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Research Article

Effect of Transcutaneous Electrical Nerve Stimulation on the Pain Intensity During Insertion of Needle in Patients Undergoing Spinal Anesthesia: A Randomized Controlled Study

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ABSTRACT

Background and objectives: Needle insertion pain during spinal anesthesia is an unpleasant experience for patients. This study aimed to investigate the effects of Transcutaneous Electrical Nerve Stimulation (TENS) on the pain intensity during the insertion of spinal needles in patients undergoing spinal anesthesia.

Materials and methods: In a double-blind clinical trial, 60 candidates for elective Trans Ureteral Lithotripsy surgery under spinal anesthesia were randomly divided into intervention and control groups. The electrodes of the TENS device were placed in the space between L3-L4 and L5-S1 vertebrae. The intensity of pain during insertion of the spinal needle by Visual Analog Scale and the frequency of attempts were recorded.

Results: The mean age of the study samples was 34.26 ± 5.07 and 32.8 ± 5.28 in the control and intervention group, respectively. The pain intensity during insertion of spinal needles was less significant in the intervention group compared to the control group ($p = 0.001$). The number of attempts to insert the spinal needle between the two groups was not statistically significant ($p = 0.51$). The duration of spinal anesthesia implementation procedure by physician in the intervention group was significantly shorter than that of the control group ($p = 0.001$).

Conclusion: The use of TENS effectively reduced the pain of spinal needle insertion. Considering these beneficial effects, it is suggested that this procedure be used to relive pain in patients with spinal anesthesia.

1. Introduction

Spinal anesthesia with a spinal cord block in the subarachnoid space is obtained by a topical anesthetic solution, first introduced by Bier to the world in 1898 [1]. It includes spinal anesthesia indications, the surgery of lower abdominal, perineum and lower limbs [2]; This method has advantages such as the rapid onset of effect, less discomfort for patients, the less amount of required medication and the optimal sensory block [3].

The pain of needle insertion during spinal anesthesia is an unpleasant experience for patients, although pain is the result of many therapeutic measures, one of the most common causes is the perforation of the skin by the needle to inject the drug [4,5], which is in the acute group the same as postoperative pain [6]. This pain originates from the skin, tissues and layers from Dora. The pain caused by the needle insertion leads to discomfort, stress, and unwanted position change in the patient, the possibility of needle displacement and ultimately a failure in the block [7]. Today, there are many pharmacological and non-pharmacological pain

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management therapies [8]. Because pharmacological therapies are highly associated with complications, the use of non-pharmacological pain management therapies are more considered [9]. Methods such as mental deviation, relaxation, indoctrination and skin irritation are non-pharmacological methods. The use of electrical nerve stimulation is also one of the skin irritation method to control pain [10].

TENS is one of the non-pharmacological methods used to relieve pain by placing electrodes on the surface of the skin and electrical nerve stimulation. It is in fact a modified technique of acupuncture [11,12]. There are different theories about its mechanism in relieving pain, but most researchers agree that this device is effective in relieving acute and chronic pain with two mechanisms of gate control and secretion of endorphins [13,14]. This method has some advantages such as the simplicity of the technique, the lack of side effects, and the reduced consumption of narcotics and being inexpensive and cost-effective. Also, preparation of the patient in this method compared with other non-medical treatment methods is more convenient [15] The most commonly used conventional TENS, also called high TENS [16], has high frequency (40-150 HZ) and low current intensity (10-30 mA). In this method, pain relief is immediately achieved when the device is switched on, and disappears when it is switched off [17]. Since the pain caused by the insertion of the spinal needle leads to the patient's discomfort and can be one of the leading causes for their refusal to spinal anesthesia. Thus, this study aimed to investigate the effects of TENS on the pain intensity associated with the insertion of spinal needles on patients under the spinal anesthesia.

2. Materials and Methods

This study was a double-blind clinical trial. This study was performed on patients under the spinal anesthesia candidate for Trans Ureteral Lithotripsy (TUL) surgery who was admitted to Imam Reza hospital in Kermanshah City, Iran, in 2018. This study is registered on IRCT. Ir (Ref. No IRCT2017032727819N3) in the Iranian Registry of Clinical Trials. The research samples were patients undergoing TUL surgery who had criteria for entry into the study.

2.1. Inclusion criteria

The exclusion criteria include patients with anesthesia class ASA I and II, Not taking medications for pain control., opiate and sedative in last sex hours; the patient can understand the pain criterion culturally and answer the questions, the weight is less than 100 kg, ages 20 to 40 years old, not having spinal anesthesia contraindications, patient collaboration, non-diversion, and spinal cord diseases.

2.2. Exclusion criteria

The exclusion criteria included having pain in other areas, having a dangerous arrhythmia and a pacemaker, having a dermatological problem at the site of needle entry, diabetes or neuropathy, patient's dissatisfaction and refusal to collaborate, conversion of spinal anesthesia into general anesthesia, the need for using opiates and sedatives during spinal anesthesia.

2.3. Recruitment/randomization

Sixty patients who satisfied the inclusion criteria were divided into the control group (n = 30) and the intervention group (n = 30). The patients were then randomly divided according to even and odd numbers of patient's record in two groups.

