

The Efficacy, Use, And Safety of The Transcutaneous Electrical Nerve Stimulator

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Many people suffer every day from acute or chronic pain. For many of these people, the TENS unit may be the answer for them. The transcutaneous electrical nerve stimulator (TENS) is a noninvasive medical device for managing chronic and acute pain. This review critically assesses the effectiveness and safety of TENS when considered against a number of conditions based on the findings of clinical studies and trials. The mechanism of action of TENS is through the delivery of low-voltage electrical impulses to stimulate nerves, reducing pain perception by an alternative sensory pathway, which enhances the release of endogenous opioids. TENS efficacy is influenced significantly by its parameters, such as frequency and intensity. Understanding the parameters is crucial for optimizing TENS treatment and improving patient outcomes. Substantial literature exists demonstrating TENS to be effective in managing pain. It works with musculoskeletal, neuropathic, postoperative, labor, and fibromyalgia-related pain. Studies show that TENS can significantly reduce pain intensity (SMD for pain intensity: -0.47 to -1.28) in osteoarthritis and postoperative patients. However, available literature on this has portrayed a relatively mixed picture about its effectiveness. Most of the literature reviewed showed positive outcomes, though some showed no difference when utilizing control or placebo groups. Safety considerations include the minimal risks of adverse physiological effects because of the low voltage output produced from TENS. However, slight discomfort and skin irritation may still be encountered. Healthcare providers are vital in teaching the proper ways of using TENS amongst patients and monitoring for any total unexpected reactions. Although there are some potential side effects, the benefits of TENS outweigh its drawbacks since the side effects are minor while the benefits are many. Further research is needed to fully understand the factors influencing TENS's effectiveness and to optimize treatment parameters. Overall, TENS represents a valuable therapeutic option in pain management. This review critically evaluates the efficacy and safety of TENS, synthesizing data from a wide range of clinical studies and trials. The methodology involved a systematic review of literature focusing on musculoskeletal, neuropathic, postoperative, labor, and fibromyalgia-related pain.

Keywords: Transcutaneous electrical nerve stimulator, chronic pain, acute pain, pain management, electrodes, nerve stimulation, rehabilitation, physical therapy

Introduction

Transcutaneous Electrical Nerve Stimulation is a widely recognized modality for pain relief. This non-invasive therapy uses low-voltage electrical currents to alleviate pain across a spectrum of conditions. The idea of using electrical stimulation to prevent pain has existed since the year AD 63 by ancient Roman physicians. The concept of TENS was first explored by Dr. Melzack and Wall, who proposed the gate control theory of pain in 1965. However, it was Dr. Patrick Wall and Dr. Ronald Melzack who were key in the application of TENS for clinical pain management. Their work laid the foundation for the use of electrical stimulation in pain relief as they demonstrated that electrical impulses could modulate pain perception through nerve stimulation.

The scope of this literature review is to critically evaluate the breadth of research surrounding the efficacy and safety of TENS.

This is done by offering a synthesis of findings from various clinical studies and trials. The importance of this work lies in its ability to guide healthcare professionals in their treatment decisions and by empowering patients with knowledge about a pain management option that can have a very positive impact on their daily lives. For example, this paper explains and supports any viable uses of the TENS unit such as in sports or childbirth. Additionally, it aims to look into data and research from past studies in order to assess the TENS unit's efficacy and safety in a medical setting. By examining data, this review seeks to fill the gap in the literature regarding the optimal application of TENS, considering variations in patient responses and treatment parameters. Although first used in the 1970s, TENS continues to be relevant, with significant potential for refinement and improved clinical outcomes as research evolves.

Mechanism of Action of TENS

TENS has electrodes placed on the skin. These electrodes administer low-voltage electrical impulses through the skin and near the pain affected area¹. These impulses stimulate nerves and help block pain signals from reaching the brain via the gate control theory. Additionally, TENS can increase the release of endogenous opioids. As the body's natural pain killing hormones, they can play a significant role in modulating pain. The opioids, such as endorphins, enkephalins, and dynorphins, are released in response to pain and can inhibit the transmission of pain signals. As TENS delivers low-voltage electrical pulses to the skin, the sensory nerves below the area are stimulated. These nerves transmit the electrical signals to the spinal cord and brain. The stimulation then triggers the body's opioid receptors. After the receptors have been triggered, a signal is sent to the brain to produce and release endorphins. The endorphins can then bind to specific receptors in the Central Nervous System. This interaction results in reduced perception of pain². The gate control theory explains that the body's nervous system can only handle a certain amount of messages at once. By stimulating the nerves with low-voltage electrical impulses, TENS can overwhelm the nervous system's capacity to transmit pain signals which then closes the "gate" and reduces the perception of pain³. TENS units typically operate within a range of frequencies, often classified as high (50-150 Hz) and low (1-10 Hz). High-frequency TENS is believed to primarily operate through the gate control theory, providing rapid, non-painful stimuli that can inhibit pain transmission at the spinal cord level. On the other hand, low-frequency TENS is associated with the release of the endogenous opioids. However, studies have raised concerns about relying solely on the gate control theory and opioids to explain TENS's effectiveness. These studies suggest that psychological factors, including a placebo effect, may influence the outcomes of TENS treatment. A study by Marchand et al., 1993 investigated the effectiveness of TENS for chronic low back pain, comparing it to placebo and no treatment groups. Placebo TENS was shown to have a similar effect on reducing pain unpleasantness significantly when compared to TENS⁴. As a non-pharmacological treatment with minimal side effects, TENS can be a safer option for pain management^{5,6}.

