Title: Adductor Canal Mid-thigh and Adductor Canal Distal Thigh: Is Cutaneous Sensory Blockade Similar Among Block Techniques?

NCT02788019

Document Date: 05/06/2016 (Date IRB officially approved)

The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

Protocol (for Investigator Initiated Studies)

Title: Adductor Canal Mid-thigh and Adductor Canal Distal Thigh: Is Cutaneous Sensory Blockade Similar Among Block Techniques?

Principal Investigator: Anthony Machi, M.D.

Co-Investigators:
Gloria Cheng, M.D.
Kinnari Khatri, M.D.
Trenton Bryson, M.D.
Kanu Birdi, M.D.
Sandy Thammasithiboon, M.D.
Jose Garcia, MD

Funding Source: UT Southwestern Department of Anesthesiology and Pain Management.

1. Introduction and Purpose:

The adductor canal block (ACB), or the "sub-sartorial mid-thigh" or "distal thigh saphenous block", are relatively new approaches in which local anesthetic is deposited within an aponeurotic tunnel in the middle-third of thigh containing multiple nerves.[1-5] ACB is predominately a blockade of multiple sensory nerves block with limited motor involvement. The block is utilized for knee surgery and for medial blockade of the leg (i.e., at or below the knee).[6-9]

The primary nerves located in this area are the saphenous nerve and a single efferent motor nerve, which is the distal branch of the femoral nerve that innervates the vastus medialis of the quadriceps muscle. In the distal portion of the adductor canal, a sensory branch of the posterior obturator nerve often enters the canal.[10,11] It is unclear if other nerves are found regularly in this anatomic location though it has been suggested that the medial femoral cutaneous nerve and medial retinacular nerve may be among them.[9] Debate is ongoing within the regional anesthesia literature regarding anatomy, differences of block technique and their potential effects on block results.[12-15] While comparisons of block technique have been studied,[16,17] there are no published studies regarding cutaneous sensation in light of the newly defined block technique parameters, to our knowledge.[10,12-14,18] We seek to confirm that the areas of sensory blockade are the same or differ following the two different types of adductor canal block in the area that is proximal to the knee. This knowledge can help improve patient analgesia and lower postsurgical opioid consumption for future patients having surgery in this area.

Hypothesis 1: The area of sensory blockade is different as a result of blockade at the mid-thigh and distal locations for the adductor canal block.

Specific Aim 1: To assess if the difference in cutaneous sensation to pinprick at 20-minutes after the block in patients randomized to receive mid-thigh or distal-thigh adductor canal blockades.

Hypothesis 2: To reconfirm that the mid-thigh and distal-thigh approaches to the ACB provide similar postoperative pain control for medial leg, medial ankle and medial foot surgery.

Specific Aim 2: To evaluate differences in the postoperative verbal response score in two randomized groups of patients received mid-thigh and distal-thigh adductor canal blockade in the first 24 hours postoperative.

Hypothesis 3: The maximum voluntary isometric contraction (MVIC) generated for knee extension is similar following the mid-thigh and distal thigh approaches to the ACB.

Specific Aim 3: To test the MVIC of knee extension with a hand held dynamometer at 20 minutes after the mid-thigh and distal-thigh approaches to the ACB.

Hypothesis 4: There is no difference in block performance time and patient satisfaction of two ACB techniques.

Specific Aim 4. To evaluate the differences in block performance time and patient satisfaction for two different ACB techniques.

Primary Endpoint:

- Distribution of cutaneous sensation to pinprick at 20-minutes and 30-minutes after the block.

