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Is Transcutaneous Electrical Nerve Stimulation (TENS) an Effective Treatment for Pain Caused by Knee Osteoarthritis?

Zuhra Nassery
Philadelphia College of Osteopathic Medicine

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Zuhra Nassery, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not "is TENS an effective treatment for pain caused by knee osteoarthritis?".

Study Design: A systematic review of three randomized controlled trials (RCTs) published between 2012 and 2019.

Data Sources: All RCTs were discovered utilizing PubMed. The articles were published in English in peer-reviewed journals and selected based on applicability and pertinence to the clinical question as well as the incorporation of patient-oriented outcomes.

Outcome Measured: Knee pain was the outcome measured using the Visual Analog Scale (VAS), which requires participants to draw a mark between the ends of a 10 cm-long horizontal line. Scores range from 0 to 10 cm or 100 mm, with 0 indicating no pain and 10 cm or 100 mm the most severe pain. Distance is measured starting from 0 and recorded to the second decimal place. Cherian et al.'s study uses points instead of cm or mm to measure VAS.

Results: In Shimoura et al.'s RCT, the use of TENS led to a reduction in VAS compared to the control group ($P = 0.019$), demonstrated by mean change from baseline of 0.38 cm. In the RCT by Vance et al., the use of TENS led to a reduction in VAS compared to the control group ($P = 0.001$), indicated by mean change from baseline of 14.76 mm. Finally, in Cherian et al.'s study, there was a reduction in VAS compared to the control group ($P = 0.0416$), indicated by mean change from baseline of -0.8823 points.

Conclusion: This systematic review found the evidence regarding the efficacy of TENS for knee OA pain to be conflicting, leaving the answer to this review's objective undetermined. While Shimoura et al. and Vance et al.'s short-term studies suggested that TENS is not an effective treatment for pain due to knee OA, Cherian et al.'s longitudinal study showed a large treatment effect with considerable clinical importance. The nature of these results highlights the need for further studies that account for limitations in previous studies and provide for longer follow-ups to assess the effectiveness of TENS for knee OA pain treatment.

Key Words: Transcutaneous electrical nerve stimulation, pain, knee osteoarthritis.

INTRODUCTION

Knee osteoarthritis (OA) is a common degenerative disorder causing the progressive wear and tear of the knee's joint tissues, articular cartilage, and bone, causing pain, tenderness, and stiffness.[1] The rubbing of bone against bone causes a grating sensation as well as bone spur formation. Knee OA is diagnosed when patients have knee pain and three of the following: age over 50 years; morning stiffness for under 30 minutes; crepitus upon motion; bone tenderness; bony enlargement; and lack of palpable warmth of the synovium.[2] Joint space narrowing and the presence of osteophytes, cysts, and subchondral sclerosis are common findings of knee OA.[2]

With the rising prevalence of knee OA, its treatment has become increasingly crucial. About 27 million Americans have clinical OA and as of 2016, the prevalence rate in adults 65 and older is 33.6%.[3] There are also high costs tied to knee OA, indicating the need for affordable treatment. The sum cost of patients is about $5.7-15 billion per year as of 2017, and average yearly medical costs and outpatient visits per patient are nearly twice those of patients without OA.[1] In one study, in the year before total knee arthroplasty (TKA), over half of outpatient costs associated with knee OA were from injections, prosthetics, prescriptions, and therapy.[4] While there is no exact estimate of healthcare visits available, knee OA patients in one study averaged 13.8 visits per person per year more than those without OA and 28% more hospital stays.[5]

While there is no known cure for OA, there are treatments available intended to reduce symptoms, improve or maintain joint mobility, minimize disability, and manage knee pain.[4] Typical non-surgical treatments for knee OA pain include NSAIDS, opioids, non-opioid analgesics, corticosteroid (CCS) or hyaluronic acid injection, physical therapy (PT), and bracing. At the end of the line, patients may opt for joint replacement surgery. Since pain from knee OA causes decreased function and mobility, in theory, targeting pain with treatment can lead to

improved movement and function.[3] As life expectancy is rising, it has become crucial to extend the period of pain management accordingly before a TKA becomes necessary.

