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EFFECT OF HIGH TENS ON PERCUTANEOUS NEPHROSTOLITHOTOMY (PCNL) POSTOPERATIVE NAUSEA AND VOMITING

Radnoush Shadmehri[1], Ahmad Mahdavi Kalimi[2], Sedigheh Rastaghi[3], Hasan Khalili[4*]

1. *MSc Student of Medical Surgical Nursing, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Sabzevar University of Medical Sciences, Sabzevar, Iran,*
2. *MSc of Physiotherapy, Department of Physiotherapy, School of Paramedical, Sabzevar University of Medical Sciences, Sabzevar, Iran,*
3. *MSc of Biostatistics, Department of Biostatistics, School of Health, Sabzevar University of Medical Sciences, Sabzevar, Iran,*
4. *MSc of Medical Surgical Nursing, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Sabzevar University of Medical Sciences, Sabzevar, Iran.*

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ABSTRACT

Background: Despite advances in antiemetic treatments, complications are still problematic for a significant number of patients after percutaneous nephrostolithotomy. The purpose of this study is to examine the effect of using High Transcutaneous Electrical Nerve Stimulation (TENS) on the severity of nausea and vomiting after percutaneous nephrostolithotomyMethods & Materials: In this study, 72 patients who underwent percutaneous nephrostolithotomy in Ghaem Hospital of Mashhad in 2016, were examined. This clinical trial, included three groups and was single blinded. Patients were randomly divided into three groups: control (24 peoples), intervention (24 peoples) and placebo (24 peoples). After surgery, in the intervention group, TENS with a frequency of 100 Hz, and current intensity based on patient tolerance at a distance of 5 cm from the nephrostomy for 20 minutes twice with an interval of six hours was established. In the placebo group, TENS unit was turned on, but with zero current intensity and frequency, i.e. no electrical stimulation. The severity of nausea and vomiting before and after the intervention was measured for 18 hours. For statictical analysis SPSS Software version 20 and chi-square test, Fisher's exact test, Mnn-whitney test, kruskal-wallis test, anova and Mauchly, s test, Kolmogorov-Smirnov test were used. Meanwhile utilized P value under 0.05 was assumed as significant in statistic tests. Results: The results showed that the severity of nausea and frequency of vomiting in the TENS group was lower than those of the placebo and control group but no statistically significant difference was observed between the three groups in the 18 hours after percutaneous nephrostolithotomy. The p-value was 0.96 and 0.74 for severity of nausea and vomiting, respectively. Conclusions: High TENS has not been able to significantly reduce nausea and vomiting in patients after percutaneous nephrostolithotomy.

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Introduction

Kidney diseases have been a worldwide health issue affecting millions of people [1]. G enerally, the chronic diseases (including urinary stones) follow many clinical, social and psychological problems; these problems in turn cause reduction of patient's quality of life [2]. Iran is a country with a great diversity of geography and climate and there is a big difference between temperature and humidity in different places [3]. Therefore, there are two factors that affect the spread of urinary stones, namely the weather and geographical location, currently present in the area, which probably creates the potential of residents for the formation of kidney stones [4, 5]. Urinary stones can be formed in kidney, ureters, bladder, prostate and urethra [6]. Most urinary tract stones are smaller than 6 mm without any intervention from the body, but most of the larger stones require surgical intervention for treatment. PCNL (Percutaneous *nephrostolithotomy* or *nephrolithotomy*) surgery is

Corresponding Author: Hasan Khalili, MSc of Medical Surgical Nursing, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Sabzevar University of Medical Sciences, Sabzevar, Iran, E-mail: khalili894 @ gmail.com