Secondary Endpoints:

1. MVIC
2. Post-operative Pain scores, stratify to type of surgery
3. Opioid consumption
4. Block performance time
5. Characterization of cutaneous sensory block area by sensory mapping
6. Patient satisfaction

2. Background:

The adductor canal block is used for surgical anesthesia and/or postoperative pain control for surgeries involving the medial foot, medial ankle or medial leg. Different investigators have described varying techniques in accomplishing the adductor canal block as detailed here:

Manickam (distal thigh adductor canal): "The leg…was externally rotated, the knee slightly flexed. The medial aspect of the thigh was scanned in a transverse axial plane using a high-frequency linear probe prepared in a sterile fashion. The saphenous nerve was identified in a cross-sectional (short axis) view as it runs alongside the femoral artery in the adductor canal deep to the sartorius muscle. The transducer was initially placed on the medial aspect of the distal third of the thigh to identify the femoral artery immediately deep to the sartorius muscle. The transducer was then moved caudally along the long axis of the thigh until the femoral artery was seen "diving" deep and moving away from the anterior muscle plane (sartorius and vastus medialis muscles), toward the posterior aspect of the thigh where it becomes the popliteal artery. This area was identified as the "adductor hiatus," and the block location was selected 2 to 3 cm proximally to this area, in the distal adductor canal…The nerve was identified as a slightly hyperechoic structure with a round cross-section, in close relationship to the femoral artery, usually slightly superficial to it."[1]

Lund/Jaeger/Machi: mid-thigh adductor canal "A high-frequency linear ultrasound transducer was placed transverse to the longitudinal axis of the extremity at the mid-thigh level at a distance approximately halfway between the iliac spine and the patella. The femoral artery was identified underneath the sartorius muscle with the vein just underneath the artery. At this position, the saphenous nerve was placed lateral to the artery in the adductor canal. A 10cm Tuohy…was inserted, in plane, from the lateral side of the transducer, through the sartorius muscle with the tip placed lateral to the artery."[5]

"The midpoint between the anterior superior iliac spine and the cephalad margin of the patella was measured with slight external rotation of the leg at the hip. Using ultrasound at this midpoint, the superficial femoral artery was identified in a short-axis view deep to the sartorius muscle, medial to the rectus femoris muscle and anterior to the adductor longis muscle, with the superficial femoral vein usually posterolateral to the artery. At this position, the ultrasound image of the saphenous nerve or nerve bundle is typically anterolateral to the superficial femoral artery within the adductor canal. The corresponding anatomical positions for each structure are saphenous nerve anterior to the artery, vein lateral to the artery, and sartorius medial to the artery….the final needle tip positioning between the artery and the saphenous nerve. If the saphenous nerve could not be well visualized, the needle tip was placed at 5 o'clock relative to the femoral artery within the adductor canal."[8]

3. Concise Summary of Project:

This investigation will be a randomized interventional prospective pilot study. Patients undergoing medial foot, medial ankle, or medial leg surgery (n= 68) will be randomized to evaluate two types of adductor canal blocks. Patients will be identified during their orthopedic presurgical clinic visit, anesthesia preoperative clinic visit or Day Surgery Unit (Zale Lipshy Hospital, Clements University Hospital, UTSW Outpatient Surgery Center) for the eligibility. The electronic medical record (Epic) will also be used for prescreening of potential study participants by reviewing the clinic visit daily schedule or operating room schedule. Then patient charts will be reviewed for initial data collection to determine the eligibility of potential subjects with the use of a HIPAA waiver form. Eligible individuals may be introduced to the study in the orthopedic presurgical clinic or the anesthesia preoperative

clinic by staff. Those individuals interested in participation will then be contacted to learn about the study by study personnel.

A discussion of risks, benefits and alternatives will be performed.

Eligible and interested females of childbearing age will have a urine pregnancy test the morning of surgery. Exceptions include surgically sterile women or women with medically confirmed menopause. Urine (5 ml) will be collected for the urine pregnancy test (UPT). This is the routine clinical practice at Clements University Hospital, Zale Lipshy Hospital and the Outpatient Surgical Center as a part of the pre-procedure standard of care. Any females with a positive UPT will be excluded from the study.

Following the discussion and UPT (if necessary), informed written consent for clinical care and participation in the study will be obtained.

Once a patient is enrolled, they will be randomized to one of two groups, mid-thigh ACB or distal ACB, using a computer generated randomization program. The site will be marked, and a time out will be performed. A grid will be marked starting with anatomical landmarks at the knee joint: the medial inter-knee-joint point where the tibia meets the femur, the mid medial patella, the mid lateral patella, and along the same line at the semitendinosus tendon and 5cm posterior from that point. Then 5cm intervals will be plotted progressing cephalad to a total of 15 centimeters. This will yield 20 grid points.

