Research

Effects of Transcutaneous Electrical Nerve Stimulation in Patients with Fibromyalgia Syndrome – Literature Review

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Abstract:
Introduction: Fibromyalgia is a chronic disorder characterized by diffuse musculoskeletal pain, fatigue, depression and cognitive impairment. The aim of treatment is to alleviate symptoms, maintain physical function and improve quality of life. One of the recommended methods of a non-pharmacological approach is transcutaneous electrical nerve stimulation (TENS). The aim of the literature review was to determine the effects of TENS in fibromyalgia patients, focusing on the assessment of changes in pain intensity in relation to the minimal clinically important difference.
Methods: The literature search was conducted until the end of 2024 in the following databases PubMed, CINAHL and PEDro.
Results: Twelve studies were included in the review. Three studies looked at the immediate effects of TENS on pain and nine studies looked at the longer-term effects. The duration of the individual therapies ranged from 20 to 120 minutes, the stimulation frequency from 0.5 to 320 Hz and the intensity from pleasant to very strong but tolerable stimulation. Pain was assessed using a visual analogue scale and a numerical rating scale. **Discussion and conclusion**: The results indicate that TENS therapy is more effective when applied with sufficient intensity over multiple sessions rather than as a single treatment. While a one-time application may provide temporary pain relief, repeated treatments show more clinically significant effects. People with higher pain sensitivity tend to respond better to TENS. This therapy remains a promising non-pharmacological option for pain management in fibromyalgia, however, caution is needed in generalizing the results as the research has predominantly studied women.

Keywords: TENS; pain; clinically important difference; MCID

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1. Introduction

Fibromyalgia is a chronic condition or syndrome characterized mainly by widespread musculo-skeletal pain. At the same time, systemic symptoms such as fatigue, sleep disturbances, morning stiffness, depression, anxiety, and cognitive impairments (e.g. forgetfulness, difficulties with concentration, attention, and memory) may occur (Clauw, 2009; Wolfe et al., 2010). The etiology is unknown, but there are some theories that descending pain inhibition and enhanced excitability of the central nervous system may change the processing of stimuli resulting in increased pain perception (Amer-Cuenca et al., 2023). This is why patients can experience diffuse hyperalgesia (increased sensitivity to painful stimuli), and allodynia (feeling pain in response to non-painful stimuli) can also be present (Clauw, 2009). The prevalence of fibromyalgia is between 0,2 % and 4,7 % in general population and predominantly affects women (female-male ratio of 3:1) (Amer-Cuenca et al., 2023; García-López et al., 2024).

Because pain is the main disabling symptom and the etiology is unknown the goals of treatment are symptom relief, maintaining function and improving quality of life (García-López et al., 2024; Macfarlane et al., 2017). The European League Against Rheumatism (EULAR) published revised recommendations for the treatment of fibromyalgia syndrome in 2016. They recommend an emphasis on starting treatments with non-pharmacological approaches, with active patient participation in self-management of the condition (Macfarlane et al., 2017).

A potential non-pharmacological pain control treatment is Transcutaneous Electrical Nerve Stimulation (TENS) frequently used to relieve acute and chronic pain. The device delivers alternating electrical current through electrodes placed on the skin (Vance et al., 2014; Amer-Cuenca et al., 2023). There are two main types of TENS used. High-frequency TENS, with a frequency of 50–200 Hz, is applied at a low intensity (below the motor threshold). Low-frequency TENS, with a frequency of 2–10 Hz, is applied at a higher intensity (above the motor threshold). A combination of these two is also used (Casale et al., 2012).

Systematic reviews on the effectiveness of TENS for fibromyalgia syndrome have shown mixed results. Two systematic reviews (Johnson et al., 2017; Salazar et al., 2017), one with a meta-analysis (Salazar et al., 2017), could not make specific conclusions due to the lack of high-quality studies. However, more recent systematic reviews with meta-analysis have shown promising results (Amer-Cuenca et al., 2023; Batista de Aguiar et al., 2022; García-López et al., 2024). The most recent review, which included the largest number of clinical trials, found that TENS is effective in reducing pain and disability and improving physical quality of life in patients with FM. When compared to placebo and control, TENS was more effective, but it was not more effective than therapeutic exercise (García-López et al., 2024).

