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ORIGINAL ARTICLE

Transcutaneous electrical nerve stimulation is a promising novel non-pharmacological treatment alternative for mastalgia: A randomized clinical trial

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SUMMARY

Objectives: The main objective of this study is to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS) treatment on pain and quality of life in mastalgia, a condition for which treatment has not yet reached a consensus.

Methods: This randomized controlled clinical trial was completed with 20 women suffering from mastalgia. Patients were randomly assigned to the TENS treatment and sham application groups. Pain intensity, pain patterns, and quality of life were evaluated with the Breast Pain and SF-36 questionnaires before and 10 days after treatment in all patients.

Results: TENS treatment significantly reduced the total breast pain score (from 257.6±47.3 to 123.6±11.6 for the TENS group vs 217.7±42.7 to 209.7±54.4 for the sham group) ($p<0.001$) and analgesic use ($p=0.024$) compared to the sham group. The pain patterns of patients shifted to a more brief, momentary, or transient pattern in the TENS group, whereas they did not change in the sham TENS group. There was significant improvement in the total SF score ($p<0.001$) and six subscales of the SF-36 (physical and social functioning, energy/fatigue, pain, general health, and health change) in favor of the TENS group.

Conclusion: TENS seems to be a promising treatment for mastalgia. It is safe, has a rapid onset of action, and can be self-administered.

Keywords: Breast pain; electrical stimulation; mastalgia; pain management; pain measurement.

Introduction

Breast pain is one of the most frequent complaints among women of reproductive age.[1] It affects approximately two-thirds of women during their reproductive lives, and nearly 15–20% of these patients require pain-relieving therapy.[2,3] It can also be termed mastalgia or mastodynia.[4] Although a certain etiological factor has not yet been determined, many factors such as a high-fat diet, smoking, caffeine consumption, hormone replacement therapy, and drug use have been held responsible in the literatüre.[5–7]

Breast pain can be classified as cyclic, non-cyclic, and extramammary mastalgia, and diagnostic evaluation should be made according to this distinction.[4] Cyclical mastalgia is associated with the menstrual cycle and is more frequent in the second to fourth decades of life in young women.[8] Due to hormonal changes, pain is more prominent in the week before the onset of the menstrual cycle and usually occurs bilaterally, diffusely, and more severely in the upper outer quadrants of the breast.[1–4] Non-cyclical mastalgia is not associated with the menstrual cycle and usually affects perimenopausal women at the age of 40 or older.[4] Nearly 25% of women with breast pain suffer from a non-cyclical pain pattern, and the pain is usually located unilaterally in these patients.[3–9] Extramammary mastalgia originates from a location outside the breast tissue, such as costochondritis or referred epigastric and gallbladder pain.[1] Factors such as breast cancer and benign breast pathologies should be investigated in diagnostic evaluation.[1–4] In the remaining patients, mastalgia is often ignored by

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physicians, but treatment is required to eliminate the negative effects of mastalgia on their daily lives.[3–10]

Several treatment modalities such as using well-fitting sports bras, stress management, diet modifications (low fat consumption and restricting foods containing caffeine and methylxanthine), pharmacological and hormonal treatments [oral and topical nonsteroidal anti-inflammatory drugs (NSAIDs), tamoxifen, bromocriptine, danazol, vitamin E, and evening primrose oil] have been used.[11,12] However, there is still no consensus on the treatment of mastalgia, as some of these methods are inadequate for certain patients, and some have the potential for serious side effects.

There is a need for non-invasive approaches in the treatment of mastalgia. In our previous studies, we used balneotherapy and exercise applications as alternatives to pharmacological treatments in patients with mastalgia.[10–13] Transcutaneous electrical nerve stimulation (TENS) is a non-invasive treatment method widely used for pain control.[14–17] In the present study, we aimed to evaluate the effect of TENS treatment on pain and quality of life (QoL) in patients with mastalgia.