Additional methods of treatment for knee pain, such as transcutaneous electrical nerve stimulation (TENS), should be studied to potentially help patients keep their normal level of function. When inflammation occurs due to OA, chemical mediators are released into the joint and sensitize primary afferent nerves, causing allodynia.[6] TENS works through electrodes placed around the knee that stimulate cutaneous afferent fibers, activating inhibitory interneurons and decreasing pain signal transmission from small-diameter nociceptive receptors.[3] The mechanism of action is based on the Gate Control theory, which proposes that non-painful input from TENS "closes the gates" to painful input, preventing pain sensation from making its way to the CNS.[7] TENS has also been shown to lead to endogenous release of opioids in the CNS, making TENS a potential non-pharmacologic treatment option with a similar effect to some pharmacologic treatments.[3] It is especially crucial that a treatment like TENS be proposed so that there is an alternative to NSAIDs, which are the current mainstay of treatment for knee OA secondary to acetaminophen, due to GI effects that increase morbidity and mortality and possible deleterious effects on articular cartilage metabolism related to NSAID use.[8] This paper evaluates three randomized controlled trials (RCTs) to determine the efficacy of transcutaneous electrical nerve stimulation (TENS) as a form of treatment for pain caused by knee OA.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not "is TENS an effective treatment for pain caused by knee OA?".

METHODS

Studies were chosen based on pertinence to the clinical question at hand, inclusion of patient-oriented outcomes, and validity. Filtration occurred based on the fulfillment of certain criteria regarding the population, intervention, comparison, and the outcome measured within the studies. For selection, all studies must have examined individuals with knee OA. Transcutaneous electrical nerve stimulation, pain, and knee osteoarthritis were the keywords used to find the studies in this review via PubMed. It was mandatory that the studies utilized randomization and were published in the English language in peer reviewed journals. Inclusion criteria included full-text RCTs published in or after 2011 in English examining "TENS for knee pain". Articles were excluded if they were published prior to 2011, featured only study protocol, or included TENS plus the following in the search results: pulsed ultrasound, acupuncture, medicinal leech, genotypes, hyaluronic acid, physical therapy, therapeutic exercise, periosteal stimulation therapy, knee swelling, stair climbing, gait, skin resistance; after knee arthroplasty. Methods of statistical analysis used in these studies were the mean change from baseline in VAS in addition to p-values used for evaluating statistical significance.

The populations studied in the RCTs chosen for this review were individuals diagnosed with knee OA. Each article examined TENS as an intervention for knee OA. While TENS was compared to a sham TENS or placebo group in the studies by Shimoura et al. and Vance et al., Cherian et al.'s study compared TENS to standardized treatment including intra-articular steroids, physical therapy, and self-directed exercise. The outcome they studied that is discussed in this review is knee pain, measured using the visual analog scale (VAS). The characteristics and demographics of the studies discussed are located in Table 1.

OUTCOME MEASURED

All studies included in this selective review use the VAS, which is a subjective measure used to rate perceived pain intensity. This requires participants of the studies to draw a mark between the ends of a line that is 10 cm or 100 mm long. In Shimoura et al. and Vance et al.'s studies, the scores range from 0 to 10 cm (or 100 mm), with 0 indicating no pain and 10 cm (100 mm) the most severe pain. Distance is measured starting from 0 and is recorded to the second decimal place. Cherian et al. measured VAS similarly, except that they used points instead of cm or mm as the unit for measuring VAS. The outcome measured in this review is knee pain.

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (yr.)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Shimoura[9] (2019)	RCT	59	50-69	Pts. 50 and older with OA knee pain belonging to Kellgren-Lawrence (K-L) grade 0 or 1 with average pain rated b/w 4-9 on 0-10 scale.	K/L grade 2 +; knee surgery; hyaluronic acid or CCS shot w/in 6 mo. prior; knee replacement or tibial osteotomy; PT; other major joint pain; CI to TENS; severe medical or nervous condition; no stairs in daily living; can't walk w/o assistance	9	TENS v. Sham TENS
Vance[10] (2012)	RCT	311	31-94	Medial compartment knee OA; 18-95 y.o.; can walk to mailbox and back; stable med schedule for 3 wk. prior; pain rating > 3/10 during weight bearing	Pain < 3/10; lateral compartment OA; uncontrolled DM or HTN; cognitive impairment; neuro disorder; permanent LE sensory loss; earlier TENS use; knee surgery w/in 6 mo.; knee injection in last 4 wk.	236	TENS v. placebo TENS
Cherian[3] (2016)	RCT	40	34-85	18-85 y.o. pts. with K-L grade 3 or > knee OA on weight-bearing radiographs who were treated at 1 institution.	< 18 or > 85 y.o.; electrical implant; major traumatic event related to knee pain; flexion contracture > 5°; radiographic deformity > 7° of varus/valgus on standing in AP radiograph; CCS injection w/in 3 mo.; epilepsy; DM neuropathy; pregnant/planning pregnancy during trial.	4	TENS v. control (standard therapy like PT, CCS injection, exercise)

