EFFECTIVENESS OF POSTOPERATIVE ANALGESIA MODIFIED-THORACOABDOMINAL NERVE BLOCK PERICHONDRIAL APPROACH (M-TAPA) WITH INTRAVENOUS OPIOIDS IN LAPAROSCOPIC CHOLECYSTECTOMY PATIENTS AT PROF I.G.N.G. NGOERAH HOSPITAL

10 October 2024

(INFORMED CONSENT)

Informed Consent form for Participant Clinical Trial

We ask you, Sir/Madam/Sibling/Children to participate in the research. Participation in this research is voluntary. Please read the explanation below and feel free to ask if you have any questions/if there are things that are not clear.

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Principle Investigator	Amelia Christiana, MD
Name of Organization	Anesthesiology and Intensive Therapy/Faculty of Medicine, Udayana University
Other Investigator	1. Dr. dr. I Putu Pramana Suarjaya, Sp.An-TI, M.Kes, Subps.N.An.(K), Subsp.M.N.(K) 2. dr. Ida Bagus Krisna Jaya Sutawan, M.Kes, Sp.An-TI, Subps.N.An.(K)
Location	Central Surgical Instalation RSUP Prof. Dr. I.G.N.G Ngoerah Denpasar
Sponsor	Swadana

Background

Surgery to remove gallstones using the laparoscopic method is one of the operations that is often performed and one of the challenges faced is postoperative pain. Postoperative pain management is conventionally treated with narcotics, but this has the side effect of nausea and vomiting. These side effects of nausea and vomiting will cause postoperative recovery and a longer hospital stay. Another technique that is relatively safer and has the potential to reduce pain was then developed, namely peripheral nerve blocks by injecting medication under the skin. The optimal technique for deposition of drugs is still not clearly known, so this study was conducted to prove the effectiveness of post-operative pain relief of M-TAPA peripheral nerve block in laparoscopic cholecystectomy patients.

Clinical Trial Explaination

Laparoscopic cholecystectomy is a surgical procedure to remove the gallbladder by making 3 small incisions in the stomach. The operation will be guided by a camera that is inserted through the small incisions. The use of the Modified Thoracoabdominal Perichondrial Approach (M-TAPA) block is an anesthetic procedure for pain management in patients undergoing gallbladder removal surgery using a laparoscopic technique, to minimize

postoperative pain, extend the duration of anesthesia and reduce the consumption of narcotic drugs.

Participant

The participants in this study were all adult patients who underwent laparoscopic cholecystectomy surgery at Prof. Hospital. Dr. I.G.N.G Ngoerah aged 18-65 years in the operating room of the Central Surgery Installation who was willing to become a research participant and signed an Informed Consent. Participants who cannot take part in this study are patients who are not willing to take part in the study, patients with intelligence disorders, patients with a history of chronic kidney disorders, blood clots, patients who have a history of allergies to the agents that will be used in this study, patients who underwent laparotomy surgery. repeated and long-term use of narcotic drugs.

Procedure

Research participants will be divided into 2 groups, namely group P1 receiving Modified Thoracoabdominal Block Perichondrial Approach (M-TAPA) peripheral nerve block anesthesia after laparoscopic gallbladder removal surgery and group P2 only receiving intravenous opioids after surgery without block. Participants will be divided into 2 groups P1 and P2 randomly. The block will be carried out by an Anesthesiologist. Both parties, researchers and participants did not know whether they belonged to group P1 or P2. The block will be carried out by a specialist anesthesiologist who will receive a masking envelope for the participant group in the morning before the operation begins. The general anesthesia used by both groups was the same during the operation. All participants will receive the same pain medication after surgery in the form of 2 painkiller tablets and narcotics via IV. All study participants will be monitored, pain scale, total narcotic use and quality of recovery after general anesthesia by the acute pain management team. This study will last up to 24 hours after surgery.

This research has been approved by the Research Ethics Commission of FK UNUD/ RSUP Prof. Dr. I.G.N.G Ngoerah who has reviewed the proposal.