Materials and Methods

This study was planned as a prospective randomized controlled clinical trial. Ninety-three female volunteers who were admitted to the General Surgery Outpatient Clinic with mastalgia between February 2020 and November 2020 were screened. A written statement of consent was signed by all patients, and this study was approved by the Ethical Committee of Ankara University School of Medicine (Approval number: I2-110-20). The NIH clinical trials registration number of this trial is NCT06168110. The study was carried out in line with the Helsinki Declaration. Exclusion criteria included previous or new diagnosis of diseases that may cause extramammary mastalgia (history of previous breast surgery; inflammatory and/or tumoral breast or chest disorders such as mastitis, fibrocystic breasts, breast cancer, or chest malignancies etc.), having conditions that might prevent TENS application (pacemaker, metal prosthesis, epilepsy, etc.), and being unable or insufficient to fill the questionnaires. Patients with a family history of breast cancer and a high-risk group for breast cancer development were also excluded from the study. In patients with bilateral mastalgia, TENS was applied unilaterally to the more painful breast.

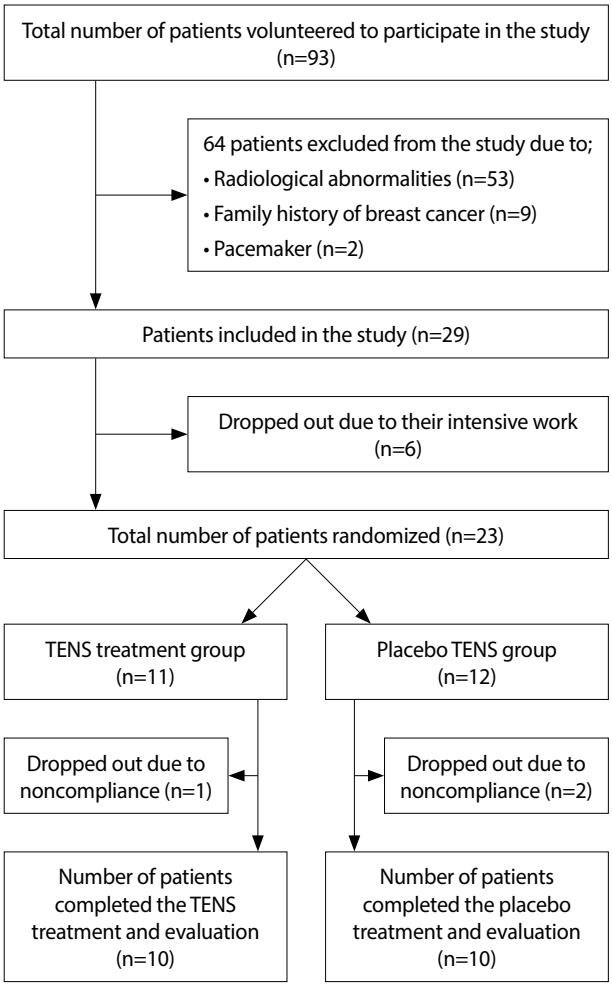

Figure 1. The flow chart of the patients participating in the study.

After a detailed history, all patients had a detailed breast examination and were evaluated using breast imaging techniques including mammography and/or sonography according to their age. Twenty consecutive patients who were eligible for the study were randomly assigned to receive either TENS treatment (TENS group, n=10) or sham TENS application (sham group, n=10) using computer-assisted randomization. The flow chart of the study is shown in Figure 1.

Intervention

TENS Treatment

In the TENS group, a total of 10 sessions of TENS treatment was applied to the breast at one-day intervals within 20 days. Patients were informed about TENS treatment in detail before application. Conventional TENS (BioMed™ 2000 TENS Unit, BioMedical Life Sys-

Figure 2. TENS electrodes (sticky patches) were placed on the breast as shown in the figure.

tems, Inc., Carlsbad, California, USA) at a frequency of 70 Hz and a wave width of 100 µs was applied for 30 minutes. Electrodes were placed around the breast at 1, 5, 7, and 11 o'clock positions (Fig. 2). The amplitude density of the TENS device was adjusted as a current with a severity of mild tingling without causing a contraction and excessive discomfort to the patient.

In the sham group, TENS administration and intervals were the same as in the TENS group, but the electrical circuit to the electrodes was disconnected and no current was given to the patient. The patients in the sham group were patients who had not received TENS treatment for any reason before and were informed that they might not feel anything during the treatment. Patients were included in the treatment program at different times in order to prevent interaction and feedback between patients. During the study, patients were allowed to use a maximum dose of 1000 mg acetaminophen if needed. Patients were asked to record the frequency and amount of drug use.

