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Original Article

Decreasing Discomfort During Shock-Wave Lithotripsy Using Transcutaneous Electrical Nerve Stimulation

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HIGHLIGHTS

- TENS can be suggested as effective and safe pain relief during ESWL.
- One of the problematic issues during Extracorporeal Shock Wave Lithotripsy (ESWL) is pain because anesthesia can have some side effects.
- we evaluate the Transcutaneous Electric Nerve Stimulation (TENS) as a non-invasive analgesic strategy during ESWL.

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ABSTRACT

Introduction
Shock wave lithotripsy (SWL) is a less-invasive procedure for treating a subgroup of renal stones. Since it may cause significant pain and anxiety during the procedure, several strategies have been proposed to reduce the discomfort during the SWL procedure. This study aimed to evaluate transcutaneous electrical nerve stimulation (TENS) as a non-invasive analgesic strategy during SWL.

Methods
A total of seventy-nine patients who underwent the SWL were included. The participants were randomly divided into two groups: the case group using conventional TENS (41 patients) and the control group without TENS. The visual analog scale (VAS) was recorded at the end of the SWL session. The analgesic (30mg ketorolac) was given in both groups due to the patient's request.

Results
Both study groups were similar in age, sex, BMI, history of SWL, hypertension, stone location, and stone size. Our data indicated less VAS in the case group than in the control group throughout the procedure, although it was not statistically significant (P-value=0.087). Conclusion: TENS can be offered as a non-invasive and safe pain relief strategy during the SWL.

Conclusions
TENS can be offered as a non-invasive and safe pain relief strategy during the SWL.

Keywords: Extracorporeal Shock Wave Lithotripsy; Transcutaneous Electrical Nerve Stimulation, Urolithiasis; Pain

Introduction

Urolithiasis is one of the most commonly encountered urological problems, with a lifetime prevalence of 1% to 15%, varying according to age, gender, race, and

geographic location. Since the 1980s, Extracorporeal Shock Wave Lithotripsy (SWL) has become one of the first-line options for treating some renal and ureteral calculi. Even though the method is considered a less invasive technique, pain caused by shockwaves is still a significant concern (1-3). The pain can be the consequence of two factors: First, the increased pressure within the kidney, and second, the SWL-related trauma of the skin and muscles. Furthermore, the effectiveness of this procedure is strongly linked to SWL-related pain and anxiety (4, 5).

Pain during SWL may lead to a higher rate of kidney hematomas due to a blood pressure increase (6). Several medications and methods, such as local, intravenous (IV), or oral non-steroidal anti-inflammatory drugs (NSAIDs) and opioid agents, are considered for pain management during SWL (7). The SWL has been widely used for treating urinary tract stones and is routinely administered as an outpatient procedure, although some patients do not tolerate it without analgesia (8). Transcutaneous electrical nerve stimulation (TENS) is a potential noninvasive pain relief strategy. In this method, low voltage electrical impulses transition through electrodes attached to the skin over the painful area. It is usually used to relieve a variety of painful conditions. A TENS unit contains an electrical signal generator, a battery, and a set of electrodes (9). Its mechanism is stranded by the 'gate control theory of pain transmission. The analgesic effects arise from the electrical stimulation of non-noxious afferent nerve fibers in the skin, inhibiting the transmission of nociceptive responses through the dorsal horn of the spinal cord. This effectively 'closes the gate', thereby decreasing the transmission of pain signals from the source of acute pain in the periphery to the central nervous system (10).

This article aimed to investigate the effectiveness of TENS, compared with 'sham' (i.e., placebo) to reduce pain in SWL.

Methods

The study was approved by the ethical committee institute in Iran (IR.TUMS.VCR.REC.1398.1041), and written informed consent was signed by patients. This prospective, randomized, comparative clinical study was done in the SWL unit in the Sina hospital and included 79 patients scheduled for SWL. All patients underwent a baseline evaluation of the renal function, urine analysis, urine culture, serum creatinine, and an abdominopelvic computed tomography (CT). The patient characteristics, including age, sex, body mass index (BMI), history of hypertension, SWL, and the size and location of the stone, were also recorded.

