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Is transcutaneous electrical nerve stimulation (TENS) effective in adults with fibromyalgia? A Cochrane Review summary with commentary

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The aim of this commentary is to discuss from a rehabilitation perspective the published Cochrane Review "Transcutaneous electrical nerve stimulation (TENS) for fibromyalgia in adults" by Johnson MI, Claydon LS, Herbison GP, Jones G, Paley CA[1], from the Cochrane Pain, Palliative and Supportive Care Review Group. This Cochrane Corner is produced in agreement with the *Journal of Musculoskeletal and Neuronal Interactions (JMNI) by Cochrane Rehabilitation*.

Background

Fibromyalgia is a complex illness to diagnose and treat with a prevalence from 2% to 5% of the population. These differing estimates may reflect differences in study populations, study designs, and measurements[2]. The diagnostic criteria for fibromyalgia were originally published in 1990 and emphasized chronic widespread pain with a number of tender points. New diagnostic criteria published in 2010 are entirely symptom based and do not require counts of the number of tender points and declare a female:male ratio of 3:1, similar to other chronic pain conditions. Fibromyalgia can develop at any age and its prevalence is similar in different countries, cultures, and ethnic groups[3]. Fibromyalgia may be defined as a long-term medical condition that is characterized by chronic widespread pain in the muscles and joints, with sensitivity to pressure stimuli. The symptoms of pain and tenderness are common, and it is difficult to identify the difference between individuals with isolated symptoms and someone with a pain-inducing illness. Pain may be described as aching, burning, stabbing, or sharp and may be accompanied by hyperalgesia and allodynia. Pain is often continuous, but it may change in severity depending on various factors including stress, physical activity, and the weather[4].

There are no definitive treatments for fibromyalgia. Pain is difficult to treat effectively, with only a minority of people experiencing a clinically relevant benefit from any one intervention. A multidisciplinary approach is now advocated, with pharmacological interventions being combined with physical or cognitive interventions, or both.

Education, cognitive behavioral therapy, and exercise are the most frequent nonpharmacological therapies studied[5].

Transcutaneous electrical nerve stimulation (TENS), a

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nonpharmacological treatment, is the delivery of pulsed electrical currents across the intact surface of the skin to stimulate peripheral nerves, principally for pain relief. The purpose of TENS is to stimulate low-threshold cutaneous afferents to inhibit onward transmission of nociceptive information in the spinal cord and brainstem and relieve pain[6].

The significant question addressed in this review is whether TENS may reduce the intensity of pain in adults with fibromyalgia and it is of great importance for rehabilitation professionals in the treatment of this clinical condition during their daily clinical practice.

Transcutaneous electrical nerve stimulation (TENS) for fibromyalgia in adults

(Johnson MI, Claydon LS, Herbison GP, Jones G, Paley CA, 2017)

What is the aim of this Cochrane Review?

The aim of this Cochrane Review was to assess the analgesic efficacy and adverse events of TENS alone, or in combination with other treatments, compared with placebo TENS; no treatment; exercise alone; or other treatments including medication, electroacupuncture, warmth therapy, or hydrotherapy, for fibromyalgia in adults.

What was studied in the Cochrane Review?

The population addressed in this review was adults with pain due to fibromyalgia diagnosed using either the 2010 Wolfe or earlier (1990) criteria in the case of older studies. The interventions studied were TENS alone or in combination with other treatments. The comparators were placebo TENS (e.g. sham (no current) TENS device); no treatment or waiting list control; usual care (including exercise); other treatment. The outcomes studied as primary were participant-reported pain relief of 30% or greater, compared with baseline; participant-reported pain relief of 50% or greater, compared with baseline; Patient Global Impression of Change scale (PGIC) much or very much improved; PGIC very much improved. As secondary outcomes: any pain-related outcome indicating some improvement; any participant-reported change in health-related quality of life, including activities of daily living and fatigue, using any validated tool; withdrawals due to lack of efficacy, adverse events, and for any cause; participants who experienced any adverse event or serious adverse event.

Search methodology and up-to-dateness of the Cochrane Review?

The review authors searched for studies that had been published up to date on the following databases: CENTRAL (CRSO); MEDLINE (Ovid); Embase (Ovid); CINAHL (EBSCO); PsycINFO (Ovid); LILACS; PEDRO; Web of Science (ISI); AMED (Ovid); and SPORTDiscus (EBSCO). There were no language restrictions.

What are the main results of the Cochrane review?

The review included eight studies (seven RCTs and one quasi-RCT) with a total of 315 adult participants (299 women) and showed that:

