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Is transcutaneous electrical nerve stimulation (TENS) therapy to the pelvic region effective in alleviating menstrual pain in adolescent and young adult females with primary dysmenorrhea?

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Is transcutaneous electrical nerve stimulation (TENS) therapy to the pelvic region effective in alleviating menstrual pain in adolescent and young adult females with primary dysmenorrhea?

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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 transcutaneous electrical nerve stimulation (TENS) therapy to the pelvic region effective in alleviating menstrual pain in adolescent and young adult females with primary dysmenorrhea?"

Study Design: A systemic review of three randomized controlled trials (RCTs) published between 2011 and 2022.

Data Sources: All three RCTs were discovered using PubMed, CINAHL, AMED, Academic Search Premier, and Alt HealthWatch. The articles were published in English in peer-reviewed journals and selected based on applicability to the clinical question.

Outcome Measured: A reduction in intensity of menstrual pain was the outcome measured in all three studies using either the visual analog scale (VAS) or numerical pain rating scale (NPRS).

Results: In the RCT led by Parsa and Bashirian, TENS therapy led to a statistically significant reduction ($p = 0.000$) in menstrual pain compared to the control group, indicated by a mean change from baseline of 3.906 in the treatment group and 1.625 in the control group; the mean difference between groups was 2.281. Lauretti et al. demonstrated a statistically significant reduction ($p < 0.001$) in menstrual pain with TENS therapy, indicated by a mean change from a baseline of 6 in the treatment group and 1 in the control group with a mean difference between groups of 5. Lastly, Manisha and Anuradha showed TENS therapy leading to a reduction in menstrual pain compared with the control group, indicated by a mean change from baseline of 4.17 in the treatment group and 0.04 in the control group with statistical significance of $p < 0.001$ in the TENS treatment group; the mean difference between groups was 4.13.

Conclusion: All three studies in this review demonstrated TENS therapy to the pelvic region led to a statistically significant reduction in menstrual pain. This suggests TENS therapy is an effective and beneficial treatment method for intense menstrual pain. However, further studies should explore varying frequency levels and treatment durations to optimize menstrual pain relief.

Key Words: transcutaneous electrical nerve stimulation (TENS), primary dysmenorrhea, adolescent females

INTRODUCTION

Primary dysmenorrhea is a common gynecological complaint characterized by painful lower abdominal cramps often associated with headache, nausea, vomiting, and mood disturbances which begin before or at the onset of menses, sometimes after; diagnosis is often made clinically.[1] In fact, up to 95% of females have or will have experienced primary dysmenorrhea sometime during their reproductive years.[1] As a result, primary dysmenorrhea disturbs the quality of life of females leading to absenteeism from school and/or work which has translated to an approximate "loss of 600 million hours per year, with an annual loss of $2 billion in the United States."[1] Although an exact total healthcare cost due to primary dysmenorrhea has not been identified, it is known to be "responsible for considerable economic losses due to the costs of medications, medical care, and decreased productivity."[2] For example, in a 2015 study, it was discovered approximately 50% of gynecological chief complaints were lower abdominal pain[3] which reveals menstrual complications are a large component of medical care in women's health.

The exact pathophysiology of primary dysmenorrhea is not well understood but current evidence suggests hypersecretion of prostaglandin F2a (PGF2a) and prostaglandin E2 (PGE2) in the uterus during the menstrual cycle which results in increased myometrial contractions and uterine ischemia leading to pelvic pain.[1] First-line therapy are nonsteroidal anti-inflammatory drugs (NSAIDs) which immediately inhibit the production and release of prostaglandins.[4] Oral contraceptive pills (OCPs) are second line therapy by reducing menstrual fluid volume which reduces the amount of prostaglandin produced; however, it takes several weeks to achieve full effectiveness.[4]

NSAIDs and OCPs are effective treatment options for primary dysmenorrhea, especially when used in combination, but 10% of women do not respond to these treatments or have contraindications to these medications[4] such as renal diseases, clotting disorders, smoking, and more. As a result, studies have been investigating the impact of TENS as a nonpharmacological and noninvasive treatment option in reducing the severity of primary dysmenorrhea.[5] The mechanism involves stimulating nerves via electrodes which inhibits pain responses in the dorsal horn.[5] This paper evaluates three randomized control trials (RCTs) on the efficacy of transcutaneous electrical nerve stimulation (TENS) therapy to the pelvic region in adolescent and young adult females as symptomatic management for primary dysmenorrhea.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not "Is transcutaneous electrical nerve stimulation (TENS) therapy to the pelvic region effective in alleviating menstrual pain in adolescent and young adult females with primary dysmenorrhea?"

