MIDCAB (Mid-Calf Block) for foot surgery: A pilot study

FUNDER:	Department of Anesthesiology, Critical Care & Pain Management
PROTOCOL NO.:	2022-0066
VERSION & DATE:	05/03/2022

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PROTOCOL SYNOPSIS

Protocol Title:	MIDCAB (Mid-Calf Block) for foot surgery: A pilot study
Protocol Number:	2022-0066
Protocol Date:	03/16/2022
Sponsor:	Department of Anesthesiology, Critical Care & Pain Management
Principal Investigator:	Enrique Goytizolo, MD
Objective:	We will investigate the duration and feasibility of a mid-calf block (MIDCAB) in place of the popliteal block for providing analgesia during foot or ankle surgery while maintaining motor function of the operated foot and ankle.
Study Design:	Prospective Cohort Study
Enrollment:	20
Subject Criteria:	1. ASA of 1 or 2 2. Age 18-80 3. Undergoing a foot or ankle surgery 4. Plan to use spinal/epidural anesthesia 5. Ability to follow study protocol
Data Collection:	Sources: EPIC, Medical Records, and Patient Report. Variables: Name, DOB, Race, Gender, Anesthesia Time, NRS Pain scores at Rest, Opioid Consumption, Patient Satisfaction, PONV, Motor Function, Block Duration.
Statistical Analysis:	No interim analysis is planned. For continuous variable, descriptive statistics will be presented as means and standard deviations or median and interquartile ranges depending on data distribution. For categorical variable, descriptive statistics will be presented as frequencies and percentages.

1.0 INTRODUCTION

At the present, the most widely-utilized analgesic intervention for patient receiving ankle and foot surgeries at HSS is the peripheral nerve block known as the popliteal nerve block which is performed. The popliteal block is performed on the sciatic nerve at the level of the popliteal fossa. Since the sciatic nerve provides sensory and motor functions to the majority of the lower leg, the popliteal block is a good choice for use during ankle and foot surgeries. However, the main disadvantage with this block is that because it's done on the sciatic nerve which is responsible for motor function of most of the lower leg, the block prevents motor function of the ankle and foot for some time after surgery. Many studies have shown that patients participating in physical therapy (PT) after surgery had short hospital stays, faster ambulation and lower chances of 30-day readmissions. Since most patients who receive foot and ankle surgery cannot move their foot/ankle after surgery they will be unable to participate in PT for some time. Thus, there is an incentive to investigate the potential benefits of a block that would provide a s similar level of analgesia while allowing patients to participate in PT which will likely aid their recovery.

The idea for the mid-calf block (MIDCAB) came from previous work and studies done on ultrasound-guided ankle blocks that have been modified. Currently these ankle blocks under ultrasound-guidance is performed distally, at the level of the ankle joint and foot. With this approach the block coverage is limited to the mid distal foot, the ankle block does not cover surgeries performed on the ankle joint. Instead of this, the MIDCAB block is performed proximally on the same nerves that are targeted with the ankle block but instead of performing it distally, it will be done proximally at the level of the mid-calf on the patient's leg. Moving the probe more proximal on the leg will provide analgesia on the ankle joint and foot while also creating an advantage compared to the current standard of care at HSS, the popliteal block.

MIDCAB is defined as a group of ultrasound guided distal nerve blocks at the level of the individual branches. The probe is placed mid-calf between the popliteal fossa and the ankle. The nerves to be blocked are the tibial nerve, superficial and deep peroneal nerves, sural and saphenous. Unlike the popliteal block, MIDCAB can provide the necessary analgesia to the foot and ankle of the patient while allowing them to preserve motor function of the foot. Right after surgery patients should be able to move their foot once the standard epidural has worn off and they should be able to participate in a PT sooner thus aiding their recovery. With this pilot study we are hoping to inform a subsequent randomized control trail (RCT) that would compare the pain scores, recovery and duration of the popliteal block to MIDCAB.

1. Hunter Warwick, Andrew George, Claire Howell, Cynthia Green, Thorsten M. Seyler, William A. Jiranek, "Immediate Physical Therapy following Total Joint Arthroplasty: Barriers and Impact on Short-Term Outcomes", *Advances in Orthopedics*, vol. 2019, Article ID 6051476, 7 pages, 2019. https://doi.org/10.1155/2019/6051476
2. Lakshmipathy Purushothaman, Anthony Allan, Nigel Bedforth **Ultrasound-guided ankle block** *Continuing Education in Anaesthesia, Critical Care & Pain | Volume 13 Number 5 2013*
3. Delbos Alain **Ultrasound-guided ankle block. History revisited** *Best Practice & Research Clinical Anaesthesiology 33 (2019) 79e93*
4. Girón-Arango L et al **Ultrasound-guided ankle block: An attractive anaesthetic technique for foot surgery** *Rev Colomb Anestesiol. 2015;43:283–289*
5. Nalini et al **Role of Regional Anesthesia in Foot and Ankle Surgery** *Foot&Ankle Specialist http://www.sagepub.com/journalsPermissions.nav. 2015*
6. Ki Jinn Chin Ultrasound Visualization of the Superficial Peroneal Nerve in the Mid-calf Anesthesiology 2013; 118:956 MIDCAB is defined as a group of ultrasound guided distal nerve blocks at the level of the individual branches.

