Pain Relief for Office Hysteroscopy: A Randomized Controlled Trial Comparing a Transcutaneous Electric Nerve Stimulation to Placebo

Hatem H. El-Gamal MD, Rania G. El-skaan MD*, Ebtihal S.A. Al-Nomany M.SC, Mortada E. Ahmed MD
Obstetrics and Gynecology Department, Faculty of Medicine, Ain Shams University, Egypt

Running title

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Abstract

Background: More research is needed to determine the efficacy of transcutaneous electrical nerve stimulation (TENS) as a non-invasive pain control technique during office-based hysteroscopy.

Objective: To assess the analgesic effects of transcutaneous electrical nerve stimulation (TENS) in office hysteroscopy procedures, as well as patient satisfaction with this intervention.

Patients and Methods: The study included 120 female volunteers who underwent office hysteroscopy and were divided into two groups: TENS group (60 individuals) who got active TENS via a healthtronic alpha wave instrument, and the Placebo group (60 participants) who received placebo TENS.

Results: The study declared that both TENS and placebo groups reported equal degrees of pain during hysteroscopy, with no significant changes in pain severity pain ($p = 0.11$) or satisfaction ratings. The VAS score linked positively with age and parity, but adversely with height and the Likert verbal scale.

Conclusion: The TENS device does not significantly alleviate the pain associated with office hysteroscopy.

Keywords: Hysteroscopy, TENS, Pain.

Introduction:

Hysteroscopy is a reliable and efficient method for treating intracavitary uterine problems, including thick endometrium caused by postmenopausal bleeding, suspected endometrial cancer, Abnormal uterine bleeding, infertility, or recurrent pregnancy loss. It is a safe and convenient procedure that requires minimal invasiveness. [1]

Corresponding author:
Rania Gamal El-skaan. Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University Cairo, Egypt, Email: dr.raniagamal2015@yahoo.com , ORCID id: 0000-0003-1338-7470

The hysteroscopy procedure involves the insertion of a device into the uterus through the cervix. It has the potential to be either rigid or flexible. Distention media, commonly saline, is employed to facilitate the enlargement of the uterine cavity. Subsequently, the hysteroscope is employed to visualize the endometrium, and if necessary, endometrial biopsies may be. performed. [1]

While the majority of women exhibit a high level of tolerance, with a successful completion rate ranging from 77% to 97.2%, the presence of pain can impede the successful completion of many subsequent hysteroscopies due to the resulting inconvenience. [2]

The efficacy of medications, paracervical or intracervical blockers, and topical analgesia in reducing pain intensity has been uneven, with no single method demonstrating the highest level of effectiveness. [3] TENS, or transcutaneous electrical nerve stimulation, is a relatively unexplored method for mitigating pain during office-based hysteroscopy. TENS is a cost-effective, non-intrusive, and secure therapy option, with few negative effects or drug interactions. The application of electrical currents to the skin is employed as a means of pain relief, bypassing the necessity for pharmaceutical interventions via both peripheral and central pathways. [4]

TENS machines administer low levels of electrical current to vibration receptors in order to stimulate them and mitigate the transmission of painful stimuli to the brain. The repeated administration of transcutaneous electrical nerve stimulation (TENS) units to a specific region elicits the secretion of endorphins, which inherently alleviates pain. Due to this rationale, they possess the capability to address both acute and chronic pain.(6)Multiple studies have demonstrated the efficacy and adequacy of transcutaneous electrical nerve stimulation (TENS) in the management of gynecological and obstetric pain, encompassing the treatment of labor pain and postpartum pain. [7], [8] Hence, it is crucial to investigate the efficacy of TENS in managing pain associated with office hysteroscopy in the study.

Patients and Methods

This study used a double-blind randomized controlled design and included 120 female patients who underwent office hysteroscopy at Ain Shams Maternity University Hospital's Early Cancer Detection & Gynecology Unit. The study ran from March to July 2019. The study was formally filed on the ClinicalTrials.gov website with the unique identifier NCT04229576.