Assessment of Pain and Quality of Life

Pain intensity and QoL were evaluated before and 10 days after treatment in all patients. The Breast Pain Questionnaire (BPQ), derived from the McGill Pain Questionnaire, was used to assess breast pain intensity.[18] It is a tool that aims to evaluate the severity, pattern, location, duration and frequency of breast pain. It is calculated on the basis of visual analog scale (VAS) and present pain intensity (PPI) scores in addition to sensory and affective component scores. Regarding the final total BPQ scores, patients' pain severity was classified as mild (0–100), moderate (100–200), and severe (>200).[19] For the premenopausal women, BPQ was completed 2 days after the onset of menses to ensure the standardization of the study.

The Turkish version of the Short Form-36 version 2 (SF-36v2) was used to assess QoL before and 10 days after treatment.[20] It comprises 36 questions that cover eight domains of health including physical functioning, physical role, pain, general health, vitality, social function, emotional role, and mental health. For interpreting differences across scales, norm-based scoring of the SF-36 was used in this study.[21]

Statistical Analysis

Statistical analysis was performed using the SPSS statistical package (version 21). Chi-square or Fisher's exact test was used for categorical variables, and Mann–Whitney U test was used for non-normally distributed continuous variables and sequential variables. Intra-group comparisons were made using the Wilcoxon test on paired samples. Differences between categorical variables with two results in paired groups were analyzed by McNemar's test. p-value less than 0.05 was considered statistically significant.

Results

The TENS group had a mean age of 42.1±12.12 years, while the sham TENS group had a mean age of 46.8±11.16 years. Sociodemographic and clinical characteristics of the groups were similar (Table 1). Mammography was made only for patients aged 40 and over (12 of 20 patients) during the diagnostic evaluation of the patients.[22]

No significant difference was found between groups in terms of pain frequency, localization, type, use of analgesics, and the impact of mastalgia on sexual life, work, and sleep patterns prior to

Table 1. Demographic and clinical data of the groups

	TENS group (n=10)	Placebo TENS group (n=10)	p
Age (years), mean±SD	42.1±12.12	46.8±11.16	NS
Educational background, n			NS
Primary or secondary school	2	7	
High school	4	3	
University	4	0	
Body mass index (BMI), mean±SD	27.76±4.46	28.07±3.56	NS
Marital status, n			NS
Single	3	1	
Married	7	9	
Daily methylxanthine intake (number of cups), mean±SD	3.2±1.6	3±1.3	NS
Psychiatric conditions, n			NS
Depression	2	2	
Anxiety	2	1	
Posttraumatic stress disorder	0	1	
Eating disorder	1	2	
Panic disorder	1	2	
Unexplained pain syndromes, n			NS
Fibromyalgia	5	4	
Chronic pelvic pain	1	3	
Irritabl bowel syndrome	1	0	
Menopausal status, n			NS
Premenopausal	8	6	
Postmenopausal	2	4	
Type of breast pain, n			NS
Cyclical pain	7	3	
Non-cyclical pain	3	7	
Localization of breast pain			NS
Unilateral	5	8	
Bilateral	5	2	
Breast density classification (BI-RADS), n*			NS
Type I	0	1	
Type II	3	3	
Type III	2	2	
Type IV	0	1	

TENS: Transcutaneous electrical nerve stimulation; SD: Standard deviation; NS: Not significant; BI-RADS: Breast imaging reporting and data system.
*: This assessment was made only for patients aged 40 and over.

the study. After the application of TENS, notable enhancements were observed in the negative effects. However, the sham group only showed an improvement in their sexual activity (p=0.046). Analgesic use was significantly decreased in the TENS group compared to the sham group after the study (p=0.024). The pain patterns that were described as continuous, unchanging, constant, rhythmic, periodic and intermittent completely disappeared or turned into a more brief, momentary or transient pattern in the TENS group compared to the sham group after the study (p=0.003) (Table 2).

The TENS and sham groups were compared for total breast pain scores (Table 3). The mean total breast pain scores of the TENS and sham groups are 257.6±47.3 and 217.7±42.7, respectively. When comparing the alterations in the overall score and its components (sensory and affective components, VAS, PPI) before and after the study, we found significant enhancement only in the TENS group (p=0.005). There was also significant difference in the changes ratio of these parameters from BS to AS between groups in favor of the TENS group (p<0.001). The SF-36 norm-based scores are shown in Table 4. After the study, there was no improvement in the total score of SF-36 in the sham group (from 62.3±14.7 to 65.7±11.7); only the pain subscale improved (p=0.04). Total score and six subscales of SF-36 (physical and social functioning, energy/fatigue, pain, general health and health change) significantly improved in the TENS group (total score of SF-36; from 65.4±9.4 to 81.8±9.4).

