Based on non-invasive cardiac output monitoring system to explore the preventive and therapeutic effect of transcutaneous acupoint electrical stimulation on hypotension after intraspinal anesthesia in cesarean section

Informed Consent Form

Research number：KYLLSL-2021-314

Version number：V4.0

Version date:：October 19，2021

Bidding unit ：First Affiliated Hospital of Xi'an Jiaotong University

The department of the bidding unit：Anesthesia operation department

Head of clinical research：Bai Juan

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Informed Consent Form

Dear participants:

We invite you to participate in the study on the effect of transcutaneous acupoint electrical stimulation（TEAS） on the prevention and treatment of hypotension after intraspinal anesthesia after cesarean section based on non-invasive cardiac output monitoring system. The study is a single-center study initiated by the First Affiliated Hospital of Xi'an Jiaotong University. The hospital will include a total of about 58 volunteers aged 18 or less than 55 years old. This study has been reviewed and approved by the Medical Ethics Committee of the first affiliated Hospital of Xi'an Jiaotong University.

It is important for you to read and understand this informed consent form before agreeing to participate in this study. This document describes to you the purpose and steps of this study, the benefits it brings to you, and the risks you have to bear. At the same time, it also tells you about other treatments you can choose from and your rights. You can withdraw from the study at any time. If you participate in this study, you will receive an informed consent form signed by you and the researcher.

1. Why is this study carried out?

Intraspinal anesthesia is the most commonly used method of anesthesia in cesarean section, which can effectively reduce maternal mortality and complications during delivery, and hypotension after anesthesia is the most common complication, with an incidence of 30% to 100%. Hypotension can lead to a series of adverse reactions such as nausea and vomiting, syncope and placental hypoperfusion in pregnant women. In severe cases, it can also cause fetal hypoxia and acidosis, endangering the safety of mothers and infants. Effective preventive measures (adjustment of posture, venous dilatation, application of vasoconstrictor drugs) can reduce the occurrence of hypotension after spinal anesthesia, but there are certain risks, such as volume overload, blood coagulation disturbance, reactive hypertension and increasing the risk of fetal embarrassment. Studies have shown that acupuncture can be used as a non-drug treatment for the prevention and treatment of hypotension after intraspinal anesthesia, safe and effective, wide adaptability and minimal side

effects. Transcutaneous acupoint electrical stimulation is a kind of acupuncture therapy which combines percutaneous nerve electrical stimulation with acupoint therapy, which simulates the local electrical activity caused by acupuncture into acupoints by changing the stimulation frequency, current intensity, pulse width and pulse interval of electrical stimulation. it has the advantages of non-toxic side effects and individualized treatment. NICAS impedance cardiac output monitoring system is similar to ECG monitoring, which continuously collects the changes of hemodynamic indexes of the body by non-invasive means. This technique has the characteristics of non-invasive and low risk, and its data is accurate, so it is convenient for clinicians to timely understand the hemodynamic changes of patients and deal with various emergencies as soon as possible.

In this study, before standardized intraspinal anesthesia, NICAS impedance cardiac output monitoring system was used to monitor the hemodynamic changes before and after transcutaneous acupoint electrical stimulation intervention, and to clarify that transcutaneous acupoint electrical stimulation had a stable effect on various hemodynamic indexes after intraspinal anesthesia after cesarean section, so as to reduce the occurrence of hypotension after anesthesia and reduce the occurrence of adverse events such as nausea and vomiting during operation. The purpose of this study is to provide a scientific basis for the clinical application of transcutaneous acupoint electrical stimulation in the prevention and treatment of hypotension after intraspinal anesthesia.

2.What do you need to do if you participate in the research?

Study design: a total of 58 patients are enrolled in a single center, which is open (patients and electroacupuncture executor know the specific grouping, while data recorders record the required data without clear grouping), randomly divided into two groups (electroacupuncture group and control group), electroacupuncture therapy (electroacupuncture stimulation is implemented in 15 minutes before anesthesia and continues to 30 minutes after subarachnoid administration)

Research process: after signing the informed consent form, you need to cooperate with your doctor to complete the following tasks:

The first part is the screening period. Before operation, your doctor will carefully record your general health and conduct relevant preoperative examinations, so that the doctor can accurately determine whether you are suitable for this study.

The second part of intervention and follow-up, if you meet the criteria, researchers will conduct research intervention and follow-up to record the efficacy, and timely detection and treatment of

complications. There is one intervention in this study. After entering the operating room, the researchers will choose whether or not to give you transcutaneous acupoint electrical stimulation therapy for 45 minutes. At the same time, we will also provide you with NICAS impedance cardiac output monitoring system to monitor the changes of your hemodynamic indexes before and after treatment in real time. In addition, the researchers will record your basic value after entering the room, the changes of hemodynamic indexes, the use of related drugs, the incidence of hypotension and other adverse reactions during 30minutes after intraspinal anesthesia. 24 hours after operation, the researchers will give you a follow-up, and accurately record the data according to the case records and telephone follow-up to understand your satisfaction with the anesthesia, so as to further clarify the impact of the intervention on your postoperative recovery. This study may help to reduce your intraoperative hypotension and related complications caused by intraspinal anesthesia, enable you to go through the operation more smoothly and safely, and promote early recovery.

3. If you decide to participate in this study, what conditions do you need to meet? (inclusion criteria)

You can participate in this study only if the following conditions are met:

- 18 years ≤ age < 55 years
- ASA classification I ~ II
- full term (37 weeks ≤ gestational weeks < 42 weeks)
- schedule for elective single cesarean section under spinal anesthesia
- no other clinical trial 3 months before the enrollment
- volunteer to participate and sign the informed consent form

If you need to know the more detailed admission requirements for this study or if you have words and information that you cannot clearly understand, please consult your research doctor.