One of the systematic reviews and meta-analysis discussed the TENS parameters (Amer-Cuenca et al., 2023). The recommended or appropriate parameters of TENS are considered as: high frequency (greater than 10 Hz and up to 200 Hz) or mixed frequency (switching between low and high frequency), with intensity set to produce a strong but comfortable sensation, or ideally the highest tolerable non-painful level. A minimum of 10 treatment sessions should be applied over the painful area. This approach led to a significant reduction in pain compared to other parameter combinations (Amer-Cuenca et al., 2023).

When evaluating outcome measures it is important to consider not only statistical significance, but also clinical importance of the change in scores. MCID is a minimal clinically important difference. That is the smallest level of change in a scale associated with a meaningful improvement in a patient. It is unique to each scale or questionnaire etc. and is important for interpretation of the results (Mease et al., 2011).

Pain intensity is most evaluated using the Visual Analogue Scale (VAS) or the Numerical Rating Scale (NRS). Both scales assess pain on a range from 0, indicating no pain, to 10, describing the worst pain imaginable (Ferreira-Valente & Pais-Ribeiro, 2011). On average, a reduction of one point or 15.0% on the NRS was found to represent the MCID for patients with chronic musculoskeletal pain. However, a reduction of 2 units or 33.0% was most strongly associated with the concept of "much better" improvement (Salaffi et al., 2004). The most used criteria for MCID in chronic pain, as established by Farrar and colleagues (2001) (who also included fibromyalgia patients), showed that a change of approximately 1.8 points or 28% in pain severity in NRS was most strongly associated with clinically important improvement. Similarly, Arnold and colleagues (2012) proposed that responder

definition in patients with fibromyalgia requires ≥ 30 % reduction in pain and a ≥ 10 % improvement in physical function.
The purpose of this systematic review was to evaluate the effectiveness of TENS in patients with fibromyalgia, with a specific focus on assessing pain intensity changes in relation to the MCID.

2. Methods

Literature review has been conducted until the end of the year 2024 in databases: PubMed, CINAHL and PEDro with keywords: transcutaneous electrical nerve stimulation OR TENS and fibromyalgia.
Studies in English language that investigated the effects of TENS in patients with fibromyalgia and reported pain intensity measured by VAS or NRS were included. Reviews and studies that investigated combined effects with other physical modalities were excluded. The search method for articles is presented in more detail in **Figure 1**.