Benefit For Participant

Participation in this research indirectly provides benefits to research participants regarding adequate post-operative pain management with lower use of narcotic drugs so that the side effects of drug use can be suppressed during the recovery process. Previous research shows that the painkiller method given in this study has good safety and can reduce the incidence of side effects that commonly occur after administering painkillers such as nausea and vomiting. The quality of recovery after general anesthesia also showed better results in previous studies. In addition, the results obtained also help to improve the quality of anesthesia services for patients undergoing subsequent laparoscopic gallbladder removal surgery.

Risk

The procedures carried out on participants in this study included low-risk procedures which could cause drug allergies, bruising to muscles or internal organs and local anesthetic toxicity. The risk of muscle or internal organ bruising is very rare because it can be minimized by using an ultrasound device (USG) as a guide. To increase safety in implementation, the dose of

medication given is the minimum dose and the maximum number of doses that can be given has been calculated

.

Risks that can occur are a result of the technique and drugs used, such as bruising at the injection site, allergic reactions, toxicity to the anesthetic used as well as complications in the central nervous system and changes in heart rate. If this condition occurs, it will be handled with planned treatment. In conditions of mild allergic reactions to anesthetics such as redness and itching, dexamethasone 5 mg and diphenhydramine 10 mg will be injected as anti-allergic drugs, in severe allergic conditions that result in a decrease in blood pressure and heart rate, airway protection will be carried out, oxygen will be given followed by injection. the sulfate drug atropine at a dose of 0.01 mcg/kg and/or adrenaline at a dose of 0.001 mg/kg. In conditions of toxicity to anesthetic drugs, basic life support procedures will be carried out as well as administration of 20% intralipid (fat infusion fluid) injections at a dose of 1.5 ml/kg as an antidote. To finance treatment in accordance with BPJS procedures. If needed, other specialist doctors who are more expert in handling it will be consulted. If serious complications occur, we will treat participants by consulting an intensive care specialist in the intensive care room in accordance with existing treatment rules until treatment is complete.

Alternative actions/treatment

If after explaining the benefits and risks of this procedure, the patient refuses, then the research action will not be carried out. Patients will be given intravenous pain therapy in accordance with the applicable standards for providing analgesia at Prof. I.G.N.G. Ngoerah Hospital, Denpasar.

Reimbursement

Researchers are responsible if negative impacts occur due to this research procedure. There was no financial compensation for participation in this study. The compensation provided is in the form of medical treatment according to standards.

Confidentiality

All data from this research is only known to the researcher and the researcher will explain the results of the examination to the research participants, the data will be guaranteed confidentiality and will not be shared. This research data can be used for further research while maintaining personal information.

Right to Refuse or Withdraw

Your participation in this research is voluntary. You can refuse to answer questions asked in the research or stop participating in the research at any time without any sanctions. Your decision to stop being a research participant will not affect the quality and access/continuity of treatment at RSUP Prof. I.G.N.G Ngoerah.

IF YOU AGREE TO BE A RESEARCH PARTICIPANT

If you agree to be a participant in this research, you are asked to sign the 'Informed Consent) form as *Research Participant/ *Guardian' after you fully understand what this research is about. You will be given a copy of this signed agreement.

If during the course of the research there are new developments that could influence your decision to continue participating in the research, the researcher will convey this to you.

If you have questions that need to be conveyed to researchers, please contact Amelia Christiana, MD on number +62 823-9856-5260.

Your signature below indicates that you have read, have understood, and have had the opportunity to ask the researcher about this research and agree to become a research participant.

Participant,	**Investigator**
_____	_____
Date :	**Amelia Christiana, MD** Date:

Witness signatures are required on this Consent form only if (Filled in by the researcher) Research Participants have the ability to make decisions, but cannot read/cannot speak or are blind ☐ Guardians of research participants cannot read/cannot speak or are blind ☐ The Ethics Commission specifically requires witness signatures in this research (for example for high risk research and/or invasive research procedures) Note : Witnesses must be family members of research participants, and cannot be members of the research team.
Witness:
I declare that the information on the explanation form has been correctly explained and understood by the research participant or their guardian and that consent to become a research participant was given voluntarily. _____ _____ Date
Name and signature of witness *(If no witness signature is required, this part of the witness signature is left blank)*