Summary of Studies And Data

Quantitative data supporting the efficacy of TENS are derived from various studies that use the Numerical Rating Scale (NRS) to measure pain relief. The data are shown in Table 1.

Clinical Applications of TENS

TENS has various clinical applications in different medical fields, making it a versatile option for pain management and re-

habilitation. An important fact to note is that the choice between high and low frequency can influence pain relief duration and intensity. High-frequency TENS is generally used for acute pain and provides immediate but short-term relief. Low-frequency TENS may be more effective for chronic pain due to its prolonged opioid release⁷.

Here are some examples of how TENS is used in different clinical settings:

Pain Management

TENS is commonly used in pain management for conditions such as:

- **Osteoarthritis:** Osteoarthritis is a degenerative joint disease that causes pain, stiffness, and decreased mobility during movement or weight-bearing activities. It can cause pain around their legs and arms and prevent patients from doing certain tasks⁸. As shown in figure 1, an older meta-analysis found that research regarding the effectiveness of TENS was inconclusive on the pain management of osteoarthritis⁹. The predictive pain reduction found was very small and not statistically significant. This hinted at the possibility that TENS had little effect in improving pain in users with osteoarthritis. However, a more recent meta-analysis, shown in figure 1, highlighted the superiority of TENS over placebo or sham treatment in reducing pain. The paper also found that TENS helped improve function in patients with osteoarthritis of the knee¹⁰. The contrast in results between the two studies could be due to variability in the older paper. In the older meta-analysis, there was inconsistent data being used that left room for speculation. No conclusions could be made with such a high level of variability. However, in the paper by Johnson et. al, more recent trials were used which could have allowed for better methodology. Additionally, most of the studies used by this newer meta-analysis showed positive outcomes among osteoarthritis patients. This newer paper demonstrates how important further research is regarding this device.
- **Neuropathic pain:** Neuropathic pain is a type of chronic pain that is typically caused by damage to the nervous system. This can be the result of pressure or lesion of the nerves. Shooting pain, numbness, and tingling are common symptoms seen with patients dealing with neuropathic pain. As shown in figure 1, a comprehensive review and meta-analysis evaluated the efficacy and safety of TENS for neuropathic pain. The study found that TENS provided pain relief reduction on a ten point scale by 1 to 2 points¹¹. The ability to control inflammation is key in reducing pain for patients dealing with neuropathic pain. Since TENS has been found to reduce proinflammatory cytokines the device can potentially alleviate neuropathic pain. These

Study	Publication Year	Indication	Data
Rutjes et al	2009	This meta-analysis found that TENS was inconclusive on osteoarthritis pain management	The predicted pain reduction (SMD of -0.07) is very small and not statistically significant, implying that transcutaneous electrostimulation might not provide meaningful pain relief for knee osteoarthritis.
Johnson et. al	2019	A more recent meta-analysis found that TENS was better at reducing pain and improving function of osteoarthritis patients compared to placebo treatment	The pooled analysis showed a small but statistically significant reduction in pain with TENS compared to placebo/no intervention. SMD for pain intensity: -0.47 (95% CI: -0.85 to -0.09), indicating that TENS was associated with reduced pain.
Krumme et. al	2020	Study found that TENS provided pain relief for neuropathic pain	It may help reduce pain by 1 to 2 points on a 10 point pain scale.
Viderman et. al	2024	Systematic review and meta-analysis that TENS reduced postoperative pain and symptoms	Pain intensity at rest and during coughing for all types of surgeries combined was lower in the TENS group (standardized mean difference (SMD) = 0.51 [0.61, 0.41], p < 0.00001, 29 studies, and 1.28 [2.46, 0.09], p-value = 0.03.
Avic	1999	Effective in relieving muscle spasms	Statistically significant decrease of muscles spasm in patients treated by TENS (p < 0.05)
Mayah & Al-Jarrah	2010	Effective in treating neck pain from musculoskeletal injuries	The study showed that 11 subjects (73%) in the tens treatment and 7 subjects (43%) in the control groups had gained improvement. These results are statistically highly significant, (P = 0.01) at the end of the follow-up assessment.
Njogu et al	2021	Effective in reducing pain intensity in first stage of labor	The experimental group demonstrated a statistically significant shorter duration of the active labor phase than the control group (p < 0.001).
Dowswell et al	2009	TENS was shown to be more effective when placed on certain spots of the back compared to others	Women receiving TENS to acupuncture points were less likely to report severe pain (risk ratio 0.41, 95% confidence interval 0.32 to 0.55).
Hughes et. al	2015	TENS aids athletes as it helps treat muscular soreness, cramping, or degeneration	N/A
Arik et. al	2020	TENS was effective in reducing primary dysmenorrhea related pain	TENS was statistically more effective than sham TENS in reducing primary dysmenorrhea related pain (SMD=1.384; 95% CI=0.505, 2.262; p = 0.002).

