PROTOCOL

Effect of Transcutaneous Electrical Nerve Stimulation on the Intensity of Postoperative Pain: A Protocol of Systematic Review

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ABSTRACT

Introduction: Pain is the most common complaint experienced by patients after major surgery, leading to complications and affecting the quality of life if not handled properly. TENS (Transcutaneous Electrical Nerve Stimulation) is a nursing intervention that uses electrical stimulation to activate beta-A fibers to control pain. TENS may also stimulate the production of body's natural painkillers namely endorphins. This systematic review aims to analyze the effect of TENS on the intensity of postoperative pain.**Methods:** This study is a systematic review that will use six databases (Pubmed, CINAHL, Proquest, Sciencedirect, ResearchGate, and Google Scholar) to search for randomized controlled trial articles in 2012-2020. The Center for Reviews and Dissemination, Cochrane Handbook for Systematic Reviews of Interventions, and PRISMA checklist as a guide in preparing the review and The Joanna Briggs Institute Critical Appraisal tools will be used to assess the quality of the study. This study will determine if TENS reduces the intensity of postoperative pain and will be synthesized using a narrative method by grouping the extracted data. **Discussion and Trial Registration:** The results of this review can be useful to determine the effectiveness of TENS in reducing postoperative pain intensity. This protocol has been registered on the protocol registration site for a systematic review, namely PROSPERO, with registration number CRD4202125439.

Keywords: Pain, Pain management, Postoperative, Transcutaneous electrical nerves stimulation

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INTRODUCTION

Surgery is a medical procedure that aims to save lives, prevent disability and complications (1). According to the latest data of WHO (2020), the number of surgical procedures from 62 countries is 71 million cases (2). Pain is the most common complaint experienced by patients after major surgery. Postoperative patients often experience pain due to tissue discontinuity or surgical wounds due to surgical incisions (6, 8). Based on the International Association for the Study of Pain (IASP), pain is defined as "an unpleasant sensory and emotional experience related to existing or potential tissue injury or described in terms of such damage"(7 p. 2). Pain intensity ranges from mild to severe and will decrease as the healing process (11).

Based on one study in the United States, almost more than 80% of postoperative patients experience postoperative pain (12). Garcia et al found that out of 80% of clients who experienced postoperative pain, 11-

20% experienced severe pain (13). This result is in line with research conducted in Indonesia (14), which 76% of patients continue to experience moderate to severe pain after being given analgesics. Walsh asserts (15), postoperative pain complaints in patients can disrupt comfort for clients. In addition, it is stated that "about 50% of post-elective postoperative patients experience pain which leads to an increase in the incidence of chronic pain and a decrease in patient satisfaction with health services" (10 p. 98). In patients experiencing major surgery, chronic pain is a major postoperative consequence (6). Postoperative acute pain continues to become chronic pain that impacts the emergence of mental disorders such as anxiety and decreased quality of life (9, 16). Chronic pain is usually caused by inadequate pain management. Inadequate postoperative acute pain management will make postoperative recovery difficult and lead to various health complications. Complications that can occur are infection, pneumonia, deep vein thrombosis, and depression (10).

Pain can be overcome with postoperative pain management in patients who have undergone surgery and occurs immediately or several hours after surgery (17). Management of postoperative pain can be done with pharmacological management in drugs and nonpharmacological management. Non-pharmacological pain management is a nurse's independent action to relieve pain without using drugs and focuses on applying caring behavior to patients (8). Non-pharmacological pain management has several advantages compared to pharmacological pain management, namely having fewer side effects (18). Non-pharmacological pain management conducted by nurses is very diverse, including anticipatory guidance, ice and heat therapy/ hot and cold compresses, distraction, relaxation, guided imaginary, hypnosis, acupuncture, biological feedback, massage, and transcutaneous electrical nerve stimulation (19).

The 2019 Nursing Intervention Classification (20), classifies TENS as a form of independent intervention from a nurse that aims to reduce pain. TENS is the most common and frequently used modality of the many physical therapy modalities (21). TENS is a modality using electrical stimulation to reduce pain sensations by blocking pain impulses sent to the brain (22). TENS works by stimulating beta-A-type nerve fibers, which can reduce pain (19). Its mechanism of action is thought to be through 'closing the gate' of pain transmission from small nerve fibers by stimulating large nerve fibers. Large nerve fibers will block the path of pain messages to the brain and increase blood flow to the painful area. In addition, TENS also stimulates the body's natural antipain production in the form of endorphins through the release of endogenous opioids in the CNS. TENS can cause analgesic effects through the endogenous opioid inhibitory system by activating the brain stem (23). TENS can be used in various conditions, one of which is postoperative patients and acute conditions (24). In its use, TENS has various advantages, including noninvasive, free from systemic side effects, simple, safe, does not require expensive costs, and allows patients to control therapy independently (25).