RESULTS

All studies in this review involved individuals diagnosed with knee OA and investigated the efficacy of TENS for pain due to knee OA. Shimoura et al. conducted an RCT using blinded raters, enrolling individuals age 50 and older with knee OA pain belonging to K-L grade 0 or 1. Participants had moderate to severe knee pain, averaging a pain rating between 4-9 on a 0-10 scale. The RCT was conducted over a single day with a pre-post study design, comparing TENS with sham-TENS. The primary outcome analyzed in the study was the VAS knee pain level during the Timed Up and Go (TUG) test, which was measured before and while wearing the TENS or sham-TENS device. There were 59 individuals in the cohort who were randomized to either the TENS or sham-TENS group.[9] In total, 25 subjects received TENS while 25 received sham-TENS. While patients were not aware of the treatment conditions, the study did not note if clinicians and study workers were aware.[9] However, the subjects acted as blinded raters to rate their pain. Both groups wore their devices under the patella of their symptomatic knee, with the control receiving sham stimulation from a non-connected channel.[9] Adverse events or worsening of pain were not noted with either device.[9] Nine were excluded from final analysis due to their K-L grade of two; five discontinued from the TENS group and four from the sham group.[9]

Measurements of effectiveness and improvement in VAS were observed during the duration of the one-day cross-sectional study. Shimoura et al. used mean values with a 95% CI to assess knee pain before and during the intervention, when participants wore the TENS or sham-TENS devices during TUG depending on their assigned groups.[9] The results for the TENS intervention were statistically significant ($p < 0.02$) whereas the results for the sham group were not precise ($p = 0.245$). The TENS group demonstrated a decrease in mean VAS values, with 0.90 ± 1.27 cm before TENS and 0.52 ± 0.96 cm while wearing the TENS device, leading to a mean change from baseline of 0.38 cm.[9] The sham-TENS group also showed a decrease in mean

values, starting with 0.89 ± 1.04 cm before the sham intervention and ending with 0.70 ± 0.86 cm while wearing the sham device.[9] This resulted in a mean change from baseline of 0.19 cm, as seen in Table 2 below.[9] The difference between the mean changes from baseline of both groups was only 0.19 cm. Therefore, TENS was found to have a small treatment effect.[9]

Table 2. Change in VAS Knee Pain Level from Baseline to During Intervention[9]

	Before Treatment (Mean ± SD)	During Intervention (Mean ± SD)	Mean Change from Baseline	P-Value
TENS Group	0.90 ± 1.27 cm	0.52 ± 0.96 cm	0.38 cm	= 0.019
Sham-TENS Group	0.89 ± 1.04 cm	0.70 ± 0.86 cm	0.19 cm	= 0.245

Vance et al.'s RCT was similar to that of Shimoura et al. in that it compared a TENS group with a placebo TENS group, but it featured a larger age range of participants with knee OA, ranging from 18 to 95 years old. They enrolled participants aged 18 to 95 years old with medial compartment knee OA that caused moderate or greater knee pain, with a pain rating between 3-10 out of 10 during weight bearing.[10] Like Shimoura et al., this study was also conducted over a single day with a pre-post study design, comparing TENS with a placebo-TENS group. The primary outcome related to this review and analyzed in the study was the VAS knee pain level during TUG, which was measured before and after a single TENS or placebo-TENS treatment. There were 311 individuals in the cohort who were assessed for eligibility.[10] 87 people declined to participate, 31 were unable to be contacted, and 116 were excluded based on the exclusion criteria in Table 1.[10] Out of the 77 people remaining in the cohort, two people were excluded due to reduced sensation and lateral joint pain while the remaining 75 were randomly allocated to TENS and placebo TENS groups using specific allocation concealment protocol.[10] In total, 50 participants received TENS (25 low intensity, 25 high) while 25 received placebo-TENS. For the purposes of this review, VAS values from the high-intensity TENS group were analyzed due to their similarity to the intensity levels of TENS in the other two studies. Vance et

al. achieved blinding of patients, clinicians, and study workers, ensuring masking from treatment assignment. Both groups received 1 session of either TENS or placebo TENS during the duration of the study, lasting 40-50 minutes.[10] No adverse events or worsening of knee pain were noted with TENS or sham TENS. While some subjects were excluded in the primary and secondary screenings, all who were allocated to the groups completed the study and none from the final groups were excluded from analysis.[10]