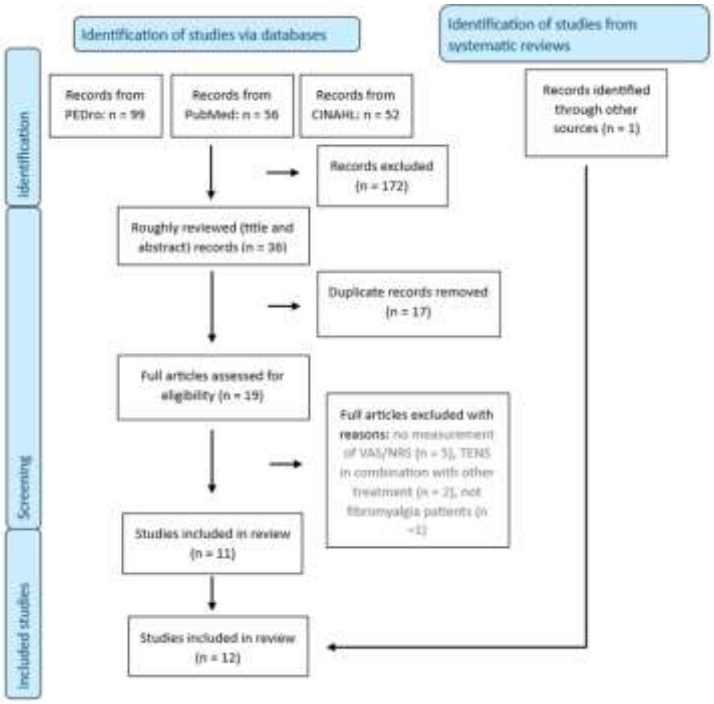

Figure 1. PRISMA diagram of the process of searching and collecting articles (Moher et al., 2009)

3. Results

A total of 12 articles were included in the review (Carbonario et al., 2013; Castro-Sánchez et al., 2020; Dailey et al., 2013; Dailey et al., 2020; Dailey et al., 2022; Di Benedetto et al., 1993; Jamison et al., 2021; Lauretti et al., 2013; Löfgren & Norrbrink, 2009; Riachi et al., 2023; Sunshine et al., 1996; Yüksel et al., 2019). In two studies they used a cross-over study design (Dailey et al., 2013; Löfgren & Norrbrink, 2009). Overall, there were 1022 (955 women, 26 men and 42 not specified) participants. Out of those, 457 (425 women, 11 men and 21 not specified) participants had active TENS treatment. Detailed study protocols, general results and quality of studies are reported in **Table 1**.
In three studies (Dailey et al., 2013; Riachi et al., 2023; Yüksel et al., 2019) they only applied TENS therapy for one session and looked for immediate effects of TENS on intensity of pain. Parameters of TENS treatment and results of the in-group change of pain intensity are reported in **Table 2** in greater detail.

In nine studies (Carbonario et al., 2013; Castro-Sánchez et al., 2020; Dailey et al., 2020; Dailey et al., 2022; Di Benedetto et al., 1993; Jamison et al., 2021; Lauretti et al., 2013; Löfgren & Norrbrink, 2009; Sunshine et al., 1996) they applied TENS for several sessions. Carbonario and colleagues (2013) investigated effects of TENS when applied during exercise. **Table 3** provides a detailed overview of the TENS treatment parameters and the in-group changes in pain intensity.

Table 1. Study characteristics and general results from studies

Author, year	Groups	Sample (gender. age)	General results	PEDro
Riachi et al., 2023	G: TENS (suit)	50 W (53.33 ± 7.08)	↓ pain ($p < 0.001$) immediately after treatment and 24 hours later	/
Dailey et al., 2013 *crossover	G1: TENS G2: PB-TENS G3: N-TENS	42 W, 1 M (49.2 ± 12.0)	No withih group results reported ↓ pain ($p < 0.05$) in G1 compared to G2 and G3 for MEP, but not for PAR	9/10
Dailey et al., 2020	G1: TENS G2: PB-TENS G3: N-TENS	76 W (44.7 ± 14.3) 68 W (47.2 ± 12.6) 94 W (48.6 ± 11.8)	↓ pain ($p < 0.05$) in G1 ↓ pain ($p < 0.05$) in G1 compared to G2 and G3 for MEP and PAR	8/10
Dailey et al., 2022	G1: TENS G2: PB-TENS G3: N-TENS	103 W 99 W 99 W SG-O 52^{Me} (45 – 58) SG-NO 47^{Me} (35 – 56)	↓ pain ($p < 0.05$) in G1; regardless of the subgroup (SG-O or SG-NO)	8/10
Jamison et al., 2021	G1: TENS G2: PB-TENS	58 W, 4 M (52.3 ± 13.8) 53 W, 4 M (38.3 ± 13.1)	↓ pain ($p < 0.029$) in G1 compared to G2	6/10
Lauretti et al., 2013	G1: 2 TENS G2: 1 TENS, 1 PB-TENS G3: 2 PB-TENS	13 W (30 ± 12) 12 W, 1 M (32 ± 8) 9 W, 1 M (35 ± 8)	↓ pain ($p < 0.05$) within G1 and G2 No between group comparison	5/10
Sunshine et al., 1996	G1: massage G2: TENS G3: PB-TENS	10 W 10 W 10 W (49.8)	No change in pain ($p > 0.05$) in G2 No between group comparison.	2/10
Castro-Sánchez et al., 2020	G1: dry needling G2: TENS	28 W, 9 M (49.35 ± 5.82) 32 W, 5 M (47.84 ± 8.12)	↓ pain ($p < 0.05$) within G2 ↓ pain ($p < 0.05$) in G1 compared to G2	8/10
Di Benedetto et al., 1993	G1: pharmacotherapy G2: TENS	14 W, 1 M 15 W (51 ± 9.5)	No change in pain ($p > 0.05$) in G2 No between group comparison	4/10
Löfgren, Norrbrink, 2009 *crossover	G1: thermopack G2: TENS	32 W (41.5 ± 8.3)	↓ pain ($p < 0.05$) within G2 No between group comparison	6/10
Yüksel et al., 2019	G1: TENS G2: acupuncture G3: healthy control	21 (38.1 ± 11.3) 21 (44.6 ± 10.34) 21 (30.2 ± 6.5)	↓ pain ($p < 0,001$) within G1 No between group comparison	6/10
Carbonario et al., 2013	G1: exercise + TENS G2: exercise	14 W (52.9 ± 5.9) 14 W (51.9 ± 9)	↓ pain ($p < 0,001$) within G1	4/10