The distribution of baseline sensation will be evaluated at the grid and documented. The degree of sensory block will be evaluated over the grid area with Neuropen prick testing on a scale of 0-1, with 1 = normal sharp sensation, 0 = change of sensation. The Neuropen will be used for the standardization of force.[19-21] The primary outcome will be the number of grid-points with a change in sensation at 20 minutes and 30 minutes after the block. The second post block measurement is to ensure that the block is effective, as this will vary with each patient, and there is potential to miss important sensory change if measurement is taken too early. The current clinical guidelines list a block onset time between 15-30 minutes.

MVIC of the ipsilateral quadriceps muscle will be assessed using a handheld dynamometer and recorded.[22-25]

Patients will receive a preoperative ultrasound-guided single-injection ACB at either the mid-thigh or distal approach according to their randomization and according to the technique descriptions provided in the Background section of this protocol and consistent with standard UTSW peripheral nerve block procedures.

A research assistant who is blinded to ACB approach will record the time taken to perform the block as defined as the time from the start of local anesthetic infiltration of the skin to the time the block needle was removed from the patient (Block performance time).
At the end of block performance a stopwatch will be started. Pinprick sensation and MVIC will occur at 20 minutes after block completion.

The efficacy of postoperative analgesia will be evaluated by using a 0-10 Likert scale (0=no pain, 10= worst imaginable pain). Pain will be evaluated in the PACU within 1 h postoperatively and postoperative Day 1 (POD1). If the patient is discharged to home, a phone interview will be performed within 24 h following the surgery for evaluation of POD1 pain scores, patient satisfaction, and monitoring adverse events.

Patient satisfaction as a measure of quality of pain management will be assessed POD1 via phone call on the scale of 1 to 5 (Poor=1, Fair=2, Good=3 Very good=4, Excellent=5).

The duration of the study period is 24 hours. Although participants will be participating in a research protocol, their clinical care will be the standard of care as if they were not involved in a research protocol (i.e. both types of blocks are performed routinely in clinical practice at Clements University Hospital and Zale Lipshy Hospital). As such, adjunct pain control using multimodal analgesia will be used to achieve adequate pain control. Preoperative gabapentin, acetaminophen or opiate medications as well as intraoperative opiates, ketamine, alpha-2-agonists, NSAID, acetaminophen or other analgesic may be used according to the standard of care multimodal analgesia practice. Postoperative adjuvant analgesics may include but is not limited to acetaminophen, NSAID, gabapentin, oral and IV opiate as needed, as well as opiate by IV patient controlled analgesia. For some types of surgery, concurrent sciatic nerve block may be desired and performed according to the anesthetic plan devised by the patient's faculty anesthesiologist in collaboration with the attending surgeon and patient wishes. To ensure appropriate completion of study protocol, the adductor canal block and all study procedures would occur before the sciatic block, which would still occur before surgery as is the standard of care. Those individuals who receive a sciatic block would have pain analyzed in a separate group from those receiving only an adductor canal block.

Billing should be in accordance with standard practice and not paid for by the study, as all procedures are deemed standard of care. Patients will not be reimbursed for participation of the research.

Recorded Measures:

1. Baseline number of grid-points with full sensation.
2. The number of grid-points with a change in sensation at 20-minutes after the block to determine distribution of cutaneous sensory blockade.
3. Baseline ipsilateral quadriceps MVIC: 3 measurements of 5 seconds each separated by 30 seconds while seated with hip and knee at 90 degrees
4. MVIC at 20 minutes and 30 minutes as tested with same method as baseline test
5. Block performance time (needle in skin until needle out of skin)
6. Patient satisfaction for postoperative pain management
7. Pain scores on a 0-10 Likert scale at PACU (1-h) and at postoperative Day 1 (POD1) approximately 24 h following to surgery (0=no pain, 10=worse imaginary pain)
8. For inpatients, all recorded pain scores in the first 24 hours
9. Opioid consumption in PACU and for first 24 h

PHI including name, date of birth, MRN number, contact information including phone number will be recorded. Demographic information such as age, height, weight, BMI, race/ethnicity, and gender will be recorded. Medical and surgical history including allergies, pre-existing condition such diabetes, and medication list, ASA classification, type of anesthesia, laboratory results, regional anesthesia techniques, sensory mapping for adductor canal block, postoperative pain management, postoperative pain scores, and type of surgery will also be recorded.