Table 1 Summary of Studies And Data

findings support the use of TENS as a therapeutic option for neuropathic pain, as it¹².

- **Postoperative pain:** Post operative pain is common after surgical operations and is usually caused by tissue damage and inflammation¹³. The Journal of Clinical Medicine examined the efficacy of TENS for postoperative pain control and found that TENS significantly reduced pain intensity at rest and during coughing for various types of surgeries. Additionally, as shown in figure 1, TENS was associated with a decrease in morphine(a type of painkiller) requirements and a reduction in the incidence of postoperative nausea, vomiting, dizziness, and pruritus. This study showed how TENS can limit the need for opioids and painkillers for acute pain¹⁴.

Physical Therapy and Rehabilitation:

In the field of physical therapy and rehabilitation, TENS is used to:

- **Relieve Muscle Spasms and Cramps:** TENS devices have shown effectiveness in relieving muscle spasms compared to passive exercise, as shown in figure 1¹⁵. The study involved 60 patients with muscle spasms due to upper motor neuron lesions. 50% of the patients received passive treatment exercises while the rest were given TENS treatment. Results showed a significant reduction in muscle spasms for the TENS group (p < 0.05) but improved passive range of motion in both groups. Additionally, the longer duration of TENS unit of stimulation, the more pronounced reductions in muscle spasms.
- **Enhance physical therapy outcomes for musculoskeletal injuries:** As seen in figure 1, patients with musculoskeletal injuries can benefit from the TENS unit as it was shown to improve pain relief. The device demonstrated its versatility in treating different musculoskeletal injuries. Some examples include neck pain and orofacial pain. Research indicates that TENS is effective in treating neck pain that are caused by musculoskeletal disorders as a single intense treatment session leading to significant pain relief¹⁶. TENS

is also used as a physiotherapeutic way for orofacial pain¹⁷.

- ***Aid in the management of labor pain during childbirth:*** TENS is often used to help mothers while in labor as a way to relieve pain. Research indicates that TENS therapy in the first stage of labor significantly reduces pain intensity, with a lower mean pain score compared to general care¹⁸. Additionally, a plot analysis displayed a small but statistically significant effect of TENS on pain intensity reduction in women in childbirth. However, while TENS may offer benefits in managing labor pain, further high-quality research is needed to confirm and build upon these findings¹⁹. On top of this, the TENS unit was shown to reduce pain when placed on acupuncture points compared to cranium, as shown in figure 1²⁰. Although this study showed how there is variability between outcomes and how the device is used, TENS remains a valuable option for women seeking a non-pharmacological pain relief method during labor.

Other Clinical Areas

TENS is also applied in other clinical areas, including:

- ***Sports medicine for managing sports-related injuries:*** TENS units are commonly utilized in sports medicine for managing sports-related injuries. Exercise-associated muscle cramping (EAMC) is a prevalent issue among athletes participating in sports. For example, different athletic events such as triathlons, marathons, ultra-endurance competitions, and recreational distance running report high rates of EAMC. Studies have shown that the prevalence of EAMC ranges from 30% to 67% in different sports^{21,22}. In sports medicine, some TENS devices incorporate vibration and mechanical muscular manipulation to promote the release and disbursement of lactic acid. This helps aid in treating muscular soreness, cramping, or degeneration in athletes, as seen in figure 1²³.
- ***Women's health for managing menstrual pain and pelvic pain:*** As shown in table 1, studies have shown that TENS is statistically more effective than sham TENS in reducing pain intensity related to primary dysmenorrhea which is a common menstrual pain condition in young women^{24,25}. Additionally, TENS has been found to mildly reduce pain in women with chronic pelvic pain. This is with the help of its specific parameters such as pulse duration and frequency²⁶.

