Effect of dexmedetomidine combined with ropivacaine transversus abdominal block (TAP) on opioid dosage after cesarean section under multimodal analgesia

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informed consent page

Dear patient/legal representative:

We sincerely invite you and your family members to participate in a study of "Effect of dexmedetomidine combined with ropivacaine transversus abdominis block (TAP) on opioid consumption after cesarean section under multimodal analgesia". The cases included in the study will be treated according to the medical routine of the department. The information and data collected in this study are all routine clinical information and data, and will not add additional treatment or inspection items, and will not increase patient risks and treatment costs. Before you decide whether to participate in this study, please read the following content as carefully as possible, it can help you: 1. Understand the background knowledge of this study and the purpose and significance of this study; 2. Know the procedure and duration of the study; 3. Clearly clarify the possible benefits, discomforts and risks to you after participating in the research. If you want, you can also discuss it with your relatives and friends, or ask your doctor to give an explanation to help you decide whether to participate in this clinical research. If you have any questions, please ask the doctor in charge of the study.

Research background and purpose

Pain after cesarean section has always been one of the key points and difficulties in perioperative management. Multiple guidelines advocate providing multi-modal optimized analgesia to improve postpartum pain, so as to reduce the dual impact of pain on maternal psychology and physiology. TAP block has now become one of the important components of multimodal analgesia for cesarean section. At present, the most commonly used local anesthetic for TAP blockade is ropivacaine, but its short duration of action limits its clinical application. Dexmedetomidine, a highly selective α2-receptor agonist, is widely used as a local anesthetic adjuvant in regional blockade. When dexmedetomidine is used in combination with local anesthetics, it can enhance the analgesic effect and prolong the duration

of analgesia, reducing the need for postoperative opioid analgesics. Postoperative intravenous analgesia is the routine analgesic program after cesarean section in my country, and within 2 days after cesarean section, the milk secretion of parturients is generally small (average <10 ml/d), and the postpartum short-term use of clinically routine doses of opioids Drugs, the concentration of drugs in colostrum is extremely low, and the intake of newborns is negligible. Therefore, intravenous analgesia for only 48 hours after surgery is also safe from the perspective of breastfeeding. In this study, the use of background-free PCIA in the context of multimodal analgesia can greatly reduce the amount of postoperative opioids used, and it is easier to meet the analgesic needs of obstetrics to reduce opioids while improving postoperative pain. Therefore, we conducted this study to evaluate the efficacy of dexmedetomidine as an adjuvant to ropivacaine in TAP block in women undergoing cesarean section under multimodal analgesia, and to optimize multimodal analgesia in the perioperative period of cesarean section. Program to guide perioperative analgesic management of cesarean section.

Research Design, Methods and Procedures

The sponsor of this project is the Department of Anesthesiology and Perioperative Medicine of the First Affiliated Hospital of Air Force Military Medical University. The Ethics Committee of the First Affiliated Hospital of Air Force Military Medical University reviewed this research in compliance with the principles of the Declaration of Helsinki and in line with medical ethics. The participating researchers are all clinicians from the Department of Anesthesiology and Obstetrics. They have the qualifications of practicing physicians, relevant treatment skills including rescue, have received training in clinical trials, and have obtained relevant certificates. This study is a single-center, randomized, double-blind, parallel-controlled clinical trial, and it is expected that 90 eligible cesarean section women will participate voluntarily.

These patients have certain inclusion criteria, including: 1) gestational age of 37-42 weeks; 2) plan cesarean section; 3) postoperative PCIA analgesia; 4) age > 18 years old; 5) ASA I - III; 6) Voluntarily participate in the trial and obtain informed consent. At the same time, patients with the following events were not included, the exclusion criteria including: 1) Cesarean section anesthesia method was general anesthesia or spinal anesthesia receiving epidural administration; 2) Intraoperative combination of other opioids; 3) High-risk pregnancy (multiple pregnancy, in vitro fertilization, etc.) or pregnancy-related complications (hypertension, preeclampsia, chorioamnionitis, etc.); 4) The number of previous cesarean sections ≥ 3; 5) BMI ≥ 50kg/m[2] Not suitable for TAP block; 6) Allergy to the drugs involved in the study or contraindications; 7) Combined with surgery other than tubal ligation and oophorectomy; 8) Severe renal impairment (SCr>176μmol /L and/or BUN>17.9 mmol/L]), severe liver damage (ALT and/or AST more than 3 times the upper limit of normal value); 9) coagulation dysfunction or increased risk of bleeding (PLT<80×109 /L or INR>1.5); 10) History of chronic pain or opioid abuse; 11) Enrolled in other clinical trials in the past three months.