2.4. Study design

This randomized, double-blind, placebo-controlled clinical trial, was performed on patients under TUL surgery. Neither the studied samples who had no previous history or familiarity with TENS nor the researcher, was aware of the treatment group they were in (double-blind).

In both groups, pharmacological premedication was not performed before anesthesia. When the patient entered the operating room, necessary blood pressure monitors, electrocardiogram and pulse oximetery were used, and all patients received 10 cc/kg/min ringer serum.

2.5. Intervention

The electrodes of TENS device were spaced 6 cm apart in the upper and lower parts of the needle insertion (the space between L3-L4 and L5-S1 vertebrae). The electrodes were circular with a diameter of 3 cm and a cross section of 28.26 cm^2.In the intervention group, a high-frequency TENS device (100 Hz) and a low-current intensity (20 mA) was performed. This pain relief method was performed immediately after the device was switched on [18]. In the control group, the electrodes of the device are attached to the patient, but the device is inactive and switched off. The area was disinfected by Betadine and then dried.

One minute after placing the TENS device electrode (intervention and control group), spinal anesthesia was performed in sterile conditions and the same method, using Quinck needle number 25, through modeling approach, sitting position by a 2.5 cc Bupivacaine drug 0.5% (Marcain) in the L4-L5 space by a specific and constant anesthetist in two groups. After insertion of a spinal needle and injection of anesthetic drugs in the subarachnoid space and removal of the needle, the intensity of the pain caused by the insertion of the spinal needle was measured by the Visual Analogue Scale (VAS) scale and recorded by the questioner in each of the groups.

2.6. Pain assessment

VAS is a 10 cm line with the word “no pain” at the left end of the line and “severe pain” at the right end of the line (zero marks no pain and 10 indicates the most severe pain). This scale is a self-reported pain measure, in which pain rate is determined by the patient and the amount of pain is measured with the ruler by a researcher. Its validity and reliability are confirmed in various sources and researches [19-21].

The number of attempts to enter the spinal needle was also recorded in the groups. Needle insertion time and finding subarachnoid space to the end of the anesthetic drug injection was also measured. In order to observe the double-blind study, the patient and the interviewer were not informed of activation or inactivation of TENS.

2.7. Statistical Analysis

The data collected in the present study were analyzed by SPSS software, version 19. The qualitative results were reported as an absolute and relative frequency, while the quantitative results were expressed as mean ± standard deviation (SD). The data analysis was performed using the independent t-test. The level of significance was set at $p < 0.05$.

2.8. Ethical Consideration

This study was approved by the ethics committee of Kermanshah University of Medical Sciences, Kermanshah, Iran (With approval No. IR.KUMS.REC.1395.762). Written informed consent was obtained from patients and they were assured of the anonymity and confidentiality of their information.

3. Results

The research samples were 25 (41.66%) female and 35 (58.33%) male that were not statistically significant ($p > 0.05$) using Chi-square test. The mean age of the research samples in the control group was 34.26 ± 5.07 and in the intervention group was 32.8 ± 5.28, which was not statistically significant ($p > 0.05$). The two groups were homogeneous in terms of underlying variables.

Analytical analysis of quantitative data was investigated by Kolmogorov–Smirnov test and samples had normal distribution.

Table 1 compares the amount of pain during the spinal needle insertion in the subarachnoid space for the intervention and control group. The results of the table show that the pain of needle insertion and drug injection for spinal anesthesia in the intervention group was significantly lower than in the control group ($p < 0.05$).

Table 2 shows the average number of attempts to insert a needle and perform spinal anesthesia. The results of the table show that the number of physician attempts to insert a needle and perform spinal anesthesia in the intervention group was less, but not statistically significant ($p > 0.05$).

Fig. 1 shows the duration of implementation spinal anesthesia procedure by physician. The Duration of implementation was higher (81.9 ± 20.38 sec, 66.2 ± 15.14 sec, respectively) in the control than in intervention group. This difference was statistically significant ($p < 0.05$). The results show that the duration of the procedure by the physician in the intervention group was significantly less than the control ($p < 0.05$).

Table 1
The amount of pain based on the VAS scale.

Group	Amount of pain	*p*-value
Intervention	2.66 ± 0.54	0.001*
Control	3.12 ± 0.48	

Data are presented as mean ± standard deviation of amount of pain based on the VAS scale in the control (n = 30) and the intervention group (n = 30). $p < 0.05$ was considered statistically significant differences.
* By using the T test.

Table 2
The number of attempts to insert a needle and perform spinal anesthesia.

Groups	Number of attempts	*p*-value
Intervention	1.36 ± 0.55	0.51*
Control	1.46 ± 0.62	

Data are presented as mean ± standard deviation of duration of number of attempts to insert a needle and perform spinal anesthesia in the controls (n = 30) and the intervention group (n = 30). $p < 0.05$ was considered statistically significant differences.
* By using the T test.