G – group, MEP – movement evoked pain, N-TENS – no TENS (control), PAR – pain at rest, PB-TENS – placebo TENS, SG-O – subgroup regularly taking opioids, SG-NO – subgroup not taking opioids regularly, ↓ - reduction

Table 2. Parameters of TENS and results of studies with only 1 treatment session

Authors, year	Characteristics of TENS treatment				Results			
	Parameters	Area	Duration	Frequency			Before	After
Riachi et al., 2023	20 Hz; 25 – 170 μs 2mA	20 pairs of muscles	1 hour	1 session	VAS	immediately	6.20 ± 1.73 cm	2.36 ± 1.44 cm
						24 hours later	6.20 ± 1.73 cm	4.7 ± 1.97 cm
Dailey et al., 2013 *crossover	100 Hz; 200 μs max. tolerable	C7–T1 or L5–S1	60–75 minutes	1 session	VAS	30 minutes	PAR: 5.0 ± 0.5 cm	Δ = – 0.38 ± 0.26 cm
							MEP: 5.4 ±0.4 cm	4.0 ± 0.4 cm Δ = - 1.1± 0.26 (6MWT)
Yüksel et al., 2019	70 Hz; 100 ms comfortable	T2–T7	20 minutes	1 session	VAS	immediately	5.19 ± 2.20 cm	2.86 ± 2.01 cm

MEP – movement-evoked pain, NRS – numerical rating scale, PAR – pain at rest, VAS – visual analog scale, 6MWT – 6-minute walking test, Δ – change (after – before)

Table 3. Parameters of TENS and results of studies with several treatment sessions

