

Original Article

Effect of transcutaneous electrical nerve stimulation on pain intensity in reduced consciousness patients: A randomized clinical trial

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ARTICLE INFO

Received 11 November 2016

Revised 30 December 2016

Accepted 15 March 2017

Published 20 March 2017

Available online at:

<http://npt.tums.ac.ir>

Key words:

pain,
transcutaneous electrical
nerve stimulation,
non-pharmacological
methods,
abdominal surgery,
intensive care unit

ABSTRACT

Background & Aim: Pain is the main stressful factor in patients hospitalized in intensive care units (ICU). Non-pharmacological methods for pain relief are preferred by ICU patients due to lack of considerable side effects. The present research aims to determine the effect of TENS on pain intensity followed by surgery in patients hospitalized in intensive care units. Setting of the study was Besat Hospital in Hamadan, Iran. In this cross over clinical trial, thirty five patients hospitalized in intensive care unit with level of consciousness 9-12 based on Glasgow Coma Scale (GCS), assigned randomly to active/placebo TENS (18 patients) or placebo/active TENS (17 patients) sequence.

Methods & Materials: Patients received each intervention for two hours by a random order. A card was allocated to each patient on which the order of interventions was written. In placebo TENS, the system was off and no electrical stimulation was applied. Active TENS was applied by conventional TENS with frequency of 80 Hz within 330 milliseconds that is a subset of high TENS. Pain intensity were measured and recorded using Behavioural Pain Scale (PBS) before and 6 hours after intervention. Statistical analysis used: Data were analysed using SPSS 19 and independent t-test, chi square and Wilcoxon tests.

Results: Mean scores of pain intensity before and after active TENS was significantly different in both intervention order ($P=0.001$). Mean scores of pain intensity after placebo TENS was not significantly different in both groups. None of patients suffered from side effects after using TENS.

Conclusion: Based on results, application of active TENS reduced significantly pain intensity in patients after surgery. Concerning the simplicity of using this method and lack of considerable side effects, it is suggested to be used as pain relief in similar situations.

Introduction

Pain is as old as human history. Pain is a multidimensional event that is affected by environmental, psychological and biological variables (1, 2). It is accounted as an alarm for injurious tissue but human being is always seeking a solution for reduction it due to unpleasant feeling of pain (3). Based

on standards of Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), pain is considered as the fifth vital sign and it has to be recorded simultaneously with other vital signs and proper intervention should be performed (4, 5). Undoubtedly, pain relief of surgery site, especially in abdomen or chest, can improve wound healing, performance of limb, ability for coughing, removal of lung secretions and reduce hospitalization time (6,7). In addition, pain influences cardio-vascular system and delays the recovery of patient (8,

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9). Patients hospitalized in ICU experienced painful procedures due to routine care protocols (10). Approximately more than 70% of ICU patients experience moderate pain (5, 11). Although such patients may have no proper consciousness to express their pain. Painful measures and pain resulted from injury bring about problems after leaving ICU such as depression and painful memory of their treatment procedure (12, 13).

In spite of various pain management efforts, the pain is still accounted as a big stressful factor for patients hospitalized in ICUs. Non-pharmacological interventions can suggest several treatment options for management of pain (12, 14, 15). Transcutaneous electrical nerve stimulation (TENS) is one of non-pharmacological methods of pain relief which done by placing some electrodes on the skin and stimulating nerves electrically. One of the mechanisms of this method has been stated by Wall and Melzak and it is based on gate control theory of pain and it activates descending inhibitory system to prevent pain transfer (16, 17). TENS is a simple method with no toxicity which can apply for long term (18). However, some studies doubted about its positive effects (19). The positive pain relief effect of TENS on caesarean section (20) and cardiac surgery (21) is known. Also it can increase the toleration threshold of pain in combination with other interventions (22). However, there are some studies that have challenged the efficiency of this method. The challenge is resulted from lack of high quality studies or lack of uniform studies in terms of population, place of TENS application or type of TENS (23). In the systemic review that evaluated the papers related to effect of TENS on pain after knee arthroplasty authors concluded that such papers are methodologically weak. Also, bias may be probable against

therapeutic effects of TENS (24). Results of Toker et al (2015) suggested that mean pain intensity experienced by control and case groups after TENS was not significant (25). In another study, researchers found that there was no significant difference between the effect of active and placebo TENS on pain intensity during rehabilitation following total knee arthroplasty (26).