The study included female patients aged 21 to 74 with leiomyoma or endometrial polyps, postmenopausal hemorrhage with thick endometrial lining, menstrual disturbance, or suspected uterine deformity. Women with unexplained vaginal hemorrhage, neurological impairments, opioid or psychotropic drug use, either preprocedural or chronic, prior transcutaneous electrical nerve stimulation (TENS), automatically implanted pacemakers, or cardiac defibrillators were excluded from this trial.

The patients were randomly assigned to two equal-sized groups, as indicated below. Group 1 (the study group) included 60 patients who received Active TENS during office hysteroscopy. In contrast, group 2, sometimes known as the control group, included 60 patients who got Placebo TENS. Participants in the Placebo TENS group were attached to the TENS device in the same way as those in the Active TENS group. However, during office hysteroscopy, the equipment produced the active indication light and sound but provided no electrical stimulation. All patients received Upon arrival, a thorough clinical examination was performed, and a precise medical history was obtained (Figure 1).

The allocation concealing strategy employs the use of successive numbers on opaque, sealed envelopes. These envelopes are assigned the letters "A" or "B" depending on

a computer-generated sequence. Each envelope includes a letter corresponding to a number from the randomization list. The note enclosed in the mail determined the allocation of participating ladies to each group.

The TENS intervention is also known as the active TENS instrument. The Healthtronic Alpha Wave comes with four wide pads, two channels, and two leads. The pulse width is 200 μs, and the frequency ranges from 40 to 100 Hz. The MB-1004 model had a tunable high-frequency range of 80 to 100 Hz with a pulse duration of 400 microseconds. The TENS treatment began 5 minutes before the hysteroscopy surgery and continued throughout the operation. Two sets of self-adhesive electrodes (circular pads) were placed parallel to the spinal cord at T10-L1 and S2-S4 levels.

The primary outcome of the office hysteroscopy approach was pain level, which was assessed five minutes after operation. The assessment was performed on a visual analog scale (VAS) with a horizontal line of 100 mm (0 mm = no pain, 100 mm = intense pain sensation). Every hysteroscopy procedure included documentation of unpleasant or unexpected vasovagal symptoms, such as dizziness and nausea. TENS complications can include skin allergies, pain, or a burning feeling when the electrode is implanted.

After completing the procedure, the level of satisfaction with hysteroscopy was assessed using a verbal Likert scale with the following response options: "very dissatisfied," "dissatisfied," "natural," "satisfied," and "very satisfied."

Results

Table 1 presented the demographic data. In both the active TENS group and placebo group, the mean ages of the patients were found to be comparable ($p = 0.91$), with values of 39.32 ±11.9 and 39.58 ±12.2 years, respectively. The statistical analysis revealed that there were no significant variations in weight and height between the two study groups ($p = 0.44$ and $p = 0.54$, respectively). Moreover, no statistically significant disparity was seen between the groups with regards to parity ($p = 0.64$), as well as the frequency of nulliparous women ($p = 0.51$), gravidity ($p = 0.16$), previous vaginal deliveries ($p = 0.38$), and previous cesarean sections ($p = 0.35$).

In all groups, hysteroscopy was the most commonly requested procedure for the following indications: abnormal uterine bleeding, postmenopausal hemorrhage with suspicious endometrial thickness, and abnormalities observed in ultrasound. After considering any signs of office hysteroscopy or previous office hysteroscopy ($p = 0.53$), there was a non-significant difference between the groups. ($p > 0.05$).

The pain levels during the office hysteroscopy operation were found to be comparable between the TENS and placebo groups. However, no statistically significant differences were observed in the VAS assessment ($p = 0.311$) or pain intensity ($p = 0.11$). Table 2

In relation to the verbal Likert satisfaction rate, it was determined that there was no statistically significant difference in the satisfaction rate between the TENS and placebo groups. ($p = 0.351$). (Table 3)

Both groups reported experiencing symptoms during and after hysteroscopy. There were no statistically significant differences seen in the frequency of vertigo, perspiration, shoulder discomfort, nausea, and dizziness, there were differences with no significance statistically between the groups. (Table 4)

The associations between various factors and VAS scores are presented in Table 5. Positive correlations were seen between the VAS score and the age ($r = 0.256$, $P < 0.001$), as well as parity ($r = 0.404$, $p < 0.001$). Conversely, negative correlations were found between the VAS score and the patients' height ($r = -0.317$, $p < 0.001$), and the Likert verbal scale ($r = -0.278$, $p < 0.001$).