Author. year	Characteristics of TENS treatment				Results		
	Parameters	Area	Duration	Frequency		Before	After
Sunshine et al.. 1996	0.5 – 320 Hz	over painful areas	30 minutes	5 weeks. 2x/week (10 sessions)	VAS	7.5 cm	7.3 cm
Castro-Sánchez et al.. 2020	100 Hz; 200 μs tolerable	active and latent trigger points (5 muscles)	50 minutes (10 minute for each muscle pair)	6 weeks. 1x/week (6 sessions)	VAS		Δ = – 1.86 cm
Lauretti et al.. 2013	2 Hz and 100 Hz; 200 μs 60 mA	C7–T1 and L5	20 minutes	1 week. 2x/day. every day (14 sessions)	VAS	G1: 8.5 ± 2	4.3 ± 2 (Δ ~ 4 cm)
						G2: 8.5 ± 1 cm	6 ± 1 cm (Δ ~ 2.5 cm)
Löfgren & Norrbrink. 2009 *crossover	80 Hz strong but comfortable	painful area	at least 30 minutes	3 weeks. every day (21 sessions)	NRS	8.0 (IQR 6.0; 9.0)	6.3 (IQR 4.3; 7.3) 36 % responders
Jamison et al.. 2021	60 – 100 Hz; 290 μs strong but comfrotable	upper part of calf	60 minutes	3 weeks. at least 2x/day (average 68.9 sessions)	NRS		Δ = – 1.83 ± 0.19 ≥30 % pain reduction: 28.4 % – 52.1 %; ≥50 % pain reduction: 12.6 % – 37.6 %
Dailey et al.. 2020	2–125 Hz; 200 μs max. tolerable	C7–T1 and lower back	at least 2 hours each day	4 weeks. every day (28 sessions)	NRS		PAR: Δ = – 1.9 MEP: Δ = – 1.8 (6MWT); Δ = – 1.6 (5STS) 44 % responders
Dailey et al.. 2022	2 – 125 Hz; 200 μs max. tolerable	C7–T1 and lower back	at least 2 hours every day (30 minutes per session)	4 weeks. every day (atleast 28 sessions)	NRS	(SG-O)	RAP: Δ = – 1.6 MEP: Δ = – 1.7 (6MWT); Δ = – 2.0 (5STS)
						(SG-NO)	RAP: Δ = – 2.0 MEP: Δ = – 1.9 (6MWT); Δ = – 1.5 (5STS)
Di Benedetto et al.. 1993	80 – 100 Hz; 70 μs pleasant	4 painful points	80 minutes (20 minutes per point)	6 weeks. 5x/week (30 sessions)	VAS	5.6 cm ⊗	2 weeks: 4.8 cm ⊗ 4 weeks: 5.0 cm ⊗ 6 weeks: 4.6 cm ⊗
Carbonario et al., 2013	150 Hz; 150 μs strong but comfortable	m. trapezius and m. supraspinatus	30 minutes during exercise	8 weeks, 2x/week (16 sessions)	VAS		Δ = – 2,0 ± 2,9 cm 30 % clinical gain

MEP – movement-evoked pain, NRS – Numerical Rating Scale, PAR – pain at rest, SG-NO – subgroup not taking opioids regularly, SG-O – subgroup regularly taking opioids, VAS – Visual Analog Scale, ⊗ - score extracted from the graph, 5STS - Five Times Sit-to-Stand test, 6MWT – 6-Minute Walking test, Δ – chang

4. Discussion

The current studies done in research of effects of TENS offer important insights for potential pain management in patients with fibromyalgia but also reveal several important limitations. In studies where they used only a one-session treatment using electrodes paravertebrally Dailey and colleagues (2013) and Yüksel and colleagues (2019) did report statistically significant pain reduction with-in group with active TENS. Interestingly movement evoked pain (MEP) showed improvement for more than 1 point on VAS, but with that not reaching completely the MCID, whereas paint at rest (PAR) didn't reach the statistical significance (Dailey et al., 2013). On the other hand, Yüksel and colleagues (2019) reported change of average pain enough for a clinically significant decrease of pain already in one session. Riachi and colleagues (2023) also showed clinically important improvement in pain reduction using a suit with electrodes that activated 20 pairs of muscles. Their study showed that a one-time treatment with low-frequency TENS with higher intensity resulted in a substantial pain reduction that lasted for up to 24 hours. This is probably because low-frequency TENS stimulate endogenous opioid release (Macedo et al., 2015). Despite these observations we cannot say for certain that one session of TENS treatment would give significant improvements in pain perception.

