation process enhances the acoustic micro streaming process, where the structure, function, and permeability of cell membranes increase cellular activity, thus stimulating the tissue repair. The present study results indicate that the addition of 5% lidocaine patches between the ultrasound therapy sessions significantly alleviated pain intensity and improved the functionality and quality of life in patients with plantar fascia tendinopathy both post-treatment and at the 4-week follow-up. A significant decrease in pain and functional and quality of life impairment was observed when patients were treated with ultrasound alone. Nevertheless, these findings were less pronounced compared to combined therapy. Thus, the addition of 5% lidocaine patches can help during the healing process and therefore is a useful asset for the treatment of tendinopathies. It is a safe and well-tolerated local analgesic with minimal adverse effects observed during the therapy. From the total sample who used the 5% lidocaine patch (126 patients), only mild severity adverse effects were observed in 11 patients, all dermal reactions at the application sites caused by adhesive properties. Besides, all patients reported no skin sensitivity loss to light touching during the therapy, indicating that 5% lidocaine patches' daily application provides pain alleviation without producing local anaesthesia. Thus, it provided adequate analgesia without generating any anaesthetic effects on the skin, which can be found in other topical lidocaine formulations commonly used for their local anaesthetic properties. Topical administration of 5% lidocaine patches reaches a therapeutic plasma concentration of 0.15-0.23 μg/mL, and this range is not able to produce antiarrhythmic action. In contrast, lidocaine's systematic administration can reach a therapeutic plasma concentration of 1.5-5 μg/mL, with anything above this value been characterized as toxic levels [6].

The 5% lidocaine patch is designed as a targeted peripheral analgesic to treat peripheral neuropathic pain with no systemic adverse effects. The therapeutic effect provided by the 5% lidocaine patch is not produced due to systemic absorption, which has been regarded as minimal. Instead, the patch formulation enables the diffusion of lidocaine across the skin, where it binds to voltage-gated sodium channels that are found in abnormally high numbers or due to damaged nociceptors. Once lidocaine is attached to the sodium channels, it reduces or even inhibits the abnormal action potentials produced by the damaged and/or dysfunctional peripheral nerves and alleviates pain . Consequently, topical lidocaine administration can inhibit the sodium channels in the injured or dysfunctional Aδ and C nerve fibres without inhibiting the sodium channels in the sensory fibres Aβ.

Conclusion

The present study is the first to demonstrate the effectiveness and the contribution of the 5% lidocaine patch to pain alleviation when combined with therapeutic ultrasound to treat plantar fascia tendinopathy. Therefore, there are no direct studies to compare therapeutic ultrasound and the 5% lidocaine patch in the treatment of tendinopathies. However, the effectiveness and safety of the 5%lidocaine patch have been previously demonstrated in various studies for pain management involving postherpetic neuralgia, osteoarthritis, low-back pain, myofascial pain syndrome, and diabetic polyneuropathy. The present study showed that the addition of 5%lidocaine patches between therapeutic ultrasound sessions in patients with plantar fascia tendinopathy reduces the pain and enhances the functionality and quality of life.

Conflict of Interest

The authors declare that there are no conflicts of interest.

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