Protocol Title: Evaluating the addition of obturator nerve block to adductor canal block for total knee arthroplasty

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Research Question: Does the addition of obturator nerve block to a regional anesthesia technique with adductor canal block and local infiltration analgesia for total knee replacement surgery reduce opioid consumption in the PACU?

Primary objective: Compare the rate of IV opioid consumption in patients who receive a combination of adductor canal block, obturator nerve block, and local infiltration analgesia at the surgical site versus patients who receive adductor canal block and local infiltration analgesia.

Secondary objectives:

a. Measure the severity of pain at rest using an 11-point Likert scale at 1, 6, 12, 24 hour marks postoperatively in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration analgesia

b. Compare time to breakthrough pain after surgery in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

c. Measure rate of post-operative nausea/vomiting in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

d. Measure time to ambulation in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

e. Compare analgesia satisfaction score at time of first postoperative followup visit in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration.

Background

The management of postoperative pain after total knee arthroplasties remains a challenging issue. Even though postoperative pain typically ranges from moderate to severe, patients are encouraged and expected to start physical therapy and ambulate as soon as possible because early rehabilitation may lead to improved long-term functional status of the knee.1 Integrated multimodal analgesic strategies have been employed for postoperative pain management; the aim of such strategies is to utilize different mechanisms of action to provide superior analgesia while limiting side effects and adverse events.2 Multimodal analgesic strategies for total knee arthroplasties most commonly combine regional anesthesia techniques, including femoral nerve block and local infiltration analgesia, with a combination of low-dose opioids, acetaminophen, and nonsteroidal anti-inflammatory drugs.2

The optimal peripheral nerve block or combination of blocks is not yet known. Since the knee joint is innervated by an anterior and posterior group of sensory nerves, an approach that provides regional anesthesia to both groups seem reasonable. The femoral nerve block provides analgesia of the knee in the anteromedial region.3 However, despite the improved analgesia and shortened hospital stays provided by the use of femoral nerve blocks in total knee arthroplasties, the motor weakness that can be caused by these regional blocks can delay mobilization and increase the risk of falls.4

Recently, the adductor canal block has become more frequently used because of claims that femoral nerve block can increase fall risk. The adductor canal block blocks the saphenous nerve and is primarily a sensory block, even though it can result in the partial motor block of the vastus medialis muscle. Overall, the adductor canal block has exhibited relative spring of quadriceps strength and was shown to be not inferior in providing analgesia and opioid consumption.5

The obturator nerve block has also been utilized for total knee arthroplasties. The obturator nerve provides innervation to the posterior group of sensory nerves.6 The femoral nerve block has not been shown to provide consistent block of the obturator nerve, and the addition of sciatic nerve block to a femoral nerve block does not further improve analgesia of the posterior knee.3,7 However, the addition of the obturator nerve block to a femoral nerve block has been shown to improve postoperative analgesia after total knee arthroplasty.8 The addition of obturator nerve block to femoral triangle block has also been shown to reduce opioid consumption without impairing ambulation.9

Based on the above studies, various multimodal analgesic strategies, including various combinations of regional anesthetic techniques, have been utilized, with varying success. There is no consensus on the optimal strategy that provides the most effective postoperative analgesia while preserving ambulation and limiting side effects such as nausea and vomiting. We believe that the obturator nerve block in addition to adductor canal block and local infiltration analgesia can target both the anterior and posterior distribution of nerves to the knee to provide superior analgesia while not limiting ambulation. To date, we are not aware of any studies that have examined this particular combination of regional anesthetic techniques.

Primary and Secondary Study Endpoints

Primary objective: Compare the rate of IV opioid consumption in patients who receive a combination of adductor canal block, obturator nerve block, and local infiltration analgesia at the surgical site versus patients who receive adductor canal block and local infiltration analgesia.

Secondary objectives:

f. Measure the severity of pain at rest using an 11-point Likert scale at 1, 6, 12, 24 hour marks postoperatively in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration analgesia

g. Compare time to breakthrough pain after surgery in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

h. Measure rate of post-operative nausea/vomiting in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

i. Measure time to ambulation in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration

j. Compare analgesia satisfaction score at time of first postoperative follow-up visit in patients who receive adductor canal block, obturator nerve block, and local infiltration analgesia versus patients who receive adductor canal block and local infiltration.

Description of the Study Design

If you agree to participate in this research study, the following information describes what may be involved.

You study involvement will begin on the day of your surgery at Mount Sinai Hospital. Prior to starting surgery, you will undergo two regional anesthesia blocks. You will receive an intravenous medication called midazolam to reduce anxiety and help tolerate the procedures. One of them is called the adductor canal block, which is typically performed for your surgery regardless of the research study. An ultrasound will be used to identify the location of nerves in your upper leg, and a numbing medication called bupivacaine will be injected around the identified area. The other is called the obturator nerve block, which is being evaluated in this research study. Once again, an ultrasound will be used to identify the location of nerves in your upper leg close to the groin area, which will be appropriately draped. Once this area is identified, a solution will be injected which is either bupivacaine or saline that does not contain any active medication. Once these procedures are completed, the rest of the anesthesia for the surgery will proceed the same as if you are not part of the research study. This includes a spinal anesthesia that will make the lower part of your body numb, and any sedation given by the anesthesiologist to help you feel relaxed and comfortable enough to tolerate the surgery.