The initiation of nurses to use TENS as an alternative therapy in nursing care is a form of problem-solving in reducing postoperative pain in patients. The use of TENS needs to be based on various kinds of research that can scientifically prove the effect of TENS therapy on patients. Therefore, the researcher is interested in conducting another literature study on "The Effect of Transcutaneous Electrical Nerve Stimulation on the Intensity of Postoperative Pain". The formulation of the research question for this study was based on PICO mnemonic. It has been used most frequently in qualitative systematic reviews and centred on four key concepts: Population or Problem, Intervention or Exposure, Comparison and Outcome Measures. Based on these principles, in which the comparison aspect is not applicable, studies must include three main aspects in the review, namely adult patients with major postoperative pain (Population or Problem), Use of TENS (Intervention or Exposure) and Pain intensity (Outcome Measures), which will then guide this study to

formulate its main research question "Are TENS effective in reducing postoperative pain?".The general objective of this systematic review is to analyze the effect of TENS on the intensity of postoperative pain and will provide evidence for or against the hypothesis that TENS plays a role in reducing pain intensity.

METHODS

Study design

This systematic review uses the Center for Reviews and Dissemination, Cochrane Handbook for Systematic Reviews of Interventions and PRISMA (Preferred Reporting Items for Systematic Reviews and Metaanalyses) as a guide in developing a research protocol systematically. This review has been registered on the protocol registration site for a systematic review, namely PROSPERO, with registration number CRD4202125439. The PRISMA checklist containing 27 items will be used as a guide in preparing the review (26). The PRISMA flow diagram will be used to determine the selection of studies of a systematic literature review (27). The overall goal of PRISMA is to help ensure clarity and transparency in reporting systematic literature reviews (28).

Search strategy

Researchers will use electronic databases consisting of Pubmed, CINAHL, Proquest, Sciencedirect, ResearchGate and Google Scholar as sources of information to identify relevant studies. Each search will be limited to randomized controlled trial designs and randomized clinical trials published in English and Indonesian during 2012-2020. The article's search will use keywords to be matched with MeSH (Medical Subject Heading). Boolean operators (AND, OR NOT or AND NOT) will also be used to expand and specify the search results so that it can make it easier to select articles to be included in the review (30). The search strategy was described in English: (transcutaneous electrical nerve stimulation OR TENS) AND (operative procedure) AND (postoperative pain) AND (pain management) AND (pain measurement) and in Indonesian (stimulasi saraf elektris transkutan OR TENS) AND (prosedur operasi) AND (nyeri pasca operasi) AND (manajemen nyeri) AND (intensitas nyeri).

Eligibility criteria

The review questions' limitations were precisely specified through the implementation of inclusion and exclusion criteria applying the PICOS format (Table I). Studies are considered for inclusion in the review, if the following criteria are met : randomized controlled trials and randomized clinical trials (RCTs) in English and Indonesian between 2012-2020; the population are adult patients (age range 18-<65 years) with postoperative pain who received postoperative TENS intervention; explains the effect of TENS by measuring using VAS (Visual Analog Scale). Exclusion criteria are: RCT's published other than 2012-2020; quasy experimental,

PICOS Framework	Inclusion Criteria	Exclusion Criteria
Population	Adults and older adults (age range > 18-<65 years) with major post- operative pain	Studies that focus on pain problems other than major surgical wounds.
Intervention	A study that examines the TENS intervention given to postoperative respondents.	Studies examining the administration of preoperative TENS interventions, combinations of preoperative and postoperative or other interventions that not relevant.
Comparison	The comparison group is the intervention group that is given other interventions or is only observed without inter- vention	None
Outcomes	A study that explains the effect of TENS on pain intensity by measuring using VAS (Visual Ana- log Scale)	A study that explains the effect of TENS on pain intensity by measuring using the NRS (Numeric Rat- ing Scale) and VDS (Verbal Descriptive Scale)
Study design and publica- tion type	Randomized control trial, Randomized clini- cal trial	Quasy Experimen- tal, Cross-Sectional Study, Case Study dan Qualitative Study
Publication years	2012-2020	Other than 2012- 2020
Language	English and Indonesian	Other Languages

Table I: PICOS Framework

cross sectional study, case study dan qualitative study; studies that focus on pain problems other than major surgical wounds; examining the administration of preoperative TENS interventions, combinations of preoperative and postoperative or other interventions that is not relevant; explains the effect of TENS on pain intensity by measuring using the NRS (Numeric Rating Scale) and VDS (Verbal Descriptive Scale). Abstracts and editorials will be excluded. There are no geographic restrictions on the included studies.