one of the methods of treating kidney and upper ureteral stones with less invasions. This method is often used when the stone is large, numerous and Staghorn calculi, or resistant to Extracorporeal Shock Wave Lithotripsy (ESWL)[4, 5]. Non-treatment of Staghorn calculi leads to the destruction of suffering kidney and in 30% of cases leads to the death of the patient [7]. Today, the use of PNL, especially for the treatment of Staghorn calculi's, is increasing [8]. Postoperative nausea and vomiting is one of the most common surgical problems and usually occurs after any type of anesthesia [9]. Occurrence of postoperative nausea and vomiting causes dehydration, electrolyte disturbances, and hypertension. This complication can increase the risk of pulmonary aspiration if airway reflexes is reduced due to the remaining effects of anesthetic drugs [9]. Also, nausea and vomiting increase the cost of treatment and delay the discharge of the patient from the hospital [10]. Postoperative nausea and vomiting is a complicated and multifactorial condition that a number of effective factors on it are known. These factors include intravenous and inhaled anesthetics, muscle relaxants, age, sex, history of nausea and vomiting, and motion sickness, obesity, decreased movement and delay in gastric emptying, postoperative pain, especially visceral and pelvic pain, Pain management with opioids and inadequate control of pain [11]. Symptoms and signs of gastrointestinal tract often associated with urologic disorders, due to autonomic and common sense nerves and renal-intestinal reflexes. The proximity of the right kidney to the colon, duodenum, pancreas, biliary duct, liver and bile duct may cause digestive disturbances. Also, the proximity of the left kidney to the colon (flattening), the stomach and spleen may lead to intestinal symptoms. The most common symptoms are nausea, vomiting, diarrhea, discomfort, and abdominal distension. One of the symptoms and symptoms of kidney and urethral pain is nausea and vomiting [12]. Because anti-nausea and vomiting drugs have unpleasant side effects or are expensive, alternative treatments are being investigated [13]. According to the evidence, Trascutaneous Electrical Nerve Stimulation (TENS) has been shown to reduce nausea and vomiting due to various conditions [14]. In the research, various types of TENS have been used to reduce postoperative nausea and vomiting, including: using TENS around the surgical incision to reduce pain and nausea and vomiting; using TENS at the neiguan acupressure point (P6) and use of TENS in the Vestibular system [14]. Despite a large search, there was no research on the effect of TENS on nausea and vomiting after PCNL surgery. Therefore, we decided to investigate The Effect of Using High TENS on the Severity of Nausea and Vomiting after Percutaneous Nephrostolithotomy, given the increasing incidence of this surgery in Iran and the importance of controlling nausea and vomiting after this research.

Methodology

The present study is a single-blind randomized clinical trial which was performed on 72 patients aged 15-70 years' old who were candidates for one side PCNL surgery who referred to surgery department of Ghaem Hospital. After approval by the ethics committee of the research and technology group of Sabzevar University of Medical Sciences with IR code number IR.MEDSAB.REC.1395.78 and Obtain informed consent from patients, the patients were randomly assigned to three groups of control (24 patients), intervention (24 Patient) and placebo (24 patients). The inclusion criteria of this study included consciousness of the patient, aged 15-70 years, unilateral PCNL surgery, ability to understand and speak Persian. Exclusion criteria included the incidence of unwanted complications recorded in the patient's case during and after surgery, using different anesthetic protocol with other patients, receiving anti-nausea in recovery, motion sickness, gastrointestinal diseases causing nausea and vomiting, mental retardation, mental illness and epilepsy, pregnancy, heart disease and cardiac arrhythmia, any scarring Scratches and deformities in electrodes placement areas, neuralgia and diabetic neuropathy, history of using and familiarizing with the TENS device, and any physiotherapy with the device, receiving anti-nausea drugs before operative, blindness and visual impairment Was considered.

The data collection tool included a checklist of demographic characteristics and surgical information, assessment of the severity of nausea, the amount of anti-nausea drug and the number of vomiting. The Visual Analog Scale (VAS) tool, numbered from zero to ten, was used to measure the severity of nausea from the patient's arrival to the department after completing surgery and complete consciousness until 18 hours later. The zero number indicates the absence of nausea and the number 10 indicates the most severe nausea. The VAS scale has been standardized and used in most research work and its validity and reliability have been measured.

Regarding the fact that the research units in this study were divided into three groups: control, intervention and placebo, in the intervention group: nephrostomy dressing in the operating room was done by a surgeon's physician with a size of 4 × 4 cm. After completing surgical and alertness of the patient so that there is complete awareness of the place, time and person and When the patient was admitted, the severity of nausea was evaluated using the relevant criteria and recorded. Then the skin of the patient was cleaned at the place where the electrodes were laid, with alcohol cotton and hot water for any secretion and fat and subsequently, electrodes coated with double-layer disposable wet pads, with a one-sided leather-coated layer to prevent loss the flow of the device, were connected 5 cm away from the nephrostomy of the kidney undergoing surgery. TENS Therapy was performed for 20 minutes at 100 Hz and the intensity of the flow was based on the patient's tolerance.