4. Study Procedures:

- Potential subjects will be identified at the orthopedic presurgical clinic, the anesthesia preoperative clinic or the Day Surgery Unit. The electronic medical record (Epic) will also be used for prescreening potential subjects.
- Recruitment and consenting at Anesthesia preoperative clinics, Day Surgery Unit.
- Randomization: A computer generated randomization list will be used for randomization list.

  - **Anatomical landmarks at the knee joint**:

- Sensory blockade will be assessed over a grid area. The grid will be marked starting with anatomical landmarks at the knee joint: the medial inter-knee-joint point where the tibia meets the femur, the mid medial patella, the mid lateral patella, and along the same line at the semitendinosus tendon and 5cm posterior from that point. Then 5cm intervals will be plotted progressing cephalad to a total of 15 centimeters. This yields 20 grid points.
- The study will use a 20 point-grid to standardize evaluation of sensory blockade in the anticipated border zone of block distribution. It will take approximately 1-2 minutes to make the grid and perform the testing. This is specifically for research purposes.

  - **Pinprick testing:**

- The Sensory block for sharp sensations will be assessed by using Pinprick testing. Pinprick testing will be tested on a scale of 0-1, with 1 = normal sharp sensation and 0 = dull change of sensation, using a Neuropen for standardization of force.[19-21]
- Sensation to the Neuropen will be performed gently across the skin with the end of the device to assess sharp touch. The subject will be asked to determine whether the stimulus feels sharp. The number of grid-points with a change in sensation from baseline will be recorded at 20-minutes and 30-minutes after the block.

- Mechanical stimulation with pinprick testing is routinely used to test nociception in the bedside neurologic examination. Sharpness can be considered a surrogate for nociception because, whereas sharpness is not necessarily painful, mechanical thresholds for sharpness closely parallel those for pain.[26]

  - **Maximum Voluntary Isometric Contraction**:

- The MVIC will be assessed with a handheld dynamometer (Lafayette Instrument Company; Lafayette, Indiana).

- The patient will be in a seated position with the thigh parallel to the floor and the knee at a 90-degree angle with the feet off the floor. The dynamometer is applied to the leg 5 cm above the transmalleolar axis and perpendicular to the tibial crest. The patient is instructed to extend the leg at the knee with sustained maximal force for 5 seconds. This will be repeated 3 times with 30 seconds rest between each movement, and the force will be recorded. MVIC will be assessed at baseline and again at 20 minutes and 30 minutes post block.

    - **Adductor Canal Blockade:**
- The adductor canal block will be performed using a linear HFL38xp or a linear HFL38x ultrasound probe (X-Porte or M-Turbo; SonoSite; Bothell, Washington). The site that is to receive the ACB will be sterilized with chlorhexidine gluconate 2% and 70% isopropyl alcohol prep. A skin weal of lidocaine 1% (2-5mL) will be delivered. A Tuohy needle (17 gauges) will be inserted through the skin wheal under ultrasound guidance towards the target nerve location. Ropivacaine 0.5% 15ml will be injected for either adductor canal locations.[27]

- The research intervention of this study will take place within the standard clinical context. The patient will receive an ACB regardless of their participation in this research in accordance with their anesthetic plan and their desires.

- **Follow-up visit**:
- A follow-up visit will be performed in person for inpatients or via phone for outpatients within 24 hours from discharge to assess for pain control, and monitoring side effects. It will take 10 minutes.
- **Monitoring Adverse Events**
- Adverse events will be monitored during the 24-h study period.