Since it is necessary to control and relieve pain in patients with low consciousness level with the least side effects. TENS as a non-pharmacological and safe method can be used for postoperative pain in patients hospitalized in ICU. The present study aims to determine the effect of TENS on pain after abdominal surgery in patients with reduced consciousness level, hospitalized in ICU.

Methods

This is a random crossover clinical trial. The participants were patient hospitalized in ICU in Beasat hospital of Hamadan, at the west of Iran. The subjects include 35 patient which selected through purposive sampling and assigned randomly to active/placebo (18 patients) or placebo/active TENS (17 patients) sequence. Random allocation was done using balloting cards which the number of group has been written on them. The sample size was considered as 15 persons concerning previous studies and based on following sample size formula with confidence of 95% and power of 80% and standard deviations derived from the Parsa & Bashirian study (2013). Thirty five persons were chosen due to statistical considerations.

$$n = \frac{\delta_d^2 \left(z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2}{2(\Delta)^2} = \frac{15.25(1.96 + 0.84)^2}{2(2)^2} = 15$$

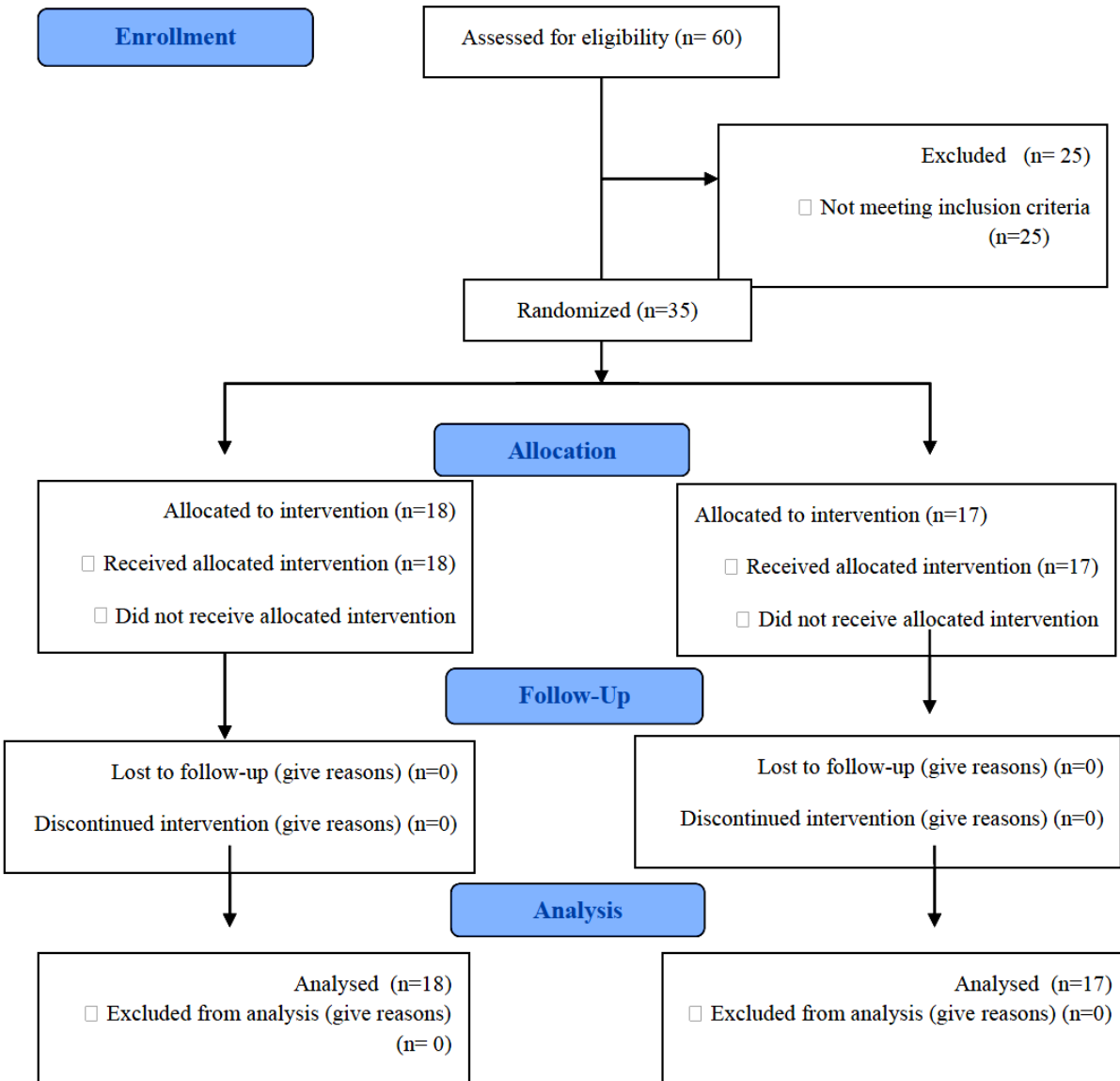


Figure 1. Consort flow diagram

Inclusion criteria include age of 18-65 years old, no severe facial injury, ability to move at least one upper limb, consciousness level based on Glasgow coma scale score between 9-12 with or without endotracheal tube. Concerning that the most pain is

experienced after operation within 48 hours, TENS has been used within abovementioned time duration. Exclusion criteria were variable consciousness of patient (higher or lower than the range), using drugs or performing painful procedures during

intervention and transfer of patient to another ward or hospital. The order of interventions was determined using mutual balance technique. A card was allocated to each patient on which the order of interventions was written (placebo TENS, active TENS and vice versa). A card was chosen randomly and the intervention was done based on the order included on the card. Therefore, each patient received both of placebo and active TENS. A 12hours stabilising period considered between two interventions in order to control the carry over effect. CONSORT 2010 Flow Diagram show the sampling process (figure 1).

