



Electromagnetic Transduction Therapy in Patients with Chronic Aseptic Osteitis Pubis

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Abstract

Objective: Chronic aseptic osteitis pubis is a common cause for groin pain in athletes and is associated with uni or bilateral inguinal pain. MRI images document bony stress of the pubis, however the pathophysiological mechanism has not been clarified. Therapy is difficult and often frustrating because of insufficient specific treatment options. More recently, Electromagnetic Transduction Therapy (EMTT) has been utilized in musculoskeletal disorders but to date, its effects in osteitis pubis have not been determined.

Design/Methods: After at least 2 months of unsuccessful conservative therapy nine sport active patients with chronic aseptic osteitis pubis were treated with 4 sessions of EMTT (15 minutes at 80mT with an impulse frequency of 2.5 Hz). Visual Analogue Scale (VAS) was tested pre and post intervention as well as 3 months follow-up. Anthropometric data, stages of osteitis pubis and duration of rehabilitation were documented.

Results: Pain (VAS) decreased significantly after EMTT. Patients were able to return to sport and work after treatment without any medication.

Conclusion: EMTT is a novel and effective way in reducing pain in patients with chronic aseptic osteitis pubis.

Keywords: EMTT; Groin Pain; Osteitis Pubis; PEMF

Introduction

Groin pain is a common overuse ailment and due to a multiplicity of causes it can be challenging for orthopedic surgeons. A differential diagnosis to consider is aseptic osteitis pubis, which is more prevalent in sports related diseases [1]. Patients with osteitis pubis usually present with uni or bilateral inguinal pain referring into the adductors, abdominal muscles or directly over the symphysis. Athletes with osteitis pubis often suffer from debilitating symptoms, a slow recovery and have a high recurrence rate [2]. MRI images of the pelvis document bony stress reactions of the symphysis pubis, the surrounding soft tissues, tendons and muscles. However, the pathophysiological mechanism has not been fully identified. It is assumed that osteitis pubis constitutes a biomechanical overloading of the pubic symphysis adjacent

parasympyseal bone and soft tissue. This may explain why common track and field sports like soccer, hockey and rugby as well as overloading (i.e. lifting heavy loads) may provoke osteitis pubis. Other predisposing factors may include injuries, pregnancies, rheumatological pathologies, gynaecological or urological interventions. Osteitis pubis is staged based on level of severity as described by Rodrigues, et al. [3]. Conservative treatments including oral analgesics, physiotherapy, injections and reduction of weight bearing are first line management strategies. Other treatments that have been discussed include bisphosphonates, platelet rich plasma and shock wave therapy [4-6]. Patients often require long periods of rehabilitation with recovery times varying between 2 and 12 months [7]. In 5 -10 % of cases conservative treatments fail and surgical intervention may be indicated [8]. However, surgery is costly, may result in peri- or postoperative complications and longer periods of rehabilitation. Given this, new

treatment alternatives are warranted.

A promising technology for non-invasive treatment of musculoskeletal disorders is Pulsed Electromagnetic Fields (PEMF). PEMF are selected low-frequency electromagnetic fields without ionising or thermal effect [9]. The growing interest in their mechanisms of action leads to numerous in-vitro trials confirming their effectiveness as an agonist of adenosine receptor A2A and A3 under exposure of PEMF, reducing PGE2 and pro-inflammatory cytokine IL-6 and IL-8 and inhibiting factor NF-kB transcription in human chondrocytes, synoviocytes and osteoblasts [10-12]. Several studies have documented the effectiveness of PEMF in stimulating activity and differentiation of specific cell cultures of the musculoskeletal system. PEMF devices have FDA approval to fuse broken bones, reduce tissue and joint pain and support muscle function [13]. Due to inadequate electromagnetic field power and missing dynamic oscillation,

PEMF was enhanced and a new technology based on PEMF called Electromagnetic Transduction Therapy (EMTT) was developed. With EMTT, magnetic field strength between 80 and 150mT and oscillating frequencies of 120Hz of each impulse can be reached. Impulses were emitted by a high-speed generator to build up a voltage of up to 30 kV, which is released in nanoseconds and an impulse release frequency of 3 Hz. The very short duration of each impulse ensures full electrophysical reaction without any temperature increase in the tissue. Currently, the effects of EMTT on osteitis pubis have not been determined in clinical trials. The aim of this study was to analyse the efficiency of EMTT in patients with chronic aseptic osteitis pubis.

Methods

Design

The study was performed as a prospective non-randomised trial between April 2015 and June 2017.