After your surgery, you will be taken to a surgery recovery area before you are able to go to your own hospital room. There, you will be given a button to push to receive an intravenous opioid medication. You will have the freedom to decide when to receive the medication but it will be set up so that you cannot receive more than your doctors intended. You will also have nausea medications available. The study doctor will ask you about your pain level and nausea level. The doctor will also review how much opioid medication you received by pushing the button.

You will periodically be asked questions regarding your pain and nausea and vomiting during the rest of your hospital stay. Your performance during your physical rehabilitation sessions will also be reviewed by study doctors.

At your first postoperative visit with your surgeon after your discharge from the hospital, you will be asked about your pain levels after your discharge and your overall satisfaction with your pain control.

The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what study treatment you get. You will have an equal chance of being given each

study treatment. Neither you nor the study doctor will know which study treatment you are getting. This information could be obtained in an emergency, however.

Description of Procedures Being Performed

Subjects who consent to and are scheduled for total knee arthroplasty under regional anesthesia will be invited to participate in the study during a routine preoperative visit prior to surgery. The details of the study will be reviewed and written informed consent will be obtained.

The patient will be randomized into the study group or the placebo group. On the day of surgery, the group allocation will be revealed to an anesthesiologist not part of the research study, who will receive specific instructions to prepare a injectate solution for the obturator nerve block, which will consist of 0.25% bupivacaine for the study group or saline for the placebo group.

The patient will receive midazolam for anxiolysis at the discretion of the attending anesthesiologist. An adductor canal block with 10mL 0.25% bupivacaine will be performed. An obturator nerve block will be performed with the previously prepared injectate solution. Patients will undergo spinal anesthesia with a 3mL solution of 0.75% bupivacaine. Sedation may be administered during surgery at the discretion of the anesthesiologist.

Total knee arthroplasty will be performed by the orthopedic surgeon with insertion of bicopartmental or tricompartmental prostheses using a standard medial parapatellar approach and hand-mixed cementing techniques. A local intraarticular injection will be performed intraoperatively by the surgeon, as is routinely done for total knee arthroplasties by the surgeon involved in our study, regardless of research involvement.

In the Post Anesthesia Care Unit, the patient will be administered hydromorphone using intravenous patient-controlled analgesia (PCA). Fentanyl will be administered if hydromorphone is not tolerated. Additional oral oxycodone consumption will also be recorded.

Relevant preoperative, intraoperative, and postoperative data will be obtained from the anesthesia record, the EPIC electronic medical record. The patient will also be interviewed by study personnel at time of first post-discharge follow-up visit to obtain analgesia satisfaction scores.

Description of the Source of Records that will be used to collect data about subjects

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, date of birth, telephone number, date of surgery, date of discharge, and medical record number.

The researchers will also get information from your medical record including your electronic anesthesia record and electronic medical record that documents your postoperative care at Mount Sinai. They will also get information from your first postoperative visit with your surgeon.

During the study the researchers will gather information by completing the chart review and interview explained in the description section of this consent.

Description of data that will be collected including long-term follow-up

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Your authorization for use of your protected health information for this specific study does not expire.

Description of instruments created by research team

The data collection sheet created by the research team will be used to gather preoperative, intraoperative, and postoperative data relevant to the study. Preoperative data to be collected includes patient demographics including age and gender. Intraoperative data include duration of surgery, total narcotics administered during surgery, and total fluids administered. Postoperative data include total narcotics administered, pain scores at regular various intervals, incidence of postoperative nausea and vomiting, and time to ambulation. Data will also be extracted from the patient's first completed physical therapy session, including total distance ambulated, pain at time of assessment, and functional mobility impairment percentage. Post-discharge data to be collected include total dosage of narcotics used after discharge, pain score, and any complications.

Where and when consent will be obtained

Patients will be introduced to the study in the surgeon's office at 5 East 98th Street offices for the Department of Orthopedics (FPA). Patient will be informed about the study in more detail via telephone call prior to surgery. Official written consent will be obtained in the preoperative assessment area at Mount Sinai Hospital on the day of surgery.

Waiting period for obtaining consent

Official written consent will be obtained on the day of surgery. Patients will be given anywhere from 3 days to 2 weeks from when they are first introduced to the study until time of obtaining consent.

Description of health information that will be viewed, recorded, or generated

As part of this research project, the research team at the hospital involved in the research will collect your name, date of birth, telephone number, date of surgery, date of discharge, and medical record number.

The researchers will also get information from your medical record including your electronic anesthesia record and electronic medical record that documents your care during your recovery at Mount Sinai Hospital. They will also get information from your first postoperative visit with your surgeon.

During the study, the researchers will gather information by completing the chart review and interview as explained in the description section of this consent.