Data collected using Behavioural Pain Scale (BPS) and demographic questionnaire including age, gender, type of surgery, number of hours after surgery, GCS score and amount of received analgesic. BPS is used for low consciousness patients in ICU who are not able to make verbal relationship and it includes three parts: the face status (one to four scores), sigh, whine and lack of coordination with ventilator (one to four scores), movement of upper limb (one to four scores). The scoring was based on 1 (without pain), 2 (mild pain), 3 (moderate pain) and 4 (sever pain). BPS was presented by Payn et al in 2001 and it is valid and reliable for evaluating pain of ICU patients^{12,25}. This instrument has been used in different studies in Iran such as the research conducted by Safari et al in ICUs of Hemedan hospitals in 2012²⁶. The first author applied the intervention and completed the pain intensity scale. Data analysed by a person who was not the member of research team in order to prevent bias against therapeutic effect.

The TENS Device used in this study was Novin 620 s and size of electrodes was 6×4 cm. Adhesive electrodes were attached on both sides of abdominal incision with one inch distance from the wound edge within 2

hours. In placebo TENS, the system was off and no electrical simulation was applied. Active TENS was applied by conventional TENS with a frequency of 80 Hz within 330 millisecond that is a subset of high TENS. Electrodes were placed regionally. Before and 6 hours after intervention, the pain intensity was measured and recorded using behavioural pain scale. Second intervention was done six hours after completion the BPS. In order to control the effect of painkiller, methadone was injected routinely and subcutaneously after permission of anaesthesiologist. TENS was done two hours after injection of painkiller based on its effective time duration. In order to control the effect of pain resulted from suction and position change, TENS was done at least 30 minutes after above mentioned measures.

Data were analysed by SPSS version 19 and statistic test including mean, standard deviation Wilcoxon test (to compare the mean score of pain before and after intervention), Chi square test (to compare heterogeneity of groups), Mann-Whitney test (to compare mean scores of pain intensity after active and placebo TENS. Residual effect of first intervention on second intervention (Carry over effect) was measured in pilot study. Based on Higgins and Green

if neither carry-over nor period effects are thought to be a problem, then an appropriate analysis of continuous data from a two-period, two-intervention cross-over trial is a paired t-test²⁸. Significance level has been considered as 0.05 in all tests.