Patients or Participants

Nine patients aged between 22 and 68 years with overuse related aseptic osteitis pubis who participate in moderate sport activity (3 hours per week) such as tennis, volleyball, cycling and running were included in this study. Criteria for diagnosis of osteitis pubis included unilateral or bilateral groin pain, tender

to palpation, positive squeeze test and evidence of bone marrow oedema on MRI scans. All patients in the trial were staged as level 3 to 4 according to Rodriguez, et al. [3]. Patients were required to have undergone at least 2 months of unsuccessful conservative treatment, such as physiotherapy or pharmacological treatments. In the case of pharmacological treatments, oral and/or topical analgesics and non-steroidal anti-inflammatory drugs were tried

Exclusion criteria included infection, tumor of the pelvis or pathological neurological findings. All patients provided written informed consent. The trial was conducted in accordance with the standardized guidelines of good clinical practice from the International Conference on Harmonization.

Procedures

Patients underwent identical EMTT electromagnetic transduction therapy twice a week for two weeks (a total of four sessions). To perform EMTT the Cellactor MT1 device (Storz Medical AG, Tägerwilten, Switzerland) was utilized. Each treatment was performed over 15 minutes at 80mT with an impulse frequency of 2.5 Hz and an electric power of 30 kV as suggested by the German Society for electromagnetic transduction therapy (DIGEMTT). During treatment intervals patients were allowed to take up to 1600mg of Ibuprofen and 2000mg of Metamizol per day if needed. No other therapies were allowed. The primary outcome parameter for assessing the effect of EMTT was groin pain reduction measured by a VAS scale. Subjective rest pain sensation quantified by scoring on the 10-point VAS was documented pre and post intervention as well as at 3 months follow-up. In addition, a patient's return to work duration and sports related activity was documented.

Statistical Analysis

The sample size was based on the model of stochastic superiority within the parametric student t-test or non-parametric Mann-Whitney test. A value of $p < 0.05$ was considered statistically significant.

Results

All participants were treated according to the study protocol whereof all patients reached the 3-month-follow-up. The required number of pulses was achieved in all treatments. A mean age of the included patients was 53 years (± 13.5) (Table 1).

| patient | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|-----------------|----------------|--------------------|----------|----------------|----------------|---------------------|----------------|----------|-----------|
| stage | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3 |
| dominance | right | left | left | left | right | right | both sides | left | right |
| trigger | weight lifting | tennis | soccer | weight lifting | car accident | standing profession | gardening | soccer | badminton |
| sport | cycling | tennis/volley ball | soccer | cycling | Nordic walking | cycling | nordic walking | soccer | badminton |
| time until EMTT | 6 months | 3 months | 4 months | 2 months | 2 years | 1 week | 3 weeks | 8 months | 9 months |

| | | | | | | | | | |
|---------------------------------------|-------|---------|--------|-------|---------|-------|-------|-------|---------|
| return to work (after last session) | 1 day | 1 day | 1 day | 1 day | 1 day | 1 day | 1 day | 1 day | 1 day |
| return to sports (after last session) | 1 day | 2 weeks | 1 week | 1 day | 3 weeks | 1 day | 1 day | 1 day | 2 weeks |

Table 1: Anthropometric data, stages of osteitis pubis, duration of rehabilitation.

A history of 2 to 24 months (mean 12.6) of unsuccessful conservative treatment was reported. A baseline VAS of 7.5 ± 1.0 was recorded on the day of first EMTT treatment (Figure 1).

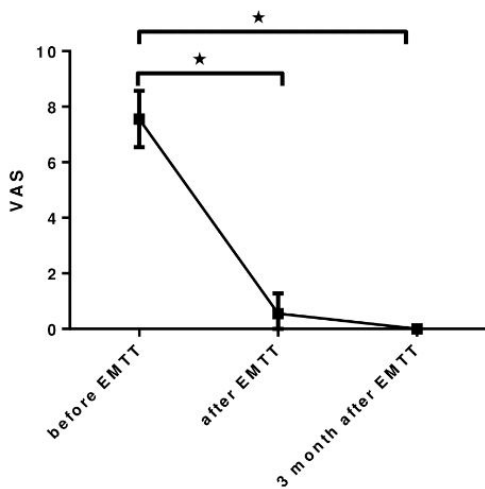


Figure 1: VAS decreased significantly after 2 weeks of EMTT treatment $P < 0.05$.

During the period of EMTT patients were allowed to take preexisting analgesic medication if necessary. At first follow up, directly after last EMTT, the pain score decreased to VAS of $0.5 (\pm 0.72)$ and after 3 months a VAS of 0 for all patients was measured. MRI images before EMTT document an edema of the os pubis, which disappeared in the follow-up examination one week after last EMTT session (Figure 2).