- *TENS vs placebo TENS* showed no data for primary outcomes of participants-reported pain relief of 30% or greater or 50% or greater or PGIC outcomes and the quality of evidence was very low. One of the studies found that a single 30-minute treatment of TENS induced a reduction in movement-related pain intensity (with no evidence between TENS and placebo for pain at rest) and in fatigue and increased pressure pain thresholds in comparison to placebo TENS. Another study reported that mean pain intensity (± standard deviation) as measured using 100-mm VAS decreased from 85 (± 20) mm at baseline to 43 (± 20) mm after one week of dual-site TENS, decreased from 85 (± 10) mm at baseline to 60 (± 10) mm after single-site TENS, and decreased from 82 (± 20) mm at baseline to 80 (± 20) mm after one week of placebo TENS. The 2 RCTs evaluated withdrawals due to adverse events, but just one study reported the reasons of withdrawal from the TENS group due to absence of symptom relief. The quality of evidence was very low and downgraded by 3 levels due to small number of studies, participants and events.
- *TENS vs no treatment* showed no data for primary outcomes of participants-reported pain relief of 30% or greater or 50% or greater or PGIC outcomes and the quality of evidence was very low. Dailey 2013 reported 2 withdrawals after the no-TENS intervention without reasons. The quality of evidence was very low and downgraded by 3 levels due to small number of studies, participants, and events.
- *TENS with exercise vs exercise alone* reported in two studies (28 participants) that 30% of participants achieved 30% or greater reduction in pain with TENS and exercise compared with 13% with exercise alone. Carbonario 2013 reported clinically important improvements in subscales of Fibromyalgia Impact Questionnaire (FIQ) for stiffness, fatigue, anxiety, depression, and work performance, for TENS with exercise compared with exercise alone. This study also reported 2 withdrawals and 2 dropouts in equal numbers from each group with no reasons. Mutlu 2013 reported no additional improvements in FIQ scores or SF-36 when TENS was added to an exercise program and reported 3 withdrawals from the exercise alone group and 3 withdrawals from the exercise with TENS groups. But the quality of evidence was very low and downgraded by 3 levels due to small number of studies, participants and events.
- *TENS vs another treatment* comparison was reported in four studies. Lofgren 2009 reported that 10/28 participants achieved a decrease in pain severity of 25% in TENS group, and 10/24 participants receiving superficial warmth (42°C), but with no evidence between groups. This study also reported that 2 participants reported increased pain during TENS. The quality of evidence was very low and was downgraded by 3 levels due to small number of studies, participants, and events.

- One study reported SAEs and found three participants experienced minor discomfort with TENS, and the rest of the studies did not measure or report AEs or SAEs.

How did the authors conclude on the evidence?

The authors concluded that it was not possible to support or refute the use of TENS for fibromyalgia because available evidence was of very low quality and there was only a small number of inadequately powered studies with incomplete reporting of methodologies and treatment interventions.

What are the implications of the Cochrane evidence for practice in rehabilitation?

This Cochrane Review aimed to evaluate the analgesic efficacy and adverse events of TENS alone or added to usual care (including exercise), compared with placebo (sham) TENS; no treatment; exercise alone; or other treatments including medication, electroacupuncture, warmth therapy, or hydrotherapy, for fibromyalgia in adults.

The quality of the available evidence was low to very low due to the small number of studies, participants and events, and serious study limitations, and so this did not allow the authors to draw any conclusions.

There were seven studies that reported the analgesic effect of TENS on pain in fibromyalgia, but the findings were inconsistently reported and most included studies did not measure the outcomes investigated by this Cochrane Review.

From rehabilitation perspective, the fibromyalgia is one of the most important chronic health condition with important effects on functioning and quality of life. The results of this review showed that there is uncertainty of evidence on the use of TENS as non-phamracological intervention on pain relief in adults with fibromyalgia. This means that we may not suggest or exclude the use of TENS in this clinical conditions in rehabilitation setting. Therefore, it is very important for rehabilitation professionals to improve the quality of evidence in rehabilitation research[7]. Further studies are necessary and should consider randomized-controlled clinical trials with larger sample size and catamnesis.

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References

1 Johnson MI, Claydon LS, Herbison GP, Jones G, Paley CA. Transcutaneous electrical nerve stimulation (TENS) for fibromyalgia in adults. Cochrane Database Syst Rev 2017; 10:CD012172. doi: 10.1002/14651858.CD012172.pub2.

2 Vincent A, Lahr BD,Wolfe F, et al. Prevalence of fibromyalgia: a population-based study in Olmsted County, Minnesota, utilizing the Rochester Epidemiology Project. Arthritis Care Res (Hoboken) 2013;65(5):786-792.

3 Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Katz RS, Mease P, Russell AS, Russell IJ, Winfield JB, Yunus MB. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. Arthritis Care Res (Hoboken) 2010;62:600-610.

4 Clauw DJ. Fibromyalgia: a clinical review. JAMA 2014; 311(15):1547-55.

5 Fitzcharles MA, Ste-Marie PA, Goldenberg DL, et al. Canadian Pain Society and Canadian Rheumatology Association recommendations for rational care of persons with fibromyalgia: a summary report. J Rheumatol 2013;40(8):1388-1393.

6 Coutaux A. Non-pharmacological treatments for pain relief: TENS and acupuncture. Joint Bone Spine 2017; 84(6):657-661.

7 Negrini S, Arienti C, Pollet J, Engkasan JP, Francisco GE, Frontera WR, Galeri S, Gworys K, Kujawa J, Mazlan M, Rathore FA, Schillebeeckx F, Kiekens C; REREP study participants; IRCCS Don Gnocchi Foundation. Clinical replicability of rehabilitation interventions in Randomized Controlled Trials reported in main journals is inadequate. J Clin Epidemiol 2019 Jun 17. pii: S0895-4356(19)30315-4. doi: 10.1016/j.jclinepi.2019.06.008. [Epub ahead of print]