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

Study Protocol

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Study Design

1. Research design

This study is designed as a randomized, controlled clinical study, with the first affiliated Hospital of Xi'an Jiaotong University as the research center. Participants undergoing singleton cesarean section under intraspinal anesthesia are recruited from November 1, 2021 to March 1, 2022. The diagnostic indicators of hypotension in this study are intraoperative systolic blood pressure < 90mmHg or blood pressure decreased by more than 30% of basal blood pressure, the main outcome measures are the incidence of hypotension during 30 minutes after subarachnoid administration, and the secondary indicators are the specific changes of hemodynamic indexes, the usage of ephedrine, the incidence of nausea and vomiting, the incidence of dizziness, chest tightness and dyspnea during 30 minutes after subarachnoid administration, and fetal Apgar score. The patients are selected according to the inclusion and exclusion criteria, and the informed consent form are signed. First of all, the selected patients are numbered sequentially, and then the participants are randomly divided into control group and TEAS (transcutaneous acupoint electrical stimulation) group by SPSS software. In the TEAS group, 15 minutes before anesthesia at bilateral Neiguan points and Zusanli points begin to receive dense wave electrical stimulation with the frequency of 10/50Hz, and last until 30 minutes after subarachnoid administration. In the control group, 15 minutes is performed before anesthesia, and electrodes are connected at the same acupoint, but no electrical stimulation is given, the duration is the same as that of the TEAS group. During the trial, participants know which group they will be assigned to and which treatment they will receive. According to the grouping of random tables generated by SPSS, a researcher will independently give corresponding treatment measures to participants who has had signed the informed consent form, and cover up the screen of the electroacupuncture instrument. Another data collection researcher who does not know about the grouping records the vital signs and other complications of the participants. When the total number of cases reaches the minimum number of cases required by statistics or reaches the project case collection node (March 1, 2022), the data will be statistically analyzed and processed by professional statistical researchers.

Inclusion Criteria:

- 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

Exclusion Criteria:

- 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.

Elimination Criteria:

- be unwilling to continue the trial during the trial
- 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

2. Research methods

In this study, a randomized, controlled design method is used to study the pregnant women who meet the inclusion criteria of singleton cesarean section.

Sample size estimation:

Based on the pre-experimental results from July 5, 2021 to July 28, 2021, the incidence of hypotension is 40% in the TEAS group and 80% in the control group. The sample size and the incidence of hypotension in the TEAS group is compared with that in the control group are estimated by GPOWER3.1 software,. Using the z test of two independent samples in the non-parametric test, double tails, α=0.05、1- β =0.85、N2/N1=1，P1=0.40、P2=0.80, 26 cases in each group are calculated. A total of 52 cases. According to the 10% lost follow-up rate, the minimum sample size in each group is 29 cases, with a total of 58 cases.

Random:

Randomized grouping is obtained by using SPSS software programming. First of all, the determined sample size is numbered from small to large according to the order of the operation, and then the number is inputted into the SPSS software. The random number is generated by the random number generator in the SPSS software program, and the generated random numbers are randomly grouped.

Control:

The number,Rrandom,group appears in the software in the running program is the patient serial number that has been arranged before, the random number generated by the software, and the grouping after randomization. 0 is defined as control group (Control group), and 1 is defined as transcutaneous acupoint electrical stimulation group (TEAS group).

Open:

The specific method of operation is that participants know which group they will be assigned

to and what kind of treatment they will receive. According to the grouping of random tables generated by SPSS, a researcher will independently give corresponding treatment measures to the participant who has had signed the informed consent form, and cover up the screen of the electroacupuncture instrument. Another data collection researcher who does not know about the grouping records the vital signs and other complications of the participant. Finally, all the data will be saved, and after all the data are collected, the professional statistical researchers will deal with the data accordingly.

Clinical intervention program

(1) group

- transcutaneous acupoint electrical stimulation group (TEAS group): 15 minutes before anesthesia, begin to receive dense wave electrical stimulation with the frequency of 10/50Hz at bilateral Neiguan and Zusanli points, and last until 30 minutes after subarachnoid administration.
- Control group (Control group): 15 minutes before anesthesia, begin to connect the electrode at the same acupoint, but no electrical stimulation is given, the duration is the same as that of the TEAS group.