Safety of TENS

TENS is a very safe device to use. TENS utilizes a low voltage output that is designed to be safe for the human body as it remains below the threshold for causing any tissue or skin

damage. Additionally, the ability to adjust parameters such as intensity and frequency of electrical stimulation allows healthcare providers to adjust TENS treatment in a specific and personalized way²⁷. This allows every patient to receive optimal comfort that is specifically designed for them. Nevertheless, mild side effects do occur that should be noted. These side effects include skin irritation, muscle spasms, and discomfort²⁸.

TENS therapy offers several advantages in terms of safety. As a non-invasive device, the use of TENS removes the need for any riskier invasive procedures²⁹.

In clinical practice, healthcare providers play an important role in educating patients about proper TENS usage and monitoring for any adverse reactions. Patients should be instructed on appropriate electrode placement, device operation, and duration of treatment sessions to maximize safety and efficacy. An important parameter to note is the intensity or the strength of the electrical impulses delivered to the skin. Higher intensities can lead to more sensory stimulation and lessen pain through the gate control mechanism. However, excessively high intensities may cause discomfort or skin irritation as mentioned previously. Adjusting intensity based on patient feedback and treatment goals can help achieve optimal results while preventing adverse effects.

Doctors should have information on the device's settings, including current and impulse duration, and ensure the electrodes are properly attached for effective treatment³⁰. These precautions and standards for good treatment are in place to increase patient confidence and limit the possibility for harmful side effects. In addition to this, regular follow-up appointments are also important as they allow healthcare providers to assess treatment outcomes. Overall, the benefits of TENS outweigh the drawbacks of skin irritation seen in patients. With the help of healthcare providers, patients using this device can be confident in feeling comfortable while treating pain management.

Future Research

As of June 2024, ongoing research of the TENS unit is centered around studying its efficacy and addressing any uncertainties regarding its effectiveness in treating various forms of pain. Future research should not only be done to answer its effectiveness in different settings such as labor pain management but also explore its potential applications in new fields, like chronic pain in pediatric populations or integrating TENS with emerging technologies like wearable health monitors. Any future studies that will be done should answer any of these uncertainties in order to maximize confidence in the device. Moreover, TENS research must look into the long-term benefits and potential side effects of regular TENS use when treating chronic issues. By addressing these uncertainties and expanding into new fields, researchers and health professionals can maximize the device's potential.

Methodology

This paper used a comprehensive literature search, utilizing databases such as PubMed, Google Scholar, and Cochrane Library. Keywords such as “TENS unit”, “Physical therapy”, and “pain management” were used to compile data and information. The papers and studies used were from the period January 1990 to May 2024. We summarized studies and took empirical data in order to support information presented in this literature review. Much of the extracted data came from the summarized charts. The gathered information was collected and organized through thematic synthesis which allowed for grouping of similar papers. In order to check for quality of the studies, more recent papers were used with limited areas of possible bias. Although extensive searches were conducted in these databases, ongoing or completed clinical studies from ClinicalTrials.gov were not included. Future work should incorporate data from ClinicalTrials.gov to provide a more robust analysis of ongoing clinical trials.

Discussion

Transcutaneous Electrical Nerve Stimulation unit is a noteworthy and useful non-pharmacological device for pain management across a spectrum of conditions. The clinical literature presents a clear view regarding its effectiveness. Although some studies showcase specific scenarios where TENS, as demonstrated by Weber-Muller et al. (2004), has shown unfavorable side effects, overall consensus remains confident that no major harmful side effects would occur. Nonetheless, TENS stands as a safe option for pain relief, albeit with the side effects of skin irritation. Continued research and refinement are imperative to fully ascertain TENS’s role in modern pain management strategies, ensuring its integration as a versatile and well-tolerated alternative to other interventions. Several theories have been proposed, including the gate control theory by Melzack and Wall in 1965, which suggests that TENS stimulates large nerve fibers that inhibit the transmission of pain signals to the brain. Another proposed mechanism is the release of endogenous opioids, suggesting that TENS promotes the body’s natural pain-relieving pathways. Both theories have their flaws. The gate control theory does not explain the varying efficacy across different types of pain. On the other hand, the opioid based theory must be tested on individuals who do not respond to opioid-based therapies in order to understand this mechanism. Future research should aim to clarify the mechanism of the device. Exploring the role of variables such as electrode placement, stimulation frequency, and patient demographics will be crucial in building our understanding of TENS’s mechanisms. In the coming years, more research will need to be done in order to fully grasp TENS’s potential.

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