METHODS

The criteria for article selection were based on relevance to the clinical question, specifically the population, intervention, comparison, and outcomes measured in the studies, and included patient-oriented outcomes (POEMS). All articles were published in peer-reviewed journals in English, with exclusion criteria including articles that were published before 2011. Inclusion criteria consisted of RCTs published after 2011 and found using the key words "transcutaneous electrical nerve stimulation (TENS)," "primary dysmenorrhea," and "adolescent females" through the resource databases of PubMed, CINAHL, AMED, Academic Search Premier, and Alt HealthWatch.

The statistics reported in the articles for measuring menstrual pain intensity included the mean change from baseline, p values, and t-scores. The population of the studies targeted in this selective EBM review were adolescent and young adult females with primary dysmenorrhea. Demographics and characteristics of these studies can be found in Table 1.

OUTCOMES MEASURED

The main outcome measured in the RCTs was the intensity of menstrual pain. Subjective pain intensity was measured using the visual analog scale (VAS) by Parsa & Bashirian[6] and Lauretti et al.[7] The VAS ranges across a continuum from 0-10 with zero representing no pain and ten representing worst possible pain.[6,7] In the study conducted by Parsa and Bashirian,[6] the patients ranked their pain level before and immediately after a single treatment, while in the study conducted by Lauretti et al.,[7] patients ranked their pain level before and then every 24 hours after for a 24-hour overall impression over seven days of treatment. The study conducted by Manisha and Anuradha[8] measured the intensity of menstrual pain by utilizing the numerical pain rating scale (NPRS) before and immediately after a single TENS treatment. The NPRS is like VAS, but it is a segmented numeric scale ranging from 0-10 with options only being integers; zero representing no pain and ten representing worst possible pain.[8]

RESULTS

Parsa and Bashirian[6] conducted a randomized controlled trial to evaluate the effects of transcutaneous electrical nerve stimulation (TENS) therapy in females with primary dysmenorrhea between the ages of 14 and 18 years old. A total of 64 females were enrolled and randomly assigned into active TENS group or placebo group; each group consisted of 32 participants.[6] All participants were assessed and treated on day one of menstruation.[6] In the active group, the participants were positioned prone with a thin pillow under their abdomen and

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Parsa[6] (2013)	RCT	64	14-18	Female patients 14-18 years old who were diagnosed with primary dysmenorrhea based on their menstrual history, ultrasound, and physical examination	History of secondary dysmenorrhea	0	TENS vs. Placebo TENS (control)
Lauretti[7] (2015)	RCT	40	16-24	Female patients 16-24 years old who have a past medical history of primary dysmenorrhea and regularly took rescue analgesics (NSAIDs) for pain control	History of secondary dysmenorrhea (endometriosis, uterine, myoma, uterine malformations, other similar uterine diseases, pelvic inflammatory disease, congenital Mullerian anomalies, ovarian cysts, or inflammatory bowel disease)	0	TENS vs. Placebo TENS (control)
Manisha [8] (2021)	RCT	140	14-19	Female patients 14-16 years old who have self-reported pain for three consecutive menstrual cycles with no identifiable gynecologic pathology	History of mild or infrequent dysmenorrhea, secondary dysmenorrhea, previous use of drugs or physical methods for pain relief, and current psychiatric illness	0	TENS vs. control (no intervention)

two electrodes applied bilaterally on the lower back and the remaining two on the lateral gluteal region. The TENS device had a frequency range of 0-100 Hz and 90-100 pulse/second, but the intensity of stimulation was set at the highest tolerable level per participant; duration of treatment was 20 minutes.[6] The placebo group had an identical set up as the active group regarding the placement of electrodes and body positioning but received no stimulation from the TENS device during the 20 minutes.[6] The same physiotherapist provided treatment to both groups.[6]

Menstrual pain was assessed before and immediately after the completion of treatment using the Visual Analog Scale (VAS).[6] The scale ranged from 0 to 10, with zero representing no pain and ten representing the worst possible pain.[6] The statistical data used to measure the pain intensity in the study by Parsa and Bashirian[6] was presented as mean change from baseline, standard deviations, and p-values to measure outcomes prior and after treatment. The treatment group showed a significant decrease in mean values with 6.312 ± 2.023 prior to treatment and 2.406 ± 1.682 immediately after treatment resulting in a mean change from baseline of 3.906.[6] The placebo group showed a minor decrease in mean values with 6.625 ± 2.012 prior to treatment and 5.000 ± 2.109 immediately after treatment resulting in a mean change from baseline of 1.625.[6] TENS was found to have a significant treatment effect in comparison to the placebo group, as reflected by the 2.281-point difference. The results are summarized in Table 2 below.