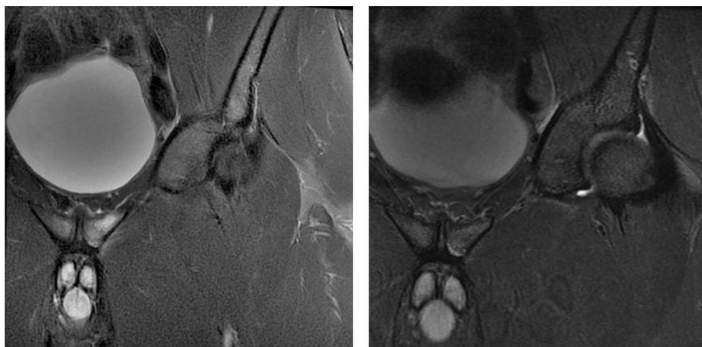


Figure 2: (A) Before the first EMTT session MRI of the pelvis documents intraosseous oedema of the pubis in patient with aseptic osteitis pubis. (B) After last EMTT session the oedema has disappeared.

All patients returned to work after the last EMTT session. Two patients returned to sport activities after one day, one patient

returned after a week, another patient returned after 2 weeks and the final patient returned after 3 weeks.

No clinically significant adverse effects such as erythema, hematoma, neurologic disorders, tendon rupture, infection, or necrosis were observed in any of the patients during the course of the study.

Discussion

Due to long-lasting pain and high recurrence rates, aseptic osteitis pubis is known as a debilitating disease in active people. Currently there are no standardized diagnostic or therapeutic guidelines established [14]. Therapy is difficult and often frustrating because of low specific treatment options. Athletes with groin pain often need to refrain from sport for more than 6 months, which is hardly acceptable in professional athletes. With respect to health economics, patients with aseptic osteitis pubis are unable to work for several weeks. Therefore, it is crucial to establish new effective and non-surgical treatment modalities with minimal side effects. The current trial provides evidence for the efficiency of EMTT in patients with chronic aseptic osteitis pubis for the first time. All patients had constant severe pain for several months and showed significant pain reduction after two weeks of EMTT. In the first 2 weeks after EMTT doses of analgesia could be reduced in all cases and after the last EMTT session, no patient required any analgesia. After a 3 month follow-up all patients were asymptomatic. Even the edema of the bone disappeared after last EMTT intervention. During the last decade the interest in PEMF treatment of musculoskeletal disorders has increased significantly. The benefits of PEMF have been shown for lateral epicondylitis pain [15], rotator cuff tendinopathy [16], particularly in fracture healing based on stimulating cell proliferation and induce osteoblastogenesis and the differentiation of osteoblasts [17]. Overuse of the osteitis pubis caused by the attached ventromedial muscular-tendinous string with the abdominal and adductor muscles may result in repetitive microtrauma. PEMF may stimulate bone healing in osteitis pubis.

Several studies have demonstrated the anti-inflammatory effect of PEMF exposure in human synoviocytes, chondrocytes, and osteoblasts with a significant reduction in the most relevant pro-inflammatory cytokines (interleukin-6 and interleukin-8), tumor necrosis factor-alpha [12,18,19]. In addition, neovascularogenesis, release of growth factors and improvement of blood supply are affected by electromagnetic impulses. These effects of proangiogenesis and increased tissue regeneration of PEMF might be the main reason for pain and disability reduction in our study population. One of the most important physical parameters of PEMF is defined as electromagnetic power measured in Millitesla (mT). PEMF acts via electromagnetic transduction resulting

in engineering a larger treatment area up to 30cm in diameter. Most clinical trials initially failed to prove efficacy, due to less power, inducing significant biological reaction and activate repair mechanism. In the current study we used EMTT with 80mT, to initiate significant clinical effects, which is a promising electromagnetic power [20]. To our knowledge, there are no serious side effects of EMTT and the study did not identify any adverse effects. Considering the aforementioned, EMTT therapy is safe and easily applicable. Although a small cohort of patients was included in this trial, we could demonstrate significant reduction in pain levels, even amongst patients with chronic pain. Another limiting aspect of the trial was the short follow-up time. However, this was a

pragmatic trial: it is unlikely that, in clinical practice, patients would accept to be monitored for two years following treatment if they were no longer symptomatic. Our study was created as a feasibility trial to analyze EMTT as a possible option for cases, which are resistant to common therapies. Further placebo-controlled and randomized studies will strengthen the evidence for the effectiveness of EMTT in treatment of chronic aseptic osteitis pubis. They have to be designed the way that sports specific effects and the effect of different level of activities will be analyzed to give specific recommendations to treat chronic osteitis more efficient. To conclude it can be said, that EMTT is an effective way in reduce pain in patients with chronic aseptic osteitis pubis.

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