4. If you participate in the study, when can it be terminated?

1) if you agree to participate in this study, you can terminate the study after you have completed the above research under the guidance of the research team.

2) during the study period, you may stop midway if the following circumstances do not suit you to continue to participate in the study:

- have adverse reactions caused by transcutaneous acupoint electrical stimulation during the trial

- the effect of intraspinal anesthesia is not good and drugs are added or intubation is changed to general anesthesia during the trial,
- intraspinal block level is too high above T4 or too low to below T10 during the trial
- loss of blood more than 400ml during the trial

3) you ask for automatic exit.

5. What are the diagnosis and treatment options available?

If hypotension occurs during the operation (systolic blood pressure < 90mmHg or 80% of the basal value), ephedrine 10-30mg or norepinephrine 100-200ug can be injected intravenously; if bradycardia occurs (heart rate < 50 beats / min), atropine 0.3-0.5mg can be injected intravenously.

6. Who is not suitable to participate in the study? (exclusion criteria)

If you have one of the following situations, it is not appropriate to participate in this study:

- severe preeclampsia or hypertension
- diabetes
- cardiac insufficiency
- mental abnormality or cognitive impairment or inability to communicate
- acupuncture points skin breakage, infection, allergy
- the researchers believe that there are any conditions that are not suitable for inclusion.

7. What are the risks of participating in the study?

(1) possible risks:

Electroacupuncture treatment can cause local pain, patient tension, etc.; in general, this technique is safe and effective to the human body with minimal side effects.

(2) treatment measures:

a) before the implementation of electroacupuncture treatment, fully and objectively explain the clinical medical process and the contents of the informed consent form to the patients, so as to win the trust of the patients and their families.

b) implement a strict access system and operate in strict accordance with treatment norms.

c) strictly grasp the indication of operation and invasive operation, fully evaluate the patient's condition before operation, and rule out the taboo sign of test.

d) establish a plan to deal with all kinds of accidents and adverse events.

8. What are the possible benefits of participating in the study?

- In the course of the study, experienced research doctors will actively pay attention to the changes of your condition and provide timely and detailed guidance and treatment, and your condition may be improved by effective treatment.
- We provide you with NICAS Impedance Cardiac output Monitoring system free of charge to monitor your hemodynamic indicators in real time. The monitoring technique is accurate, safe and non-invasive, can continuously and dynamically reflect and evaluate cardiac function, help doctors quickly carry out basic hemodynamic state assessment and early treatment, and optimize fluid management and drug treatment.
- As a result of participating in this study, you will get more attention from doctors throughout the diagnosis and treatment process. Your participation in this study may benefit from reducing intraoperative hypotension and related complications caused by intraspinal anesthesia, maintaining intraoperative hemodynamic stability and promoting rapid postoperative recovery. The clinical results obtained by you and other subjects participating in this study may make a significant contribution to you and to the treatment of hypotension caused by the same anesthetic method.

9. Do I have to pay a fee to participate in the study?

1）In the course of the study, electroacupuncture treatment and NICAS non-invasive cardiac output monitoring are free of charge.

2）There is no biological sample collection.

10. Compensation:

In the process of electroacupuncture treatment, it can cause local pain and other adverse reactions, which has almost no toxic side effects on the body. If you have any discomfort during or after the operation, please communicate with your doctor and our researchers in time, and we will actively treat you according to your specific conditions.

11. Is personal information confidential?

Your research materials will be kept in the First Affiliated Hospital of Xi'an Jiaotong University,

and your medical records can be accessed by researchers, research authorities and ethics review committees. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy and personal information of your personal medical data to the extent permitted by law.

12. Do I have to take part in the study?

Participation in this study is completely voluntary. You can refuse to participate in the study, or withdraw from the study at any stage of the trial without discrimination and retaliation, and your medical treatment and rights and interests will not be affected. If you decide to withdraw from this study, please contact your doctor for proper diagnosis and treatment of the disease.

13. Who can I consult when I have any questions?

When you have questions about research information and participants' rights and interests, as well as research-related damage, you can contact the researchers and ethics committees and their contact information. Researcher: Bai Juan, contact telephone: 15319767869; Medical Ethics Committee of the First Affiliated Hospital of Xi'an Jiaotong University, contact telephone: 029-85323473.

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Participant states: I have read the above introduction to this study, and my researchers have fully explained to me the purpose and operation of this study, as well as the possible risks and potential benefits of participating in this study. And have answered all my questions. I volunteer to participate in this study.

I agree□or reject□ the use of my research data and biological samples for studies other than this study.

Name of the participant in block letters:_____

Signature of the participant:_____ Date:_____year____month____day

Participant's contact telephone:_____ Cell-phone number:_____

Name of the legal representative in block letters:_____ (if applicable)

Relationship with the participant:_____

Signature of the legal representative:_____ Date:_____year____month____day

The reasons why the legal representative is required to sign:_____

Name of the witness in block letters: _____ (if applicable)

Signature of the witness:_____ Date:_____year____month____day

The reason why the witness is required to sign:_____

The doctor states: I have explained the details of the study to the above volunteers and provided him / her with an original signed informed consent form. I confirm that I have explained to the participants in detail the situation of this study, especially the ethical principles and requirements that may arise from participating in this study, such as risks and benefits, free and compensation, damage and compensation, voluntary and confidentiality.

Signature of the doctor：_____ Date:_____year____month____day

The doctor's contact telephone:_____

Medical Ethics Committee of the First Affiliated Hospital of Xi'an Jiaotong University

Tel: 029-85323473