Discussion

Given the extensive utilization of transcutaneous electrical nerve stimulation (TENS) in the management of acute and chronic pain, our objective was to investigate its efficacy in pain reduction during office hysteroscopy and assess patient satisfaction with the operation. Our findings indicate that TENS was not efficacious in alleviating pain during a hysteroscopy, as there was no statistically significant difference observed in the VAS scores (p=0.311) or pain intensity (p=0.11) between the study groups. Furthermore, the present study revealed poor outcomes in relation to pain alleviation through the utilization of TENS, as evidenced by comparable satisfaction rates (as measured by the verbal Likert scale) between the two groups (p = 0.351).

This observation aligns with the findings of a study conducted by Hruby et al. (2010) including 142 patients who were divided into two groups: TENS and controls. The results indicated that the Visual Analog Scale (VAS) scores were comparable before and after the operation, with no statistically significant differences observed between the study groups at time intervals of 30 seconds, 1 minute, and 5 minutes. The study found that the TENS device did not provide any notable alleviation of pain, and the increase in pain scores observed in the control group might be attributable to the higher level of difficulty. This study employed the office cystoscopy method instead of office hysteroscopy.

Nevertheless, our results diverged from those of other research, such as Angelis et al. (11), who assessed the pain level using VAS during office hysteroscopy. The TENS group (A) achieved significant results compared to the control group (B) (group A mean, 3.71 + -2.06; group B mean, 5.07 + -2.03; P <.0004). The observed disparity can be attributed to variations in the utilization of the TNSE device. Specifically, the patients in the TENS group were required to effectively manage their discomfort throughout the hysteroscopy procedure.

During the five to ten minutes preceding the assessment, the patient had the placement of two electrodes in their abdominal region. Due to the device being set to a baseline level of stimulation, the patient experienced a mild tickling sensation in the gap between the electrodes. Subsequently, the patient was instructed on the proper operation of the gadget. If she experienced agony. Lisón et al. (9) conducted a comparison of the VAS scores between persons who received TENS and those in the placebo group. They saw a decrease in pain and discovered the smallest difference that was clinically significant. (P<0.001).

The authors attribute the substantial improvement in pleasure experienced after the surgery to the statistically and clinically significant pain reduction observed in the TENS group. Given this information, it is logical to conclude that the utilization of TENS could enhance the acceptance and frequency of office-based hysteroscopy procedures. The disparity in our study may be attributed to the utilization of an active TENS intervention by Lisón et al. (9), which involved a fluctuating high-frequency (80–100 Hz) and 400-microsecond duration.

However, in a study entitled "Effects of high-frequency, high-intensity transcutaneous electrical nerve stimulation versus intravenous opioids for pain relief after hysteroscopy," Platon et al. (12) conducted a comparison between two distinct methods of pain management after hysteroscopy surgery performed under anesthesia. The researchers found no statistically significant disparities between the two groups when evaluating pain scores exceeding 3. Patients who scored less than 3 on the Visual Analog Scale (VAS) were shown to have a substantially shorter duration of stay in the post-anesthesia care unit (91 minutes compared to 69 minutes, P=0.013) when compared to the opioid responders. He determined that employing TENS as an initial analgesic can reduce the need for postoperative opioids.

The findings of the present study indicate that there were statistically significant connections between the Visual Analog Scale (VAS) of pain and both height and Likert scale ($r = -0.317, -0.278$, and $p < 0.001, 0.001$, respectively). However, a notable positive association was seen between VAS of pain and age. The correlation coefficient is 0.256, with a p-value of 0.001. Lisón et al. (9) found a substantial positive correlation between the measurements of perceived pain obtained from the VAS and Likert scales. The VAS and Likert scale were evaluated at the beginning, contact, biopsy, and five minutes after the procedure. The Spearman rank correlation coefficients were 0.841, 0.890, 0.861, and 0.823, respectively ($P < 0.001$).

The variation in the results can be attributed to the utilization of diverse methodologies for the TENS procedure, variations in pain thresholds among women and cultural backgrounds, or the limited sample size of the study, both in terms of the total findings obtained in this study and those previously reported.