No side effects were observed in any patient. The TENS treatment was easily tolerated.

Discussion

In the present study, the effects of TENS application, a non-invasive and easily applicable analgesic method, are investigated on mastalgia, which is common in the community and significantly affects quality of life. In the present study, we found that TENS therapy has beneficial effects on pain, sleep, sexual functioning, daily activities, and overall quality of life for patients suffering from mastalgia. To the best of our knowledge, this is the initial study to investigate the impact of TENS intervention on mastalgia in the literature. Mastalgia, a common condition faced by many women throughout their lives, unfortunately still does not receive adequate attention. Despite the various treatment options discussed in the literature, there is yet to be a gold standard method. Numerous treatment methods have been proposed in the literature for mastalgia, but their efficacy remains controversial. Among these, conservative methods are defined, including dietary modifications such as methylxanthine restriction and the use of supportive bras. Initial treatment methods also include supplements such as flaxseed, vitamin E, and evening primrose oil, as well as over-the-counter pain relievers.[1,11,23]

In addition to these methods, descriptions of pharmacological and non-pharmacological treatments are available. Pharmacological treatments include topical and oral NSAIDs, tamoxifen, bromocriptine, and danazol. The long-term use of drugs other than topical NSAIDs is limited due to potential side effects.[1,12] Conversely, the effectiveness of topical NSAIDs requires long-term use, such as six months.[24] In cases of persistent cyclic breast pain, it has been suggested that short-term treatments of bromocriptine or danazol, lasting 2–6 months, can be used if the benefits outweigh the side effects. Surgical options, such as bilateral mastectomy and reconstruction, have even been proposed as a last resort for cases of unresponsive and severe pain.[25] As a consequence, numerous women might suffer from breast discomfort, a type of distress that could hinder their daily activities. Regrettably, there are no established standards for its treatment.

TENS delivers pulsed electrical currents across the intact skin surface to stimulate peripheral nerves and is frequently used for pain management.[26] Additionally, TENS activates central inhibitory pathways and decreases central excitability. It has been demonstrated that TENS elevates the pain threshold both within and beyond the treatment area.[14,15] In light of this evidence, it is suggested that TENS application could provide benefits from its central effects, particularly in cases of bilateral mastalgia, in addition to its potential for local effects in the treatment of mastalgia. Our study findings imply that TENS therapy, leading to a marked decrease in the total breast pain score and altering pain patterns to a more momentary and fleeting form, may be an effective treatment for mastalgia. As a result, TENS therapy has a considerable positive impact on one's quality of life. The attainment of successful outcomes with just 10 sessions administered over a period of 20 days suggests that TENS therapy might be a viable substitute when treating mastalgia, especially when considering the extended usage duration of pharmaceutical approaches (which ranges from 2 to 6 months) and the possibility of harmful side effects.

There are some limitations to this study. One of the most important limitations is the small sample size. A power analysis was not carried out for this study

Table 2. Distribution of breast pain characteristics of the groups and the effect of treatments on the breast pain pattern

Characteristics of breast pain	TENS group (n=10)	Placebo TENS group (n=10)	p
Localization, %			NS
Unilateral	60	70	
Bilateral	40	30	
Type, %			NS
Cyclical	60	40	
Non-cyclical	40	60	
Frequency, %			NS
Every hour	10	0	
Every day	40	30	
Every week	20	30	
Every month	30	40	

	TENS treatment group			Placebo TENS group			p[3]
	BS	AS	p[1]	BS	AS	p[2]	
Pattern, %			**0.011**			NS	**0.003**
Continuous	30	0		40	30		
Continuous/steady	40	0		60	50		
Continuous /constant	30	0		50	30		
Rhythmic	30	0		30	30		
Periodic	30	0		30	20		
Intermittent	40	0		20	10		
Brief	20	70		30	20		
Momentary	20	40		20	10		
Transient	0	50		10	30		
Use of analgesics, %			**0.030**			NS	**0.024**
Yes	70	10		40	40		
No	30	90		60	60		
Negative effect on working patterns, %			**0.004**			NS	**0.007**
None	10	90		40	70		
Mild	70	10		60	30		
Moderate	20	0		0	0		
Severe	0	0		0	0		
Negative effect on sleep patterns, %			**0.023**			NS	NS
None	40	100		50	70		
Mild	40	0		50	30		
Moderate	20	0		0	0		
Severe	0	0		0	0		
Negative effect on sexual life, %			**0.020**			0.046	NS
None	40	90		40	80		
Mild	40	10		60	20		
Moderate	20	0		0	0		
Severe	0	0		0	0		

TENS: Transcutaneous electrical nerve stimulation; BS: Before study; AS: After study; NS: Not significant; p1: BS values vs. AS values in TENS treatment group; p2: BS values vs. AS values in placebo TENS group; p3: The comparison of changes from BS values to AS values between two groups.