Screening and data extraction

Researchers will screen titles and abstracts based on eligibility criteria to identify studies that have the potential to be included in the review. In particular, titles and abstracts will be included, if the study reported relevant information about the effect of TENS on the intensity of postoperative pain in adult patients. The researcher will take a full-text copy of the article to be assessed in the next stage. Studies that appear to be relevant but excluded at this stage will be listed in the "Characteristics of excluded studies" table, where the reasons for exclusion will be noted. Researchers will verify the final list of included studies. To offer an overview of the decisions taken during the data collecting phase, a PRISMA flow chart of the study selection procedure will be created. Researchers will extract and manage data for each of the included studies. The data will be taken in each article consists of study demographics (author, year of publication, study objectives, location, study design, hypothesis), characteristics of respondents (age, gender, and surgical procedure), characteristics of intervention (type of intervention, format of administration, duration of intervention, consistency of administration, and study characteristics including study design, control/other intervention conditions, measurement time point and study results), and results in the form of pain intensity measurements and conclusions (27, 30).

Quality assessment

The risk of bias from the study will be assessed by Joanna Briggs Institute (JBI) critical appraisal tools for randomized controlled trial in analyzing the methodological quality in each study. The JBI used is Randomized Controlled Trial Tools (29), the checklist tools for RCTs contain 13 assessment criteria. Each criterion was given a rating of 'yes', 'no', 'unclear,' or 'not applicable, and each measure was scored 'yes' given one point. The assessment score of each article is based on JBI with a cut-off value of at least 50%. Studies with scores below 50% will not be included in the review process to avoid bias in the results and discussion (26).

Data analysis

The analysis method that will be used in this systematic literature review is a descriptive analysis using content analysis techniques that present the literature's findings narratively. In writing this systematic literature review, no other additional analytical methods will be added. The researchers will only summarize the results in the article and analyze them according to the content. The measurement results that will be analyzed are the patient's level of pain intensity in the first 24 hours after surgery. The stages of analysis will be used in this systematic literature review is a comprehensive process consisting of four interrelated stages: Reading the contents of the article in depth from all research results, Marking line by line the study findings, compiling sentences or findings marked based on similarity of meaning into themes presented in descriptive writing, and interpreting the analytical themes then written in the results of the review. This systematic review will be synthesized using the narrative method by grouping similar extracted data according to the measured results to answer the research objectives. The data is then made into a journal summary, including the researcher's name, year of publication, article title, research objectives, research location, research samples, methods, interventions, and summary of results or findings. The summary of the research articles will be entered into a table sorted according to the year of publication of the article and alphabetically according to the format (30).

DISCUSSION

Postoperative pain is often a common problem in patients with varying intensity. The "Gate Control" theory by Melzack and Wall in 1965 is one of the theories used to describe the analgesic effect of TENS which reduces pain through the activation mechanism of nerve fibers, both large and small diameter nerve fibers that will convey various sensory information to the central nervous system. The effect of TENS in reducing pain will be measured using a visual analog scale to determine changes in pain intensity before and after the TENS intervention. The most widely used interpretations of VAS values are < 30 mm as mild pain, 31-70 mm as moderate pain, and > 70 mm as severe pain. To assess the results, a ruler is placed along the line, then measure the distance from the left or "no pain" to the point made by the patient and write in centimeters (31).

One of the proposed study's features is that it uses a reproducible and transparent approach for conducting a systematic review of the literature. We explicitly define the types of studies, participants, treatments, and outcomes that will be included in this protocol, as well as the data sources, search strategy, data extraction techniques (including quality evaluation), and data merging procedures. By disseminating the study procedure, we strengthen the strategy's clarity while reducing the danger of bias, especially selective outcome reporting. Second, we shall focus only on the impact of transcutaneous electrical nerve stimulation in reducing postoperative pain intensity. This results shall provide high-level information to inform, support and customize decisions from the clinicians in medicalsurgical settings. This literature study can be used as a reference for nurses and other health workers in preparing standard operating procedures and clinical guidance in providing postoperative pain management interventions to patients (32).

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