Then, immediately after the device was shut down, at the first and second hours, the severity of the nausea was evaluated with the desired scale. After 6 hours, after assessing the severity of nausea, TENS therapy was performed for 20 minutes with 100 Hz frequency and flow intensity based on the patient's tolerance, and after the device was shut down, again the

severity of nausea was evaluated at the seventh, eighth, and twelfth and eighteenth hours. Also, the number of vomiting was counted from the beginning of the patient's admission to the department, after surgery, and after receiving TENS for up to 18 hours. During these 18 hours, the rate of anti-nausea in the department that was performed by nurses according to surgical department protocol was also evaluated in patients.

In the control group, without any intervention by the researcher, the severity of nausea and vomiting after complete surgery and complete consciousness of the patient so that complete knowledge of the location and time of the person and during the admission of the patient in the department and during the first hours, the second, sixth, seventh, eighth, twelfth and eighteenth were evaluated and recorded. During this 18-hour period, anti-nausea rate was evaluated and recorded, as with intervention group.

In the placebo group: After doing the steps like the intervention group, no current was applied after attaching the electrodes to patient, turning on the TENS device, and setting its frequency and the current intensity (ampere) was set on zero. At all times, the device lamp remained turned and the patient was told that he or she might experience the tingling feeling at some extent or no feeling. TENS was used at two turns at interval of 6 hours for 20 minutes, as with intervention group. Nausea and vomiting severity and amount of receiving anti-nausea were evaluated and recorded at patient admission time and immediately before and after receiving TENS placebo at hours of 1, 2, 6, 7, 8, 12, and 18. TENS device (NEWDYN 620L model, manufactured by Novin Medical Engineering Company) was used for consistency in procedure of study.

In addition, all PCNL surgeries were also performed by one endourology and laparoscopy surgeon and all of these patients underwent general anesthesia by one anesthetist under single protocol. Descriptive statistics of mean and standard deviation, and frequency distribution were used for analyzing the data and describing the characteristics of research subjects in each of the three groups. Then, inferential statistics were used for analyzing the data and comparing the amount of nausea and vomiting in three groups (intervention, control, and placebo). Normality of quantitative variables was checked using Kolmogorov-Smirnov test. To evaluate three groups in terms of homogeneity in quantitative variables, one-way ANOVA was used in the case of normal distribution, and Kruskal-Wallis was used in the case of non-normal distribution. Fisher exact test and Chi-Square test were used for nominal and ordinal quantitative variables and level of statistical significance was chosen at $p<0.05$ as described by AlDossari and colleagues [15]. To compare nausea severity in patients in three groups (TENS, control, and placebo), repeated measures test was used, and Kruskal-Wallis test and one-way ANOVA were used to compare the frequency of vomiting in patients in three groups (TENS, control, and placebo). Confidence coefficient of 95% and the significance level of 0.05 were considered in all of the tests. In addition, significant difference was reported in the case of $p <0.05$.

Findings

Given the Table 1, the minimum age of subjects was 18 years and maximum age of them was 69 years, and their mean age was 41.46 years. Given the Table 2, out of 72 subjects, 47 of them were male (65.3%) and 25 of them were female (34.7%). Most of the subjects in this research were married (88.9%) and 52.8% of them were not self-employed, employee, worker, student, and retired. Education level of majority of the subjects was at moderate level (29.2%) and most of them underwent left kidney surgery (52.8%). Given the findings obtained from demographic variables, significant difference was not found among three groups in terms of gender, job, marital status, age, weight, and stone size, and three groups were matched in terms of these variables. Table 3 suggests that the mean of receiving the anti-nausea ondansetron after surgery was 1.00 mg in the control group, 0.86 in intervention group, and 0.66 in placebo group. Findings of Kruskal-Wallis test did not show significant difference among between the mean of receiving anti-nausea in the three groups ($p = 0.90$).

Table 4 suggests that the mean anesthesia time among 72 subjects of the research was 142.027 minutes and it was 140.04 minutes in the control group, 130.21 minutes in experiment group, and 155.83 in placebo group. Kruskal-Wallis test findings revealed a significant difference among three groups in terms of mean of anesthesia time ($p = 0.018$) and three groups are not matched in this regard. Thus, the effect of interventionist variable of anesthesia time in analyzing the data was moderated.