Table 3. Comparison of mean values of total breast pain scores before and after the study

	TENS group (BS)	Placebo TENS group (BS)	TENS group (AS)	Placebo TENS group (AS)	p^1	p^2	p^3	p^4
Total breast pain score	257.6±47.3	217.7±42.7	123.6±11.6	209.7±54.4	0.089	0.508	**0.005**	**<0.001**
Sensory component	16.2±6.3	13.2±4.6	3.1±3.0	14.1±4.5	0.353	0.384	**0.005**	**<0.001**
Affective component	3.5±1.7	2.7±1.9	0.3±0.5	2.9±2.3	0.393	0.516	**0.005**	**<0.001**
VAS	2.8±0.8	2.2±0.6	1±0.0	2.2±0.6	0.075	1.000	**0.005**	**<0.001**
PPI	5.8±1.3	4.9±1.2	1.2±0.8	4.5±0.8	0.123	0.157	**0.005**	**<0.001**

Values are mean±standard deviation. TENS: Transcutaneous electrical nerve stimulation; VAS: Visual analog scale; PPI: Present pain intensity; BS: Before study; AS: After study; p1: The comparison of BS scores between groups; p2: BS scores vs. AS scores in placebo TENS group; p3: BS scores vs. AS scores in TENS treatment group; p4: The comparison of changes from BS values to AS values between two groups.

Table 4. Comparison of mean values of SF-36 subscales before and after treatment

	TENS group (BS)	Placebo TENS group (BS)	TENS group (AS)	Placebo TENS group (AS)	p^1	p^2	p^3	p^4
SF-36 mean score	65.4±9.4	62.3±14.7	81.8±9.4	65.7±11.7	0.579	0.093	**0.005**	**0.001**
Physical functioning	83.5±10.2	69.5±24.6	89±14.8	67.5±26.2	0.210	0.496	**0.031**	**0.035**
Role limitations due to physical health	77.5±29.9	67.5±39.1	92.5±16.8	87.5±17.6	0.532	0.063	0.109	0.656
Role limitations due to emotional problems	66.7±35.1	63.3±33.2	90.0±16.0	76.6±27.4	0.779	0.102	0.068	0.625
Energy/fatigue	59.5±20.3	60±9.7	76±10.4	57±8.8	0.848	0.303	**0.011**	**0.003**
Emotional well-being	67.2±17.6	62±12.2	71.2±13.9	57.6±7.8	0.287	0.088	0.270	0.077
Social functioning	58.7±10.2	65±24.8	86.2±18.1	67.5±16.8	0.661	0.480	**0.007**	**0.003**
Pain	55.5±8.3	57.3+16.3	82.7±11.3	64±19.6	0.699	**0.040**	**0.005**	**0.003**
General health	57.5±13.9	58.5±17.6	65±13.7	56.5±15.2	0.939	0.206	**0.035**	**0.021**
Health change	60±24.1	57.5±20.5	77.5±24.8	57.5±16.8	0.898	1.000	**0.038**	**0.036**

Values are mean units±standard deviation. TENS: Transcutaneous electrical nerve stimulation; BS: Before study; AS: After study; p1: The comparison of BS scores between groups; p2: BS scores vs. AS scores in placebo TENS group; p3: BS scores vs. AS scores in TENS treatment group; p4: The comparison of changes from BS values to AS values between two groups.

because it was the first time that this treatment was used for mastalgia. The effectiveness of the treatment was assessed on day 10, so the long-term effectiveness of the treatment could not be shown.

Conclusion

In conclusion, TENS application reduces pain intensity and analgesic use, creates positive changes in pain pattern, and improves quality of life in patients with mastalgia. Nevertheless, further research with larger sample sizes is required to ascertain the ideal duration and intensity of treatment, as well as the optimal pulse frequency since this exploratory study is the first of its kind.

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