Conclusion

This was a randomized controlled experiment designed to assess the analgesic effects of transcutaneous electrical nerve stimulation (TENS) in office hysteroscopy procedures, as well as patient satisfaction with the intervention. The study's findings show that there was no significant difference in pain reduction and satisfaction levels between people who received transcutaneous electrical nerve stimulation (TENS) and those who received a placebo during hysteroscopy. As a result, we may conclude that the TENS device has no beneficial effect in reducing discomfort during office hysteroscopy. More research is needed to investigate various combinations of analgesic drugs with the goal of reducing pain perception during office hysteroscopy.

Limitation of the study

This research was subject to specific limitations including the cost and availability of TENS equipment in Egypt.

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Funding

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Competing interest

None to declare.

Consent for publication

Consent for publication was obtained from all participants before their recruitment in the study, and subsequently, following a comprehensive explanation of the study's objectives and methodologies.

Author Contributions

Rania G. El-Skaan: Manuscript writing; Ebtihal S.A. Al-Nomany: data collection and analysis; Mortada E. Ahmed and Hatem H. El-Gamal: Manuscript data revision.

Availability of data and materials

The data that support the findings of this investigation are available on the Data.mendeley.com website, however there are restrictions on their availability because they were utilized under license for the current study and are therefore not publicly available. However, the data are available from the authors upon reasonable request and with permission of the Mendeley data portal from: https://data.mendeley.com/drafts/f9z2vk3brp.

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Figure Legends:

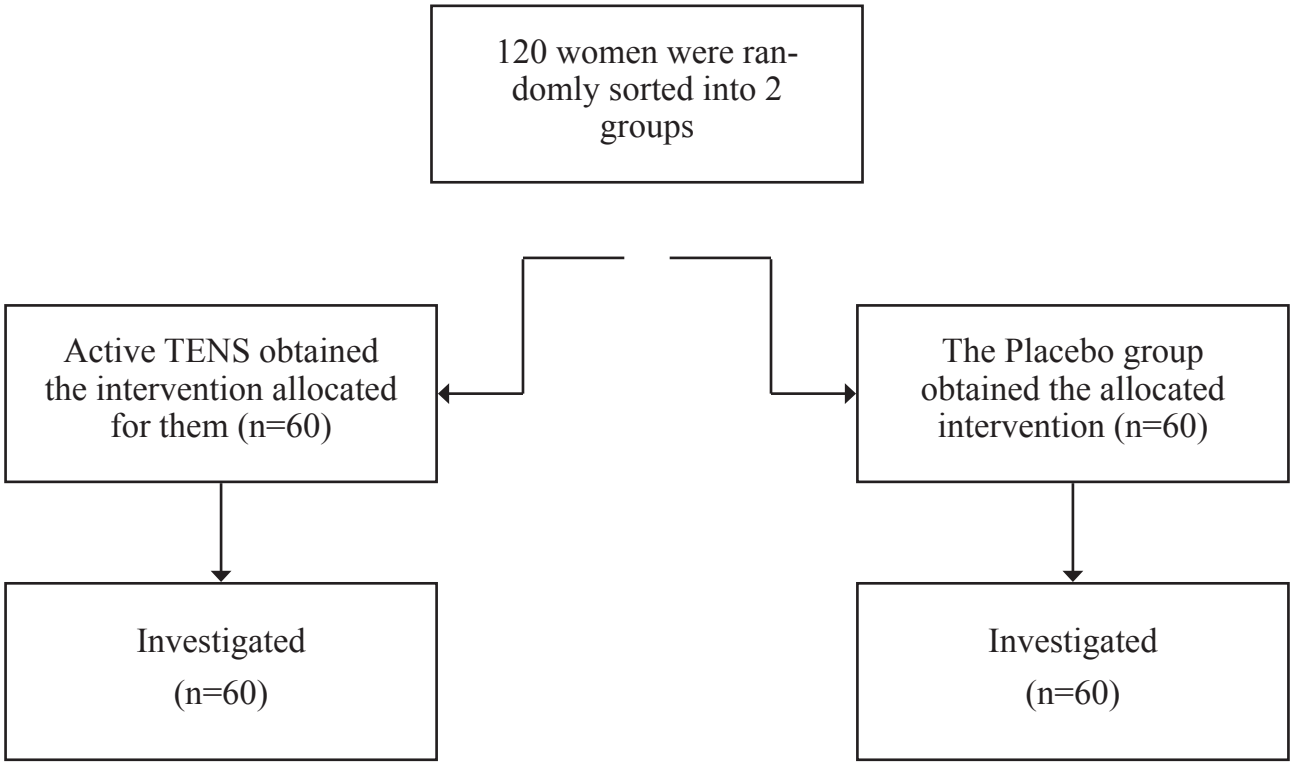

Figure 1. Flow chart.