This study with ethical code: IR.RUMS.REC.1394.186 was approved by ethical committee of Rafsanjan Medical Science University and it was registered in clinical trial centre with the code: IRCT 2016062227736N2. Since the consciousness of patients reduced, informed consent was

taken from main relatives of patients after expression of information, research objective and methodology. No patients had side effects resulted from TENS in present study.

Results

Results suggested that mean age of 35 patients was 61.19±10.54 years. Most patients were men (71%) and mean score of consciousness level was 9.91±1.14. TENS

applied 26.91±12.36 hours after surgery. Most patients had laparotomy surgery (68.6%). In most cases, 5mg methadone was taken two times a day for relieving the pain. There were 18 patients in group active/placebo TENS sequence and 17 patients in group placebo/active TENS sequence. Both groups had no significant difference in terms of demographic characteristics (table 1).

Table 1. demographic features of subjects in both groups

Personal features	Firstly active TENS	Firstly placebo TENS	P-value
Age	58.17±6.29	56.65±6.17	0.58
GCS level	9.89±1.18	9.94±1.14	0.89
Post-surgery hours	26.67±12.37	27.18±12.72	0.90
Gender	Woman (%)	4(22.2)	0.71
	Man (%)	14(77.8)	
Type of surgery	Colostomy	2(11.1)	0.61
	Cholecystectomy	3(16.7)	
	Laparotomy	13(72.2)	

Table 2. Comparing the mean pain intensity scores following abdominal surgery after application of active and placebo TENS

Pain intensity	Mean & standard deviation	N	Z	P-value
Pain intensity after active TENS	3.83 ±.61	35	Z =- 4.574	0.000
Pain intensity after placebo TENS	5.00 ±.84			

Table 3: comparing the mean pain intensity following abdominal surgery in patients with low consciousness before and after receiving intervention (active/placebo TENS sequence)

Type of TENS	Pain intensity		P-value
	Before intervention m±sd	After intervention m±sd	
Active TENS	5±0.97	3.83±0.70	(p=0/001) z=-3.247
Placebo TENS	5.17±0.98	5±0.9	z=-1.73 p=0.083

Table 4: comparing mean pain intensity following abdominal surgery in patients with low consciousness before and after receiving intervention (placebo/active TENS sequence)

Groups	Before intervention Mean±SD	After intervention Mean±SD	P-value
Placebo TENS	5.2±0.71	5±0.79	(p=0.06), z= -1.53
Active TENS	5.35±0.93	3.82±0.52	(P= 0.001), z= -3.34

Results of Kolmogorov-Smirnov test showed that data of pain intensity of patients does not follow a normal distribution (z= 1.403, p= 0.039). Therefore, Wilcoxon non-parametrical test was used to compare pain intensity before and after TENS application. In direction of research objectives, the researchers addressed the effects of active and placebo TENS in both groups and results suggested that mean pain intensity after active TENS was significantly less than placebo TENS so the active TENS, regardless of order of intervention, reduced pain intensity significantly (P= 0.000) (table 2).

In the active/placebo TENS sequence, there was significant difference in mean scores of pain intensity after receiving active and placebo TENS (P=0.001). comparing mean pain intensity before and after receiving active and placebo TENS via Wilcoxon test showed that there was a significant difference between them (P=0.001). Researchers also measured the difference of mean pain intensity before and after receiving placebo TENS which was not statistically significant (P=0.08) (table 3).

In the active/placebo TENS sequence, mean pain intensity was compared after receiving active TENS and placebo TENS. Results of Wilcoxon test showed that active TENS reduced significantly pain intensity more than placebo TENS (P= 0.002). Also, results of Wilcoxon test showed significant difference between mean pain intensities before and after receiving active TENS (P=0.001). Mean pain intensity was not statistically different before and after receiving placebo TENS (P=0.06) (table 4).