The inclusion criteria were all patients with 6–20 mm renal stones. The exclusion criteria were coagulation disorder, uncontrolled hypertension, uncontrolled arrhythmia, abdominal aortic aneurysm>4cm, pregnancy, demand pacemaker, dermatological lesions at the site of SWL(e.g., eczema or dermatitis), drug or alcohol addiction, stone in a solitary kidney, congenital urogenital anomaly, American Society of Anesthesiologists (ASA) physical status classification> II, age<18 and >80 years, multiple renal stones, history of infectious or struvite stone, stents such as double J (DJ) in urinary tract system, patients with immunodeficiency, flank pain (VAS>0). Seventy-nine patients were allocated to case (TENS) and control groups based on block randomization with blocks of size 6. All patients received 500–1000 ml of Ringer acetate solution over 30 min during the procedure. No premedication was given.

Case Group: Forty Patients in this group were informed about the TENS application before the procedure. One channel was used, in which two stimulator electrodes were applied paravertebrally just above and below the lithotripter shock tube. A stimulation frequency of 80 Hz and pulse width of 250 μs was selected. The current intensity was started at 10 mA and increased gradually until the patient perceived a prickling sensation with no pain. At that moment, shock waves were started pulse width (duration), 250-microsecond pulses for 5 minutes in a 10-seconds-on 20-seconds-off duty cycle.

Control Group: Thirty-eight patients with sham TENS.

In both groups number of shock waves was 2500-3000 shocks, with a frequency of 60-90/min, and voltage intensity was started at 1 kV and then increased gradually until a maximum of 16 kV. Pain scores were assessed with the 10-score linear Visual Analogue pain Scale (VAS). Parenteral ketorolac (30 mg) was given as the patient preference. At the end of each session, a questionnaire concerning the pain experience was completed by all patients using a visual analog scale (VAS; 0 no pain, 10 unbearable pain).

Statistical analysis

Baseline demographic and clinical characteristics are described as median (IQR) or frequency (percentage %) and compared between case and control groups. The Chi-square, Mann-Whitney U Test, and ordinal logistic regression were performed using R.4.0.2 and IBM SPSS (version 23; SPSS Inc., Chicago, IL, USA). Two-tailed (P values< 0.05) were considered significant.

Results

Out of 79 patients, 41 were in the case group, including 68% men (28) and 32% women (13) with a median age of 46 (IQR:33-54) years. In the control group, 38 patients were enrolled, consisting of 73% men (29) and 27% women (11) with a median age of 41 (IQR:35-49) years. The participants' history of SWL and hypertension were 75% and 21%, respectively. The mean ±SE of the VAS

Table 1. Comparing baseline and clinical characteristics of study subjects between TENS and control groups

Variables		Total (n=79)	Control Group (n=38)	TENS Group (n=41)	P-value
Sex (male), n (%)		55(69.6%)	27(71.1 %)	28(68.3 %)	0.678
Age (years), median (IQR)		42(33-53)	41(33-51)	46 (33-54)	0.743
BMI (Kg/m2), median (IQR)		28(25-31)	28(25-31)	27(24-31)	0.582
History of stone crushing (yes), n (%)		59(74.7%)	27(71.1 %)	32(78.0 %)	0.698
Location (right), n (%)		39(49.4%)	20(52.6 %)	19(46.3 %)	0.651
Hypertension (yes), n (%)		16(20.3%)	8(22.1 %)	8(19.5 %)	0.739
Stone size (mm), n (%)	**6-10**	31(39.2%)	16(42.1 %)	15(36.6 %)	0.599
	11-15	32(40.5%)	13(34.2 %)	19(46.3 %)	
	16-30	13(16.5%)	7 (18.4 %)	6(14.6 %)	

IQR: Inter quartile range; Chi-squared tests were used for association between categorical variable; and Man–Whitney U Tests for comparing continues variables between groups, Because of missing value, sum of percentage may not be equal to 100%.

Table 2. Pain intensity (VAS) in the end of study according to baseline characteristics

Variables		Pain intensity (VAS)				OR (95%CI)	P-value
		Mild (n=15)	Moderate (n=35)	Severe (n=25)	Very Severe (n=4)		
Group	TENS	10(24%)	19(46%)	11(27%)	1(2%)	0.48(0.21,1.10)	0.087
	Control (reference)	5(13%)	16(42%)	14(37%)	3(8%)		

VAS: Visual analog scale; values in each cell are frequency (Row percentage); OR: odds ratio; OR and P-value were calculated based on Ordinal Regression Model.

score was 4.45±0.18. The size and location of the stones were similar in both groups (P-value>0.05).

There were no significant differences between both study groups in terms of age, sex, BMI, history of SWL, hypertension, stone location, and stone size (Table 1). Figure 1 showed that the mean VAS score in the control group (4.8±0.27) was higher than the case group (4.1±0.25) but this difference was not statistically significant (P-value>0.088).