Assessments for effectiveness and improvement in VAS scores were observed during the duration of the one-day cross-sectional study. Mean values with a 95% CI were used to measure knee pain during TUG before and after the TENS or placebo TENS treatments. The results were statistically significant in both treatments ($p = 0.001$).[10] However, it is important to note there was no significant difference between the result values of the placebo and TENS groups.[10] The TENS group demonstrated a drop in mean values with 24.2 ± 4.4 mm (15.2 – 33.3) before TENS and 9.44 ± 2.56 mm (4.15 – 14.73) after TENS, resulting in a mean change from baseline of 14.76 mm.[10] The placebo TENS group showed a decrease in mean values with 27.5 ± 4.4 mm (18.4 – 36.5) prior to treatment and 14.18 ± 3.55 mm (6.86 – 21.50) after treatment, resulting in a mean change from baseline of 13.32 mm.[10] The results are detailed in Table 3 below. TENS was found to have a small treatment effect in comparison to sham-TENS, as shown by the clinically unimportant 1.44 mm difference between the mean changes from baseline of both groups.[10] This is also shown by the 46.18% drop from baseline in the placebo group compared to the 60.99% decrease from baseline in the TENS group, indicating a placebo component is possible.[10]

Table 3. Change in VAS Knee Pain Level from Baseline to After Intervention[10]

	Before Treatment (Mean ± SD)	**After Intervention (Mean ± SD)**	**Mean Change from Baseline**	**P-Value**
TENS Group	24.2 ± 4.4 mm (15.2 – 33.3)	9.44 ± 2.56 mm (4.15 – 14.73)	14.76 mm	= 0.001
Sham-TENS Group	27.5 ± 4.4 mm (18.4 – 36.5)	14.18 ± 3.55 mm (6.86 – 21.50)	13.32 mm	= 0.001

Cherian et al. also performed an RCT of participants diagnosed with knee OA. They conducted a single-blinded trial in which the clinicians and study workers were not masked from treatment assignment, with participants aged 34 – 85 years old serving as blinded raters for the measurement of VAS pain scores.[3] These subjects had knee OA with a K-L grade of 3 or higher on weight-bearing radiographs.[3] The study was a 3-month long RCT comparing TENS with standard therapy only, which consists of PT or intraarticular CCS injection and self-directed exercise.[3] The primary outcome analyzed in this study was the knee pain level of participants who received TENS or standardized treatment, and it was not identified whether VAS was measured during or after TUG. The cohort was comprised of 40 patients, two choosing not to participate and two not keeping scheduled appointments, leading to a total of 36 patients for final analysis.[3] 18 patients were randomized to each group. Of the subjects assigned to the control cohort, nine had CCS injections and nine received PT three times a week for six weeks.[3] The control cohort also performed three simple self-directed exercises 20 minutes a day.[3] The 18 participants in the TENS group wore a TENS device housed in a specialized knee wrap during daily activities except those involving water during the duration of the study.[3] No adverse events or worsening of knee pain were noted with the TENS or sham TENS treatments. While four patients were lost to the three-month follow-up, all participants who were allocated to the groups completed the study and none from the final groups were excluded from analysis.[3]

Assessments for improvement in VAS and efficacy of treatment were noted after three months of treatment. While mean values with a 95% CI were utilized to measure outcomes before and after treatment, Cherian et al. only included the mean changes from baseline in their study. The results were statistically significant ($P < 0.05$) in both groups.[3] The TENS group had a mean change from baseline of -0.882 points (-4 to 4) while the control group had a mean change

from baseline of 0.388 points (-3 to 4). The results are detailed in Table 4 below. Cherian et al. found TENS to have a large treatment effect in comparison to standardized treatment, as demonstrated by the significant decrease in mean VAS score in the TENS group and clinically important -1.27 point difference between the mean changes from baseline of both groups.[10]

Table 4. Change in VAS Knee Pain Level from Baseline to 3 Month Follow-Up[3]

	Mean Change from Baseline	P-Value
TENS Group	-0.882 points (-4 to 4)	= 0.0416
Standardized Treatment Group	0.388 points (-3 to 4)	< 0.05