4. Discussion

Spinal anesthesia is painful and unpleasant for patients due to the spinal needle insertion. This pain causes the patient moving during the needle insertion and leads to possibility of needle displacement and failure to perform spinal anesthesia. Therefore, the use of methods and interventions to reduce pain can be helpful for the patient and anesthesia performance. The results of this study showed that the TENS can effectively reduce the pain during the spinal needle insertion into the spinal cord and make it easier for the patient and help anesthesiologist archive to better anesthesia (Tables 1 and 2 and Fig. 1). Previous research on the use of TENS in painful procedures, such as inserting Intera venous catheters in vessels, showed a significant reduction in pain score [22], which is consistent with the results of our study. Xia and et al. reported the efficacy of a 12-week TENS treatment versus sham TENS treatment on the pain intensity of spinal cord injury patients, in a clinical trial study [23]. In Chen's study reported that high frequency TENS at 80 pulses per second increases pain threshold to pressure algometry in healthy participants [24] which is consistent with the results of our study. Using a TENS electrodes at the needle insertion site near the spinal cord and applying a high frequency can increase extracellular GABA concentrations in the spinal cord [25] and decreases aspartate and glutamate release in the spinal cord [26]. Therefore, it can reduce pain in this area and at the level of the spinal cord and prevent the transmission of pain messages to the brain. Hashemi and et al. compared the effect of different methods of subcutaneous infiltration of topical anesthetics on pain during spinal anesthesia. Their study results showed that subcutaneous infiltration for inducing spinal anesthesia can be effective in the anesthesia process and patient satisfaction [7]. Massoth and et al. Examined topical anesthetic effects on pain during a lumbar puncture. The results of this study showed that the use of these pretreatments can effectively reduce the procedural pain and there is no statistically significant difference between the numbers of attempts to insert the spinal needle [27]. In our study, a non-pharmacological technique with electrical nerve stimulation around the needle insertion site was used to reduce pain, but topical anesthetic drugs have been used to reduce pain in mentioned studies. Topical ointment, like Emla cream, contains a mixture of lidocaine and prilocaine that penetrates the healthy skin and provides analgesia on the surface layers of skin at several millimeters. In order to be effective, it should be applied on the desired location one hour prior to operation. This method takes a long time to get started, as well, it has some side effects, including whitening of the skin, contraction of vessels, erythema, and edema, which are short-term effects of the drug, allergic complications including fever and rash, shortness of breath are another common complication of drug [28]. This could interfere with the work of the therapeutic team and delay the surgery. It is recommended to compare the effectiveness of two methods in relieving the pain of spinal needle insertion. Studies in various painful procedures using TENS showed a significant difference in relieving pain [29] and also,

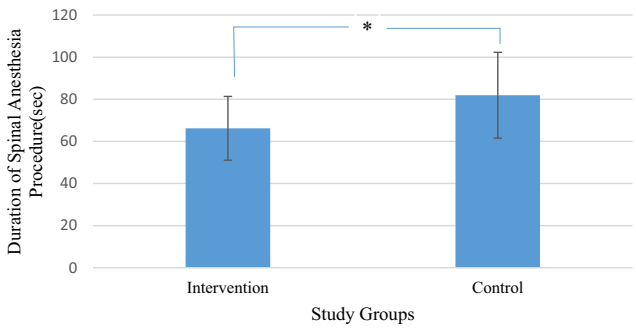

Figure 1. Graphs indicating average values ± standard deviation (SD) of duration of implemention spinal anesthesia procedure in the control (n = 30) and the intervention (n = 30). Bars indicate *$p < 0.05$. * By using the T test.

concerning the number of attempts to insert the needle, the results of these studies were consistent with the results of our study, and there was no difference between the groups. This can be attributed to the same needle insertion site and the performance by highly skilled anesthetists. There is a reduction in pain, but most researchers agree that this device is effective in relieving acute and chronic pain with two mechanisms of gate control theory of pain and secretion of endorphins [13,14]. Evidence from physiological studies has suggested that electrical peripheral nerve stimulation in the endogenous pain region is one of the most effective analgesic methods [30]. The mechanism of TENS in pain relief is not well understood; however, gate control theory provides the most widely accepted explanation of the mechanism [24]. Gate control theory postulates that the pain gate can be closed by the activity of large diameter Aβ afferents, preventing the transmission of noxious information. The closed pain gate results in low noxious information reaching the brain from the spinal cord, decreasing the sensation of pain. Therefore, the aim of TENS interventions is to activate Aβ fibers using electrical currents [23]. Pain is always a concern for researchers due to its impact on life quality, as an individuals' calmness disruptor, as well as the costs of controlling and treating it. Identification of non-pharmacological soothing treatments with the least complication and the most effective therapeutic goals in relieving pain.

5. Conclusion

The findings of this study showed that electrical stimulation around the spinal needle insertion site by TENS can relieve the pain and increase patient satisfaction. Given the fact that this method is non-pharmacological and has no side effects and no toxicity, it should be used in patients undergoing surgery and under spinal anesthesia. It is recommended additional studies for the efficacy and comparison of these analgesic effects with current methods for future studies.

Declaration of Competing Interest

All authors had an equal role in design, work, statistical analysis and manuscript writing. The authors declare no conflict of interest.

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