Table 2. Comparison of Menstrual Pain Pre-Post Study Groups (data from Parsa and Bashirian[6])

	Before Treatment (mean ± SD)	Immediately After Treatment (mean ± SD)	Mean Change from Baseline	Mean Difference Between Groups (calculated)	p-value
TENS Group	6.312 ± 2.023	2.406 ± 1.682	3.906	2.281	0.000
Placebo Group	6.625 ± 2.012	5.000 ± 2.109	1.625		

Lauretti et al.[7] conducted a double-blind randomized controlled trial assessing the intensity of menstrual pain after using a portable self-administering TENS device compared to a sham device. A total of 40 women between the ages of 16-24 years old with a history of painful and debilitating dysmenorrhea were recruited.[7] Participants were randomly assigned by a computer into the placebo or TENS group; each group consisted of 20 individuals.[7] Prior to using the TENS device, all participants recorded their baseline level of menstrual pain and were trained on the appropriate use of the device.[7] Participants were instructed to apply the TENS device upon the first occurrence of menstrual cramps which may or may not correspond to the first day of menstruation.[7] For the active group, a portable TENS device set at a frequency of 85 Hz was applied medially to the lower pelvis by the participant for 30 minutes at 8-hour intervals for up to 7 days.[7] The placebo group had an identical device and were given the same instructions as the active group, but their device delivered no stimulation.[7]

Participants self-reported their menstrual pain after every 24-hours for 7 days of treatment using the Visual Analog Scale (VAS); a mean overall pain score was calculated per participant.[7] The scale ranged from 0 to 10, with zero representing no pain and ten representing the worst possible pain.[7] The statistical data used to measure the pain intensity in the study by Lauretti et al.[7] was presented as mean change from baseline, standard deviations, and p-values to measure outcomes prior and after treatment. Both groups had a mean baseline menstrual pain of 8 ± 1 prior to treatment; VAS scores ranged between 7-10.[7] The treatment group showed a significant decrease with a mean value of 2 ± 1 after treatment resulting in a mean change from baseline of 6.[7] In comparison, the placebo group resulted in a mean value of 7 ± 2 post treatment resulting in a mean change from baseline of 1.[7] TENS was found to have a significant treatment

effect in comparison to the placebo group, as reflected by the 5-point difference. The results are summarized in Table 3 below.

Table 3. Comparison of Menstrual Pain Pre-Post Study Groups (data from Lauretti et al.[7])

	Before Treatment (mean ± SD)	24-hour Overall Impression After Treatment (mean ± SD)	Mean Change from Baseline	Mean Difference Between Groups (calculated)	p-value
TENS Group	8 ± 1	2 ± 1	6	5	< 0.001
Placebo Group	8 ± 1	7 ± 2	1		

Manisha and Anuradha (2021)[8] conducted a randomized controlled trial that evaluated the effects of TENS therapy on adolescent females between the ages of 14-19 years old diagnosed with primary dysmenorrhea. A total of 140 females were recruited and randomly assigned into two groups using sealed red and green colored envelopes containing the treatment type; each group consisted of 70 individuals.[8] All participants were assessed and treated on the first day of menstruation.[8] For the active group, participants were lying prone with four electrodes placed at the L3-L5 root level, specifically two on the lower back and other two on the gluteal region.[8] The frequency was set at 100 Hz with a pulse duration of 80 microseconds for 20 minutes.[8] The placebo group received no clinical intervention and were provided a thin pillow to be placed under their lower abdomen while lying prone for 20 minutes.[8]

Participants had their menstrual pain recorded before and immediately after the completion of treatment using the Numerical Pain Rating Scale (NPRS).[8] The scale ranged from 0 to 10, with zero representing no pain and ten representing the worst possible pain.[8] The statistical data used to measure the pain intensity in the study by Manisha and Anuradha[8] was presented as mean change from baseline, standard deviations, and p-values to measure outcomes prior and after treatment. The treatment group showed a significant decrease in mean values with 6.77 ± 1.590 prior to treatment and 2.60 ± 0.689 immediately after treatment resulting in a mean

change from baseline of 4.17.[8] The placebo group showed a minor decrease in mean values with 6.97 ± 1.702 prior to treatment and 6.93 ± 1.645 immediately after treatment resulting in a mean change from baseline of 0.04.[8] TENS therapy was found to have a significant treatment effect in comparison to the placebo group, as reflected by the 4.13-point difference. The results are summarized in Table 4 below.