DISCUSSION

Knee OA is an increasingly common degenerative disorder without a cure, indicating the need for new treatment methods to reduce pain, improve function, and delay TKA. TENS has the benefit of potentially reducing pain without systemic side effects, unlike medication. It also has the versatility of attaching electrodes to the knee for a stationary session or being worn with a brace to be put to use during activities of daily living, therefore minimizing interference with patients' lives. However, patient compliance with TENS cannot be guaranteed. Furthermore, few studies have evaluated the use of a TENS device in a specialized brace for the knee, indicating that a limited number of healthcare professionals have sufficient knowledge to maximize the utilization of TENS.[3] That being said, TENS is more affordable than long-term drug therapy and can be purchased over the counter without a prescription, making it more accessible.[11]

This review evaluated the effectiveness of TENS as a treatment for pain in those with knee OA. While all studies demonstrated statistically significant decreases in VAS scores and statistically significant p-values in the TENS groups, Shimoura et al. and Vance et al.'s single-day studies demonstrated insubstantial differences between the mean changes from baseline and small treatment effects. Despite the significant improvement in VAS in the TENS group and lack of significant difference in the control group in Shimoura et al.'s RCT, the effect TENS may

have had on pain levels was small, suggesting that TENS may not be substantially efficacious. In Vance et al.'s study, while both groups had significant changes in VAS, the lack of significant difference between the placebo and TENS group values indicates that something other than TENS may be affecting pain levels. On the other hand, Cherian et al.'s longitudinal study resulted in a substantial difference in mean change from baseline of the TENS and standard treatment groups and demonstrated a large treatment effect. These results suggest that while TENS may have little to no effect on knee pain level on a short-term basis, it is possible that it may have a more substantial effect in the long term and with longer application time. This is especially emphasized by Cherian et al.'s study, in which TENS was worn not just before, during, and after TUG but also during activities of daily living over the course of three months.[3]

Each study had limitations, such as the selection of TUG in Shimoura et al. and Vance et al.'s RCTs as the activity during which VAS was measured. TUG is a relatively shorter test that causes milder pain, which may cause a VAS score with less significance than other tests.[9] Vance et al. and Cherian et al. had small sample populations, affecting validity and reliability. The three studies had inadequate follow-up and multiple exclusions (Table 1), potentially altering results and lowering generalizability. Furthermore, whether clinicians and study workers were blinded was unclear in Shimoura et al. and denied in Cherian et al., introducing bias. While patients acted as blinded raters in those studies in an attempt to alleviate bias, this still raises questions about the studies' validity. Also, a limitation related to the search criteria for this review is the selection of full-text articles. Full text was chosen to assess validity and reliability of data via examination of methods and limitations, which are omitted from abstracts, and to ensure the consideration of evidence within the context of the whole study to allow for more thoroughness. Nonetheless, the omission of text may have impacted the way the evidence answers this review's objective.

CONCLUSION

This systematic review found the evidence regarding the efficacy of TENS for knee OA pain to be conflicting, leaving the answer to this review's objective undetermined. On one hand, TENS was demonstrated to be ineffective for pain caused by knee OA in the short term in Shimoura et al. and Vance et al.'s studies. However, Cherian et al. found TENS to have potential for being effective in the long run, after months of use. All studies demonstrated statistically significant mean decreases in the TENS group VAS scores, Cherian et al.'s longitudinal study being the only one to show a large treatment effect and a substantial difference between the mean changes from baseline. The nature of these results warrants further longitudinal research that accounts for limitations in previous studies, such as small sample sizes and insufficient length or follow-up periods, to further assess the efficacy of TENS as a treatment for knee OA pain. It is also worth conducting trials to explore the use of TENS in a wearable wrap for the knee and determine the minimum period needed for TENS to be effective in order to promote maximal benefit from TENS. Any chance to increase the convenience of supportive treatment would be worth further exploration to improve quality of life, which is the ultimate goal of OA treatment.

There is currently a trial sponsored by Omron Healthcare regarding the effects of home use of TENS on knee pain and swelling for patients with knee OA or chronic knee pain.[12] While recruitment has not begun, the study intends to recruit subjects aged 45 to 80 with knee OA.[12] It was estimated to begin in September of 2021 and be completed in July of 2022. If home use of TENS is found to be effective, this study has the potential to promote specialized TENS devices for patients to wear as they go about their daily lives, improving compliance and benefit from TENS. It is to be hoped that future studies will be able to pinpoint the most efficient application and utilization of TENS to improve the quality of life of those suffering with pain from knee OA.

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