In contrast, studies with more frequent TENS sessions and appropriate parameters have demonstrated more favorable outcomes. In their study, Castro-Sánchez and colleagues (2020), although limited by an insufficient number of treatment sessions, still reported a statistically and clinically meaningful reduction in pain intensity, in contrast to Sunshine and colleagues (1996) who didn't find any significantly important difference in pain perception, even though experimental group had enough sessions, but lacked sufficient intensity of TENS. This suggests that the intensity of TENS plays a critical role in its efficacy, with low-intensity treatments, such as those only producing a tingling sensation, failing to deliver meaningful pain reduction. There is also important to note that this study is of low quality (Sunshine et al., 1996).

The studies that included the appropriate number of sessions and mostly appropriate parameters of TENS treatment (Carbonario et al., 2013; Dailey et al., 2020; Dailey et al., 2022; Di Benedetto et al., 1993; Jamison et al., 2021; Lauretti et al., 2013; Löfgren, Norrbrink, 2009) as suggested in systematic review and meta-analysis done by Amer-Cuenca and colleagues (2023), all reported a decrease in pain intensity for at least 1 unit or about 15 % improvement. All of them showed statistically important change except for one (Di Benedetto et al., 1993). The same study showed the lowest average change. This is the only study that applied lower intensity (pleasant feeling of TENS) and is also a lower quality study.

Löfgren & Norrbrink (2009) reported that the median score of pain was lower, and they also reported that 36 % of participants were considered responders, meaning they had a pain reduction of at least 2 units). Similarly, Dailey and colleagues (2020) reported that 44 % of people had 30 % less pain. Jamison and colleagues in 2021 also reported the percentage of participants considered to be responders. They found that 28.4 % of participants in the subgroup with lower pain sensitivity and 52.1 % of participants in the subgroup with higher pain sensitivity experienced a moderate reduction in pain severity (more than 30 %). When reporting substantial pain reduction (more than 50 %), 37.6 % of patients in the subgroup with higher pain sensitivity achieved this level of improvement. This suggests that people with a higher baseline pain sensitivity respond better to TENS treatment than those with lower sensitivity. An important study by Dailey and colleagues (2022) investigated the impact of taking oral analgesics on pain reduction when using TENS. According to their study, medication did not influence the outcome, meaning that there was a similar reduction in pain intensity regardless of whether participants regularly took medication or not.

Importantly, the studies conducted by Dailey and colleagues (2013; 2020) further highlight the cumulative effects of TENS treatment over time. While one of their studies found no improvement in pain at rest after a single TENS session (Dailey et al., 2013), their study from 2020 demonstrated a clinically meaningful reduction in pain at rest and movement-evoked pain after four weeks of treatment. The pain reduction was even greater after eight weeks of TENS treatment, illustrating that prolonged TENS use may lead to sustained im-

provements in pain perception. This finding supports the notion that TENS treatment requires a sufficient duration to achieve clinically significant pain reduction, a conclusion also supported by systematic reviews and meta-analysis (Amer-Cuenca et al., 2023).
In this systematic review we see that when TENS is applied with sufficient intensity, there is some research supporting its ability to achieve not only statistically significant but more importantly, clinically meaningful reduction in pain. Generalization of these findings should be avoided due to predominantly female populations included in the referenced studies.
TENS offers a non-pharmacological option for managing chronic pain conditions, empowering patients to actively participate in their treatment. Moreover, as TENS devices are commercially available and not associated with serious side effects, patients can independently use them at home on a regular basis (Dailey et al., 2020; Jamison et al., 2021).

5. Conclusion

This systematic review highlights the potential of TENS as an option for pain management in patients with fibromyalgia. One-time treatments can have some effect on immediate pain relief, but more consistent results for a clinically meaningful reduction in pain intensity are seen when TENS is applied with sufficient intensity over several sessions. Given the promising evidence, further high-quality studies with larger sample size and diverse population (especially including more male participants) are needed to establish long-term efficacy in patients with fibromyalgia.

Conflicts of Interest: The authors declare no conflict of interest.

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