Table 4. Comparison of Menstrual Pain Intensity Pre-Post Study Groups (data from Manisha and Anuradha[8])

	Before Treatment (mean ± SD)	Immediately After Treatment (mean ± SD)	Mean Change from Baseline	Mean Difference Between Groups (calculated)	p-value
TENS Group	6.77 ± 1.590	2.60 ± 0.689	4.17	4.13	< 0.001
Placebo Group	6.97 ± 1.702	6.93 ± 1.645	0.04		

DISCUSSION

Primary dysmenorrhea is a common disorder with few treatment options available and most pharmacologic in nature. As a result, women are either achieving temporary relief with potential long-term treatment side effects, refractory to treatment, or unable to initiate treatment due to contraindications. Given primary dysmenorrhea affects up to 95% of women[1] and lacks diverse treatment options, this supports the need for more and newer methods for management.

This systemic review evaluated the efficacy of transcutaneous electrical nerve stimulation therapy to the pelvic region in alleviating menstrual pain in adolescent and adult females with primary dysmenorrhea. All three articles reviewed demonstrated a statistically significant reduction in menstrual pain after intervention with TENS therapy based upon the mean difference and p-values.[6-8] When comparing the mean change from baseline between the placebo and TENS group, all three studies demonstrated significantly larger changes in the TENS group. Parsa and Bashirian[6] demonstrated a mean pain score difference of 2.281 while Manisha and

Anuradha[8] had a score of 4.13. However, the largest mean pain score difference was in the study conducted by Lauretti et al.[7] with a score of 5. These results from the studies support the efficacy of TENS therapy.

The studies utilized in this systemic review were found to have a few concurrent limitations. All three studies recruited participants between the ages of 14 to 24 years old with primary dysmenorrhea. As a result, the findings may not be applicable for females with secondary dysmenorrhea or those within their reproductive years but older than 24 years old.[6-8] Another limitation was the subjectiveness of pain and the impact of physical, mental, and emotional factors, which vary amongst participants, influencing the overall pain rating.[6-8]

Additional limitations were identified in each study. In the study conducted by Parsa and Bashirian,[6] treatment was initiated on day one of menstruation which may not coincide with the onset of menstrual pain; therefore, some participants may have been experiencing menstrual pain prior to or after the start of menstruation which could alter the effectiveness of TENS therapy. Also, in the active group, there were minor treatment method inconsistencies as the frequency set on the TENS device varied amongst participants since the level was determined by the individuals "tolerable frequency" which creates concerns for validity. In Lauretti et al.,[7] participants were trained on the appropriate use of the TENS device since therapy was self-administered on the first day of menstrual pain, which may or may not correspond with the first day of menses. However, this approach only partially eliminates the potential for human error and requires more professional supervision to ensure proper usage. As discussed earlier, pain is subjective which creates ambiguity and possibly resulting in premature or late initiation of therapy. In Manisha and Anuradha,[8] they were limited by initiating treatment on day one of menstruation with the same reasoning as stated above regarding Parsa and Bashirian's study.

Also, the control group was not blinded with a sham device which could have influenced and created an unintentional bias such as reporting post-treatment pain level at baseline or above.

CONCLUSION

All three randomized controlled trials utilized in this selective EBM review demonstrated the use of transcutaneous electrical nerve stimulation (TENS) to the pelvic region was effective in alleviating menstrual pain in adolescent and young adult females with primary dysmenorrhea. Furthermore, treatment effect in each study was determined to be large based upon the mean pain score difference between TENS therapy and control groups. Thus, the results of this review are conclusive and found statistically significant based from the calculated p-values.

Further research should consider utilizing larger cohorts and longer evaluation periods, such as over a few consecutive menstrual cycles, to assess the long-term benefits of TENS therapy. In addition, future studies should be more cognizant of participant ethnicity, culture, and mental/emotional state and investigate their influence on pain perception. Moreover, the timeframe for treatment initiation in relation to the start of menstruation and menstrual pain, placement of electrodes, frequency levels, and duration per treatment session all need to be optimized. Lastly, research on the use of TENS therapy in conjunction with other common treatment options such as medications (NSAIDS, OCPs) would be beneficial in further improving the quality of life for these individuals.

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