(2) selection of acupoints

- Neiguan (PC6): be located on the palmar side of the forearm, two inches above the transverse carpal stria, between the tendon of the palmar longus muscle and the tendon of the radial carpal flexor muscle.
- Zusanli (ST36): be located in the anterolateral leg, three inches under the calf nose point, a transverse finger (middle finger) from the anterior tibial crest.

(3) TEAS stimulation parameters

- frequency: 10/50Hz
- waveform: dense wave
- intensity: from low to high, adjust the stimulation intensity until the patient feels slight tingling, taking the maximum inductance that the patient can tolerate, no muscle convulsions, no discomfort as the standard, and record the final stimulation intensity.
- duration: 45 minutes

3. Research steps:

Blood pressure (BP), electrocardiogram (ECG) and pulse oxygen saturation (SpO2) are measured routinely after participants included in the study entered the operating room. At the same time, the changes of cardiac function indexes such as stroke volume (SV), stroke index (SI), cardiac output (CO), cardiac index (CI), cardiac function index (CPI), systemic peripheral vascular resistance (TPR) and systemic peripheral vascular resistance index (TPRI) are monitored by impedance cardiac output measurement system. At the same time, the venous channel is established, and after the venous channel is established, the compound sodium chloride injection 10ml / kg is infused for 15 minutes to eliminate the hypotension caused by the lack of blood

volume. The blood pressure, heart rate and other hemodynamic parameters of the 5 minutes after the participants enter the room are recorded as basic values. According to the grouping situation, the participants are intervened to deal with 45 minutes. During anesthesia, the participants take the left lying position, routinely use No. 17 Tuohy needle for puncture, the puncture point is L3-4, and the No. 25 lumbar anesthesia needle is placed after reaching the epidural space. After confirming the cerebrospinal fluid outflow, the equal specific gravity local anesthetic solution is injected, the solution is 0.75% bupivacaine 2ml and cerebrospinal fluid 1ml mixture, the drug dose 2ml is injected, the injection time is 15 seconds, the lumbar anesthesia needle is pulled out, the No. 20 epidural catheter is placed, and 3-4cm is placed on the side of the head. In order to prevent the hypotension syndrome in supine position caused by uterine compression of inferior vena cava, the participants adjust the bed inclination to the left 15°~20°immediately after supine position. The mask is given to inhale oxygen with a flow rate of 2~3L/min. The anesthesia level is determined by acupuncture along the midline of the left clavicle, and the upper limit of the sensory block plane is controlled between T6~T8 by adjusting the height of the operation bed. The other adjuvant drugs are consistent.

After subarachnoid administration, the hemodynamic data of the participants are recorded in 30 minutes every 2 minutes. When hypotension occurs, ephedrine 5-10mg is given. If the blood pressure is still low after 2 minutes, ephedrine 5-10mg can be given again until the blood pressure recovers. Atropine 0.3mg is given intravenously when bradycardia occurred.

The incidence of hypotension, nausea, vomiting, dizziness, chest tightness and dyspnea in the participants in 30 minutes after subarachnoid administration are recorded.

24 hours after operation, the satisfaction of the participants are investigated.

4. Evaluation index

Main indicators:

- the incidence of hypotension during 30mintes after subarachnoid administration

Secondary indicators:

- specific changes of hemodynamic parameters during 30minutes after subarachnoid administration
- the usage of ephedrine during 30minutes after subarachnoid administration
- the incidence of nausea and vomiting during 30minutes after subarachnoid administration
- the incidence of dizziness chest tightness and dyspnea during 30minutes after subarachnoid administration

5. Follow-up content

The satisfaction of the participants will be evaluated by follow-up 24 hours after the participants' operation.

Note:

- definition of hypotension: intraoperative systolic blood pressure < 90mmHg or blood pressure decreased by more than 30% of basal blood pressure
- definition of sinus bradycardia: heart rate < 50 beats / min

- satisfaction score: scores range from 0 to 10, the higher the score, the higher the participants' satisfaction with anesthesia

6. Technical route