In Table 2, pain intensity is classified as mild pain (VAS: [0-2]), moderate pain (VAS: [3-5]), severe pain (VAS:([5-7]), and very severe pain (VAS: [8-10]). The frequency distribution of each category showed that many patients in the case group had mild, moderate, and severe pain, but many patients in the control group had moderate and severe pain. In the case group, 10 patients (24%) experienced mild pain, 19 patients (46%) experienced moderate pain, 11 patients (27%) experienced severe pain, and only one patient experienced very severe pain. However, in the control group, 5 patients (13%) experienced mild pain, 16 patients (42%) experienced moderate pain, 14 patients (37%) experienced severe pain, and 3 patients (8%) experienced very severe pain. Finally, we used ordinal logistic regression to detect any differences in pain severity between case and control groups. It was observed that patients in the case group had about 50% less pain compared to the control group, but it was not statistically significant.

Discussion

Treatment of urolithiasis has been revolutionized with extracorporeal shock wave lithotripsy (SWL) due to its simplicity, non-invasive nature, efficacy, and minimal morbidity (11-13). Pain experienced during SWL is considered multifactorial, including the type of lithotripter used, frequency, voltage, age, and sex of the patient (14). There is no consensus on the standard analgesic regimen for controlling pain during SWL. Conventionally, NSAIDs, opioids, and local anesthetics are used frequently (15). Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological, non-invasive, and inexpensive analgesic technique that has been practiced for pain control in many clinical settings (16). Previous studies have also reported that TENS can be used efficiently during SWL (17).

This article aimed to investigate the effectiveness of TENS, compared with 'sham' (i.e., placebo) to reduce pain in SWL.

The results of our study have similarities and differences with studies that have used TENS to manage acute pain. Karamaz and colleagues defined which TENS modality (conventional versus acupuncture-like)

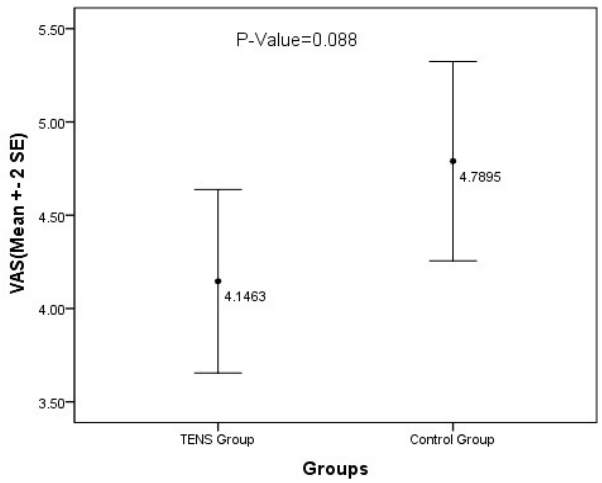

Figure 1. Comparing mean VAS score between TENS and Control Group

is more effective as an additional analgesic regimen during extracorporeal shock-wave lithotripsy (SWL). They proved that conventional TENS was more effective than acupuncture-like TENS in reducing alfentanil consumption and alfentanil-related side effects (18).

In the study, Randa Ali Shoukry and colleagues stated that TENS is an effective and safe practice in controlling pain during SWL, as it provides good analgesia and tolerability. It leads to a decrease in analgesic consumption and its side effects, with greater patient satisfaction. It decreases the time to discharge compared to fentanyl, which is ideal for outpatient procedures (9). In the study, O Reichelt and colleagues stated that TENS is a non-invasive, cost-effective method to achieve side-effect-free analgesia in SWL using third-generation lithotripters (19). Finally, due to the study's limitations and the small sample size, it is recommended that a similar study with a larger sample size be conducted more comprehensively. It is also recommended to examine the subgroups related to the demographic characteristics of patients to determine the differences in demographic variables on the effectiveness of TENS.

Conclusions

TENS can be considered an effective and safe pain relief during SWL although not established in this study.

Authors' contributions

All authors contributed equally.

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Conflict of interest

All authors declare that there is no potential competing or conflict of interest.

Funding

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Ethics statement

This study design were approved by the Ethical Committee of Tehran University of Medical Sciences (IR.TUMS. VCR.REC.1398.1041).

Data availability

Data will be provided on request.

Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body mass index
CT	Computed tomography
NSAID	Non-steroidal anti-inflammatory drugs
SWL	Shock wave lithotripsy
TENS	Transcutaneous electrical nerve stimulation
VAS	Visual analog scale

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