2.0 OBJECTIVE(S) OF CLINICAL STUDY

This is a pilot observational cohort study aiming for a future randomized clinical-controlled trial with the objective of seeing if this MIDCAB block is a better alternative to the current standard of care popliteal block. We will mainly be assessing the duration of the MIDCAB block in patients who are undergoing foot and ankle surgery at HSS.

The majority of patients undergoing foot and ankle procedures are given a popliteal for analgesia afterwards, however that block prevents patients from moving their ankle and foot for sometimes after surgery. The hope with MIDCAB is that patients will be able to move their foot after surgery while having pain relief at the same time, allowing for earlier physical therapy to take place and thus faster recovery time.

We will aim to look at the following primary outcome:

1. Block Duration (PACU, POD1, POD2 & POD7). The primary outcome will be block duration, how long the MIDCAB block provides analgesia. This will be measured via questionnaires of pain scores given to patients post surgical discharge (in PACU), 24h post-surgical discharge, 48 hours post-surgical discharge, and 1-week post-surgical discharge. Pain scores will be measured via NRS pain scale; the NRS (numeric rating scale) is a questionnaire that measures pain on a numeric scale, 0 (no pain) to 10 (worst pain imaginable). We will also measure the time that pain began and the times that sensation of the foot returned for patients.

We will also be looking at the following secondary outcomes:

1. Motor Function (Measured in PACU). The return of the patient's foot/ankle motor function which will be measured by whether the patient can dorsiflex/plantarflex at the ankle or have flexion/extension of the toes.
2. Opioid Use (PACU, POD1, POD2 & POD7). Cumulative opioid consumption in morphine equivalents will be recorded post-surgical discharge (in PACU), 24h post-surgical discharge, 48 hours post-surgical discharge, and 1-week post-surgical discharge.
3. Presence of Paresthesia/Numbness & Skin Irritation/Wounds (POD7). Patients will be asked if they have any residual numbness, skin irritation or wounds at site of surgery/block.
4. Nausea & Vomiting (PACU, POD1, POD2 & POD7). The questionnaire used asks patients if they have experienced any nausea and vomiting, they are asked how many episodes of each have occurred. Patients are also asked on a scale from 0-10 (0 being not severe and 10 being the worst severity) how severe their nausea was. This will be measured post-surgical discharge (in PACU), 24h post-surgical discharge, 48 hours post-surgical discharge, and 1-week post-surgical discharge

3.0 STUDY HYPOTHESES

This is a pilot study aiming to assess the feasibility of MIDCAB to provide acceptable analgesia for foot/ankle surgery while still allowing the patient to preserve motor function of the foot and ankle. We hypothesize that the duration and analgesia of MIDCAB block will be non-inferior to the currently standard popliteal while being superior in terms of preserving motor function

4.0 STUDY DESIGN

4.1 Endpoints

4.1.1 Primary Endpoint

- The primary outcome is duration of the block. A questionnaire will be given to the patient before discharge from PACU, at 24 hours, 48 hours and 7 days post-op to measure NRS pain scores.

4.1.2 Secondary Endpoints

- Total opioid consumption (PACU, POD1, POD2, POD7)
- Motor function of the foot and ankle (PACU)
- Presence of nausea and vomiting (PACU, POD1, POD2, POD7)
- Presence of paresthesia/numbness, skin irritation/wounds (POD7)

4.2 Study Sites

This study will take place at the main campus of the Hospital for Special Surgery (HSS).

5.0 STUDY POPULATION

5.1 Number of Subjects

20

5.2 Inclusion Criteria

Subjects of either gender will be included if:

1. ASA of 1 or 2
2. Age 18-80
3. Undergoing an ankle or foot surgery
4. Ability to follow study protocol

5.3 Exclusion Criteria

Subjects will be excluded from the study if:

- Patients with the inability to understand or follow study protocol
- Chronic opioid use (3 months or more)
- Cannot receive neuraxial anesthesia and/or peripheral nerve block
- Patients with contraindications to intra-op protocol (e.g., patient cannot take acetaminophen or ketorolac due to liver or kidney disease)
- Patients with an ASA status of IV or higher
- Patients intending to receive general anesthesia
- Patients with BMI ≥ 45
- Patients unable to communicate via telephone
- Patients with type 2 diabetes
- Patient refusal

6.0 PROCEDURES

6.1 Intraoperative Protocol (update with detailed procedure)

Following patient transfer to the operating room, neuraxial anesthesia (spinal or combined spinal epidural (CSE) with up to 60mg mepivacaine 1.5% *or* up to 60mg of chloroprocaine 2%. Sedation will be provided intraoperatively with midazolam (up to 5mg), ketorolac (up to 30mg), famotidine (up to 20mg), along with ondansetron (4mg), dexamethasone (4mg) and propofol (titrated to effect). Tranexamic acid (TXA) will be dosed per surgeon request. Patient will be placed on a supine position with the anesthesiologist on the same side to be blocked. The MIDCAB block will be administered with ultrasound-guidance via a 25-gauge needle; 30ml bupivacaine 0.5% and 4mg preservative free dexamethasone will be divided into the following five nerves:

- **Posterior Tibia**l nerve: probe placed posterior to the medial malleoli. Posterior tibial artery and posterior tibial nerve are identified. Move the probe proximally following both artery and nerve to the level of the mid-calf. Using a 25 G needle, 10cc of local anesthetic is administered with careful visualization of the local anesthetic surrounding the nerve.
- **Saphenous** nerve: Located the saphenous vein at the level of the medial malleoli Pay attention to place a very gentle pressure on the probe to not collapse the vein. Follow the vein proximally to the level of the mid-calf. The nerve is lateral to the vein usually not seen. A perivascular injection at the level of the mid-calf is performed. 5 cc of local anesthetic is administered
- **Deep peroneal** Nerve: Probe moves medially towards the medial border of the tibia between the medial and lateral maleolli. The dorsalis pedis artery is easily identified next to the tibia. The probe moves as proximally as possible keeping the artery in view. The deep peroneal nerve is most commonly found laterally to the artery at this level. 5cc of local anesthetic is used paying attention to perform a perivascular injection.
- **Superficial peroneal** nerve: Moving the probe laterally the fibula is identified. Along with the Extensor digitalis muscle medially and the peroneus brevis laterally. The superficial peroneal nerve is located between the two muscles. Follow the nerve proximally to the mid-calf. Pay careful attention, the nerve is very superficial just deeper of the muscle fascia. 5cc of local anesthetic is delivered to surround the nerve.
- **Sural Nerve:** Move the probe lateral and posterior. Identified the peroneus brevis and the achilles tendon. The short saphenous vein is also identified between the peroneus brevis and the achilles tendon. The sural nerve is usually located lateral to the vein. Follow the sural nerve proximally to the level of the mid-calf. 5 cc of local anesthetic is administered.

Postoperatively, all patients will receive oral dexamethasone 10mg every 8 hours (3 doses), intravenous ketorolac 15mg (7.5 if under 50kg) every 6 hours, and oral acetaminophen 1000mg every 6 hours until discharged. For pain not controlled on this regimen, patients will be offered oral oxycodone, and intractable pain will be treated at the discretion of the provider. After 24 hours, patients will be transitioned to and discharged on oral meloxicam 7.5mg every 6 hours and oral acetaminophen 1000mg every 8 hours for thirty days. The PA or fellow working with the surgeon will place a discharge order for 42 oxycodone 5mg with no refills. Patients will be discharged with Mobic 15mg (7.5 if under 50kg) and acetaminophen 500mg. NRS pain scores (numeric scale 0-10) will be assessed along with motor function of the foot in the PACU. Additional pain score, nausea/vomiting and medication usage assessments will be performed on postoperative days 1, postoperative day 2 and postoperative day 7.

6.2 Data Collection

The following data will be collected:

Pre-operative/Baseline

- Basic demographic data
- Patient weight & height, BMI
- NRS scores at rest & with movement
- Opioid use

Intra Op Data (Operating room data)

- Successful administration of block (time admin.)

Pre-operative/Baseline

- Length of stay in PACU
- Length of stay in hospital

Post-Operative Day 0 (PACU)

- NRS pain scores at rest & with movement
- Opioid consumption
- Nausea/vomiting
- Block duration/resolution
- Motor function

Post-Operative Day 1 (POD 1)

- NRS pain scores at rest & with movement
- Opioid consumption
- Nausea/vomiting
- Block duration/resolution
-

Post-Operative Day 2 (POD 2)

- NRS pain scores at rest & with movement
- Opioid consumption
- Nausea/vomiting
- Block duration/resolution

Post-Operative Day 7 (POD 7)

- NRS pain scores at rest & with movement
- Opioid consumption
- Nausea/vomiting
- Presence of paresthesia/numbness
- Presence of skin irritation or wounds
- Patient satisfaction

7.0 STATISTICAL ANALYSIS

The primary outcome will be the block duration and will be measured via questionnaires of pain scores given to the patient in PACU, as well as 24 hours, 48 hours and 7 days post-op. Secondary outcomes for return of motor function of the foot meaning, can the patient dorsiflex/plantar flex at the ankle or have flexion/extension of the toes? Other secondary outcomes include opioid consumption, presence of paresthesias, nausea, vomiting and the time needed to perform the block. No interim analysis is planned, no sample size calculation needed as 20 total patients will be enrolled to study the feasibility and effectiveness of MIDCAB. The is a pilot study and descriptive statistics will be presented for every outcome. For continuous variable, descriptive statistics will be presented as means and standard deviations or median and interquartile ranges depending on data distribution. For categorical variable, descriptive statistics will be presented as frequencies and percentages.

8.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report.