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Electromagnetic transduction therapy in non-specific low back pain: A prospective randomised controlled trial



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ABSTRACT

Objectives: A prospective randomised controlled trial to investigate the efficacy of electromagnetic transduction therapy (EMTT) for treatment of patients with non-specific low back pain. *Design:* Two groups with non-specific low back pain were either treated with conventional therapy alone

over 6 weeks or in combination with 8 sessions of EMTT.

Results: In both intervention groups the low back pain related pain and the degree of disability decreased significantly at follow-up visits. Combination of EMTT and conventional therapy proved significant superior to conventional therapy alone.

Conclusion: EMTT is a promising treatment in patients with non-specific low back pain.

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1. Introduction

Low back pain (LBP) is the most common ailment of musculoskeletal system among working age adults. It is affecting about 80% of the population at least once at some point in life.^{1,2} It is not only recognized as a significant medical disease problem, but also regarded as major cause for work absences in industrialised societies. Both results in huge costs for national economics and health care systems because of long lasting and cost intensive treatment options especially in chronic cases. These treatments in chronic cases include non-invasive as well as invasive or minimally invasive modalities, which are associated with high risks of adverse effects and increased morbidity.

The classification of low back pain is complicated by the varying presentation and complex nature of pain. The European evidencebased guidelines on behalf of the COST B13 working group have defined low back pain as discomfort and pain, localized below the costal margin and above the inferior gluteal with or without leg

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pain. The most common diffuse pain without radiating beyond the buttocks is classified as nonspecific low back pain.³ Pain that radiates down the leg and changes in severity in response to specific maneuvers is defined as radicular pain. The third category of this diagnostic triage is of spinal origin and is called serious spinal pathology. Red flags such as violent trauma, fever, a history of malignant tumor or structural deformity indicate further clinical diagnostics.³ Low back pain is also distinguished by duration in acute (less than 6 weeks), sub-acute (6–12 weeks) and chronic (12 weeks or more) pain, which has gained international acceptance.

The initial treatment for acute nonspecific low back pain is typically conservative, including non-opioid analgesics, physiotherapy, thermotherapy and if necessary short course of muscle relaxants. Moon et al. showed a significant reduction of low back pain by lumbar stabilisation and dynamic strengthening exercise.⁴ To stay as active as possible and to return early to normal activities, including work seems to be the best treatment option. Further conservative methods for treating nonspecific low back pain are for example traction treatment, manual therapy and transcutaneous electrical nerve stimulation (TENS). Back school is related to treatment of subacute low back pain or secondary prevention of chronic low back pain. In addition, minimal invasive treatment methods, such as selective nerve root blocks and epidural injection up to surgery interventions may be used, if no response to conservative methods is seen. Invasive options normally start with

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minimal invasive techniques. Excellent evidence was shown by percutaneous lysis of adhesions in chronic radiculopathy.^{5,6}

A promising technology for non-invasive treatment of musculoskeletal disorders are pulsed electromagnetic fields (PEMF). PEMF are selected low-frequency electromagnetic fields without ionizing or thermal effect.⁷ In 1979, the Food and Drug Administration (FDA) approved PEMF as effective and safe for the treatment of bone fractures and nonunions.⁸ The growing interest in their mechanisms of action leads to numerous in vitro trials confirming their effectiveness in up-regulating anti-inflammatory adenosine receptor A_{2A} 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 and osteoblasts.9 Furthermore PEMF increased proliferation and enhanced osteogenic differentiation of mesenchymal stem cells (MSCs) isolated from human bone in several in vitro studies.^{10,11} These results confirmed the effectiveness of pulsed electromagnetic fields in stimulating activity and differentiation of specific cell cultures of the musculoskeletal system. PEMF devices are approved by the FDA to fuse broken bones, reduce tissue and joint pain and support muscle function. However most controlled randomized clinical trials failed to show significant effects and the interest for PEMF waned within the last 2 decades. Presumed reasons therefore are inadequate electromagnetic field power and missing dynamic oscillating. Electromagnetic transduction therapy (EMTT) is a promising new technology of treatment based on PEMF with magnetic field strength between 80 and 150 mT and oscillating frequencies of 120 Hz of each impulse. EMTT acts via electromagnetic transduction. This treatment is also classified as a soft tissue engineering therapy. Impulses are emitted by a highspeed generator to build up a voltage 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.

So far, a clinical study of EMTT combined with conventional non-invasive treatment modalities on low back pain has not been performed. The aim of this randomized controlled trial was to investigate if EMTT has a significant effect on non-specific low back pain if applied as an adjunct to standardized non-invasive care.

2. Methods

The study was implemented between February 2016 and August 2016. Participants with non-specific low back pain were randomly assigned to receive either conventional non-invasive treatment with physiotherapy and analgesic drugs (k-group; n = 44) or a combination of conventional non-invasive treatment plus EMTT (EMTT-group; n = 44) for 6 weeks (Table 1). Because of surgery intervention one participant was excluded from k-group during the trial. The allocation was done in a blinded manner concealed in permuted blocks of four to eight with the use of a computer-generated random list. Concealment of randomization was guaranteed by non-transparent envelopes. The trial was in accordance with the standardized guidelines of good clinical practice from the International Conference on Harmonization.

The study was registered in the German Clinical Trial register (DRK S 00011648) and approved by the local ethical committee. No X-ray or ultrasound guidance was necessary. All patients provided written informed consent. Inclusion and exclusion criteria are listed in Table 2. Physiotherapy included core stabilisation, isometric strengthening and physical therapy such as heat plus non-opiate analgesics (Ibuprofen $2 \times 800 \text{ mg/d}$ and Metamizol $4 \times 500 \text{ mg/d}$ over 6 weeks) according to the low back pain treatment recommendations. Patients in the EMTT group received identical non-invasive intervention during the 6 weeks. In addition, EMTT was applied twice per week with a total of 8 sessions with the Cellactor MT1 device (Storz Medical AG, Tägerwilen, Switzerland). Each treatment was done over 20 min at 80mT with an impulse frequency of 3 Hz and an electric power of

Table 1

Flow chart of a the randomized controlled trial in accordance to the CONSORT Statement.



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