Table (1): The demographic characteristics, obstetric History, and indications of hysteroscopy of the included patients

Variables	TENS group (N =60)	Placebo group (N =60)	P-value
Age [years]			
- Mean ±SD.	39.32 ±11.9	39.58 ±12.2	0.91
- Median (IQR)	38 (22 -70)	37.5 (21 -74)	
Height in cm			
- Mean ±SD.	158.4 ±5.9	157.7 ±5.8	0.54
- Median (IQR)	160 (150 -170)	158 (150 -170)	
Weight in Kg			
- Mean ±SD.	70.35 ±12.2	72 ±11.4	0.44
- Median (IQR)	70 (50 -98)	70 (50 -98)	
Parity			
- Mean ±SD.	2.3 ±2	2.17 ±2	0.64
- Median (range)	2.1 (0 -7)	2.1 (0 -11)	
Nulliparous, No. (%)	19 (31.7%)	16 (26.7%)	0.51
Gravidity			
- Mean ±SD.	0.5 ±0.9	0.35 ±0.57	0.16
- Median (range)	0 (0 -5)	0 (0 -2)	
Previous Vaginal delivery			
- P0	33 (55%)	40 (66.7%)	0.37
- P1-2	10 (16.7%)	9 (15.0%)	
- P>2	17 (28.3%)	11 (18.3%)	
Previous CS			
- 0	40 (66.7%)	44 (73.3%)	0.52
- 1-2	17 (28.3%)	15 (25%)	
- >2	3 (5%)	1 (1.7%)	

*Data are displayed as mean ±SD, median (Range), or number (%).

Table (2): Pain scores of the included patients

VAS	TENS involved group (N =60)	Placebo involved group (N =60)	P-value
- Mean ±SD.	6.25 ± 3.5	5.6 ± 3.5	0.311
- Median (range)	6 (1 - 11)	7 (0 - 11)	
- No pain	9 (15%)	7 (11.7%)	0.11
- Minimal	5 (8.3%)	6 (10%)	
- Mild	0	5 (8.3%)	
- Moderate	13 (21.7%)	11 (18.3%)	
- Severe	11 (18.3%)	7 (11.7%)	
- Very severe	8 (13.3%)	11 (18.3%)	
- Worst	14 (23.3%)	13 (21.7%)	

Table (3): The participants rate of Satisfaction rates

Verbal Likert scale	TENS involved group (N =60)	Placebo involved group (N =60)	P-value
Satisfaction rate - Very dissatisfied - Dissatisfied - Neutral - Satisfied - Very satisfied	16 (26.7%) 17 (28.3%) 12 (20%) 8 (13.3%) 7 (11.7%)	13 (21.7%) 18 (30%) 10 (16.7%) 12 (20%) 7 (11.7%)	0.351

Table (4): Patients experienced Symptoms.

Variables	TENS group (N =60)	Placebo group (N =60)	P-value
Dizziness, No. (%)	1 (1.7%)	1 (1.7%)	---
Nausea, No. (%)	1 (1.7%)	0	0.5
Shoulder pain, No. (%)	1 (1.7%)	1 (1.7%)	---
Sweating, No. (%)	1 (1.7%)	0	0.5
Vertigo, No. (%)	2 (3.3%)	1 (1.7%)	0.5

Table (5): Correlation between the VAS score and a number of different parameters

	VAS	
	Correlation Coefficient	**P- Value**
Age in years	0.256	<0.001
Weight	0.041	0.56
Height	-0.317	0.001
Parity	0.404	0.001
Satisfaction rate	-.0104	0.134
Likert scale	-0.278	0.001

*Data are presented as a correlation coefficient