In present study, carry over effect analysis with t test showed that pain intensity scores before first intervention and before second intervention in active/placebo sequence (P=0.46) and placebo/active sequence (P=0.19) were not statistically different. This indicates the wash out period was sufficient.

Discussion

Results of the study showed that active TENS had a significant effect on reduction of pain intensity following abdominal surgeries while no change was seen in pain intensity after using placebo TENS. In addition, mean pain intensity was reduced after receiving active TENS in the groups. Vance (2014) believed that there was a challenge for judgment about efficiency or inefficiency of TENS in the papers and such challenge was lack of harmony of factors that affected directly efficiency of TENS. Therefore, factors such as samples, outcomes, time duration for measuring outcomes, and application of opioid should be considered for comparing studies (23). However, literature review showed that studies conducted on patients with low consciousness level who are not able to express their pain, only investigated non-verbal instruments for monitoring the pain and its importance and no paper was found similar to present study. Therefore, studies with similar methodologies used to compare results. In the study conducted by Rostaminejad et al (2010) on women who had caesarean, pain intensity, number of painful attacks and the number and amount of using drugs in the group in which drugs

were used simultaneously with TENS were lower than the group in which TENS has not been used (20). In study conducted by Soltanzadeh et al (2001), consumption of painkillers, pain intensity, time of discharge from ICU in patients who received TENS after coronary artery surgery reduced strictly and 80% of patients were satisfied with this method (29). In present study, according to anesthesiologist, painkillers were not used simultaneously with TENS. Therefore, the effect of TENS was measured merely on pain intensity and according to statistical tests; pain intensity was reduced significantly after application of active TENS which is in agreement with results of abovementioned studies. Results of Goyler et al (2014) on patients who had mastectomy surgery suggested that using two different types of TENS (TENS with low and high frequencies) reduced considerably amount of pain in patients and the type of TENS had no effect of pain reduction rather generally application of TENS was an effective method on pain reduction (30). In present study, active TENS was compared with placebo TENS and it was found that active TENS reduced significantly pain intensity compared to placebo TENS. Jerson et al used conventional TENS after coronary artery bypass graft in 2008. Results showed that the TENS used in surgical incision reduced systematic pain without any side effect (21). In present study, none of participants suffered from side effects. However, in the study conducted by Toker et al (2015), the effect of TENS and standard treatment on pain experienced during bone marrow sampling was investigated. Results suggested that mean pain intensity experienced by control and case groups was not significantly different after application of TENS. However, most of participants felt that TENS has been suitable for them and they wanted to recommend it to others (25). Although

participants were not able to express verbally the pain or application of TENS, non-verbal pain scale showed that application of active TENS reduced significantly pain intensity. The difference may be due to the population under study or the situation in which TENS is used. In the study done by Rakel (2014), the effect of TENS on pain control was investigated during rehabilitation from total knee arthroplasty and the researchers compared the effect of active TENS, placebo TENS and standard treatment. Results suggested that the effect of active and placebo TENS on pain intensity had no significant difference (26). In present study in which crossover active and placebo TENS was used, mean pain intensity after receiving active TENS was reduced significantly compared to placebo TENS. Different results may be due to the population or other interventions which such factors were controlled in present study. Since crossover method (in which each sample is accounted as its control) has been used in this study, several confounding factors were controlled. In addition, the researchers tried to implement the plan accurately by consult of specialists such as physiotherapist and anaesthesiologist.

Nowadays pain relief is along with promotion of patients' care and patient's satisfaction with healthcare services. Results of the present study suggest suitable effects of TENS (as a non-pharmacological pain relief method without any considerable side effect) in patients who are not able to express their pain. Therefore, concerning lack of information, results of the present study can create a new horizon in pain relief of patients with low consciousness level and affected patient satisfaction indirectly.

Acknowledgments

The present paper has been derived from M.S thesis in critical care nursing degree. The

authors appreciate financial supports of research office of Rafsanjan University of Medical Sciences. Also, they appreciate authorities of Besat hospital of Hamedan, personnel of intensive care unit (ICU) and patients who cooperate with this research.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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