After enrollment in this study, patients were randomly divided into two groups, that is, dexmedetomidine combined with ropivacaine TAP group and ropivacaine TAP group. If you meet the inclusion criteria and are willing to participate in this study, you will be accepted They were randomly divided into these two groups. The postoperative TAP method and PCIA analgesic scheme were the same between the two groups, and the difference was only in the use of drugs for TAP blockade. Entry into different group will not affect your doctor's usual treatment. This study will record your personal situation and disease-related data, starting from your participation in the trial before surgery, will record pre-operative, intraoperative and postoperative related conditions, including: age, gestational weeks, parity, medical history, general life Sign monitoring (such as blood pressure, heart rate, etc.), preoperative laboratory tests (such as blood routine, coagulation function, etc.), perioperative drug use (such as drug type, drug dosage, etc.), and follow-up until 2 days after surgery, and Postoperative information such as postoperative pain, sedation, postoperative satisfaction, nausea and vomiting and other adverse reactions of opioids will be collected. The above routine treatment measures and medical examination items are all necessary clinical routine items in the perioperative treatment of surgical patients. This study did not involve special examination and treatment items, nor did it impose additional burdens on patients.

Benefits of taking part in this study

Participating in this study, the clinical results obtained by you and other subjects participating in this study are likely to contribute to the optimization of the multimodal analgesic management program after cesarean section in the future.

Possible risks of taking part in this study

The dexmedetomidine used in this study is a commonly used drug in cesarean section in clinic. It will not prolong the effect time of postoperative intravenous patient-controlled analgesia. TAP block is performed under the guidance of ultrasound at the end of the operation. Local anesthetic poisoning may occur. In addition, there may be risks of routine postoperative intravenous analgesia, such as excessive sedation, and mild respiratory depression. After the operation, the puerpera will be closely monitored, and the postoperative recovery room and wards are equipped with first aid drug carts, so that adverse reactions can be quickly discovered and treated. Doctors will also try their best to prevent and treat possible damage caused by this research. If research-related harm occurs during a clinical study, a medical expert committee will determine whether it is related to the intervention. The bidding department will provide the cost of treatment and corresponding economic compensation in accordance with the provisions of my country's "Good Clinical Practice for Drug Clinical Trials". This research has prepared reasonable security measures for you, which will protect your legal rights to the greatest possible extent.

Costs associated with participating in this trial

Regardless of whether you participate in this study or not, relevant diagnosis and treatment measures will be carried out in accordance with medical routines. The drugs used in the study are commonly used clinical drugs, and no additional costs will be added.

Keep secret

After the research, we will organize and analyze the collected information and data. Finally, the obtained results and conclusions are organized into papers and submitted for publication. In various medical records of this study, your name will be replaced by pinyin abbreviations. Your medical records and materials will be kept in the hospital, and researchers, research authorities, and ethics committees can review your medical records upon approval. Any public reporting of the results of this research will not reveal your personal identity.

Your rights

You/your relatives' participation in the research is completely voluntary, and you/your relatives can withdraw from the research at any time without any reason, and it will never affect the relationship between you/your relatives and medical staff and any future medical treatment and rights; /All personal data and observation records of your relatives are confidential and are only used for this research; during the research period, you can learn about relevant information at any time. proposed by the

physician in charge. If you still have questions or encounter an emergency, you can contact the project leader: Deputy Chief Physician Nie Huang at 029-84775343.

Ethics Committee Contact Information

The trial protocol was approved by the Hospital Ethics Committee. If there is any violation of the research protocol during the trial, you can directly complain to the Hospital Ethics Committee. Contact number: 029-84771794, email: xjyyllwyh@163.com.

Subject informed consent signature page

I have read the above informed consent form in detail and understand the purpose of the study and the possible benefits and risks of participating in the study. The researchers have clearly explained the above medical terms. I had the opportunity to ask questions and all of them were answered in plain language. I can choose not to participate in this study, or withdraw after notifying the responsible doctor at any time, and any of my medical treatment and rights will not be affected. The responsible physician may terminate my participation in this study if I need other treatment, if I do not comply with the study plan, if a study-related injury occurs, or for any other reason.

I have read and obtained a copy of the above informed consent form, which has been fully explained to me by my physician. I volunteer to participate in this clinical trial. I agree that relevant parties will check and verify the data collected in the experimental study against my original medical records.

Print Name of Subject: _____ Telephone Number: _____

Signature: _____ Date: _____

(Note: When the subject has no capacity for civil conduct, the signature of the guardian is required; when the subject has limited capacity for civil conduct, the subject and his guardian need to sign)

Guardian's print name: _____ Relationship: _____

Guardian Signature: _____ Guardian Phone: _____

Date: _____

Impartial Witness Signature (if applicable): _____ Date: _____

(If the subjects or their guardians are unable to read, an impartial witness is required to sign. The impartial witness reads the informed consent form and other written materials and witnesses the informed consent.)

I confirm that I have fully explained to the patient the contents of this clinical trial, including the possible benefits and risks for the patient, and have answered all questions raised by the patient.

Investigator Signature (Print Letters): _____ Date: _____

Investigator Phone: _____ Date: _____