Discussion

Given the findings listed in Table 5, while more reduction in mean of nausea severity in the TENS group was seen compared to two other groups, no significant difference was seen among three groups of TENS, placebo, and control in this regard ($p = 0.95$). Reduction in nausea severity in the three groups might be due to passage of time. Additionally, based on the Table 6, no significant difference was seen among the three groups in terms of frequency of vomiting ($p = 0.74$). Silva et al investigated the effect of TENS on pain, nausea, and vomiting on 42 patients after laparoscopic cholecystectomy surgery in two groups of TENS and placebo. This research was the only founded research, in which electrodes of the TENS device were placed at surgical site and nausea and vomiting were evaluated. It findings revealed that the risk of nausea and vomiting in the TENS placebo group was 2.17 times more and it was concluded that active TENS reduces the nausea and vomiting in patients undergoing laparoscopic cholecystectomy surgery, while small sample size of the research reduced the

validity of the research findings [16]. In the research conducted by Neg et al, they evaluated the effect of Acu-TENS (TENS on acupuncture points) on heart rate, blood pressure, and nausea and vomiting of 60 patients in three groups of TENS, control, and placebo. Findings revealed that lower dose of antiemetic drug was required in Acu-TENS group. However, authors of the research stated that small sample size of patients suffering from nausea and vomiting in each group limited the research statistical analysis [17]. In a randomized prospective research conducted by Zou et al, they examined the effect of electrical nerve stimulation on acupuncture points in P6 area in order to prevent nausea and vomiting after craniotomy surgery. In this research, electrical stimulation was applied for intervention group 30 minutes before induction of anesthesia up to 24 hours after the surgery. Anti-nausea drugs, ondansetron at dose of 4 mg and dexamethasone at dose of 10 mg were used during the surgery. Findings of the current research revealed that vomiting incidence in the intervention group was significantly less than that in control group during 24 hours. Additionally, nausea incidence in the intervention group was significantly less than that of control group at hours 6 and 24, but the need for using anti-nausea drugs was similar in all three groups. It was concluded that electrical stimulation at P6 point might be effective help in drug treatment of nausea and vomiting in patients after infratentorial craniotomy surgery [18].

Table 1: comparing the mean age of subjects

Study group		TENS N=20	placebo N=20	Control N=20
age	mean	41.33	41.46	41.46
	SD	1.61	12.37	14.37

Table 2: frequency distribution of the patients studied in three groups of study, separately in terms of gender

variable	Group						Total	
Gender	TEST (tens) N=24		Placebo N=24		Control N=24			
	n	%	n	%	n	%	n	%
male	13	54.2%	19	79.2%	15	62.5%	47	65.3%
female	11	45.8%	5	20.8%	9	37.5%	25	34.7%
Chi-square test0.18=*p*								

Table 3: Comparing the mean of anti-nausea ondansetron in three groups of study

variable	group	n	mean	Confidence interval of 95%	
				Lower limit	Upper limit
Anti-nausea received	TENS	24	0.83	0.13	1.53
	Placebo	24	0.67	0.02	1.31
	control	24	1.00	0.10	1.90
	Total	72	0.83		
Kruskal Wallis Test 0.901=*p*					

Table 4: Comparing the mean time of surgery in the studied patients in the three groups of study

variable	group	n	mean	Confidence interval of 95%	
				Lower limit	Upper limit
Surgery time	TENS	24	130.21	121.09	139.33
	Placebo	24	188.83	142.098	169.57
	control	24	140.04	124.37	155.71
	Total	72	142.027		
Kruskal Wallis Test 0.018= *p*					

Table 5: Comparing the mean severity of nausea in studied patients in the three groups of study

variable	group	n	mean	Confidence interval of 95%	
				Lower limit	Lower limit
Nausea severity	TENS	24	0.81	0.43	1.18
	Placebo	24	0.88	0.51	1.26
	control	24	0.86	0.48	1.23
Kruskal Wallis Test 0.96=*p*					

Table 6: Comparing the mean number of vomiting in patients studied in three groups

variable	group	n	mean	Confidence interval of 95%	
				Lower limit	Lower limit
Number of vomiting	TENS	24	0.87	0.00	3.00
	Placebo	24	0.87	0.00	4.00
	control	24	1.083	0.00	4.00
	Total	72	0.94	0.00	4.00
Kruskal Wallis Test 0.74= *p*					

Conclusion

This research was conducted to evaluate The Effect of Using High TENS on the Severity of Nausea and Vomiting after PCNL surgery and data were analyzed and hypotheses were tested. The hypotheses of “using high TENS is effective in reducing nausea after PCNL surgery” and “using high TENS is effective in reducing vomiting after PCNL surgery” were not confirmed. It was found that High TENS could not significantly reduce nausea and vomiting in patients underwent PCNL surgery.

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