5. Sub-Study Procedures:
N/A

6. Criteria for Inclusion of Subjects:

1. Adult patients age ≥ 18 years
2. Individuals undergoing surgery of the medial foot, medial ankle, medial leg or knee for which the anesthetic plan includes an adductor canal nerve block

Selection for inclusion will not be based on gender, race, or socioeconomic status. The study population of interest includes men and women of all races and socioeconomic status. There will be no participants from vulnerable populations, such as pregnant women, children or prisoners.

Patients can decline enrollment. If they do so, they will still receive a peripheral nerve block for postoperative analgesia according to the plan determined by the anesthesia provider at the time of service in accordance with the patient's wishes.

7. Criteria for Exclusion of Subjects:

1. Any known deficit of the ipsilateral lumbar nerve roots, ipsilateral lumbar plexus, ipsilateral femoral nerve, obturator nerve or saphenous nerve including diabetic peripheral neuropathy
2. Any local disorder of the skin or otherwise where blockade is to be performed
3. Body mass index >50
4. ASA classification greater than 3
5. Allergy to amide local anesthetic medications
6. Pregnancy
7. Incarceration
8. Inability to understand study procedures including inability to understand the English language

8. Sources of Research Material:

- Patients undergoing medial foot, medial ankle, medial leg or knee surgery.
- Information from medical records including PHI, preoperative anesthesia report, intraoperative anesthesia report, post-operative notes, progress notes, Surgery transcript, and Acute Pain Service documentation.
- Performance of ACB for the purpose of postoperative pain
- Sensory mapping
- Evaluation of efficacy of postoperative analgesia

9. Recruitment Methods and Consenting Process:

Eligible subjects will be undergoing lower extremity surgery of the medial foot, ankle, leg or knee for which the anesthetic plan already includes an adductor canal block. Patients will be identified in the orthopedic presurgical clinic or preoperative anesthesia clinic, or by reviewing operating room master daily schedule in Epic. The patient chart will be reviewed in accordance with a HIPAA viewer authorization. Providers first proposing study participation will come into contact with patients during routine preoperative contact to ensure HIPAA compliance. Eligible patients will be approached by the anesthesia service or research coordinator/assistant within four weeks prior to surgery.

The purpose of the study and potential risks, benefits and complications of the study will be explained. Adequate time will be given to read the consent form. All questions will be answered before the patient is asked to sign the consent form. If the subject agrees to participate, written, informed consent will then be obtained using UTSW IRB-approved informed consent form and HIPAA consent form prior to any study procedures in the pre-operative period on the day of surgery or in the preanesthetic clinic.

10. Potential Risks:

There is minimal risk to subjects by participating in this study. Potential risks include loss of confidentiality or mild discomfort associated with the pinprick for sensory testing. There are no additional physical or psychological risks that may result from participation in this

research protocol since patients will have determined that they desire perineural blockade before study inclusion is even proposed.

- *Risks of adductor canal blockade:*

The needle may damage surrounding tissues, including nerves, and may cause bleeding and infection. Each of these is rare (<1%). There is a potential risk of local anesthetic toxicity; however, this too is rare (<1%). There is a theoretical increased risk of fall should local anesthetic spread to the motor nerves of the quadriceps other than the vastus medialis; however, studies have shown preserved quadriceps muscle function following ACB.

- *Risk of Pinprick testing*

There may be minimal discomfort during pinprick testing. Neuropen stimulation will be performed gently across the skin to decrease discomfort.

- Risk of MVIC testing

There may be minimal discomfort during knee extension with application of the handheld dynamometer.

- Risks to an Embryo, or Fetus

Females: A urine pregnancy test will be performed before the enrollment of any female study participants of childbearing age. Pregnant females will not participate in the study.

- *Psychological Stress*

Some of the questions that will be asked as a part of this study may make a participant feel uncomfortable.

- *Loss of Confidentiality*

Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep patient information confidential.

11. Subject Safety and Data Monitoring:

Any serious adverse reaction, including allergy and local anesthetic systemic toxicity, will result in immediate discontinuation of study related procedures and treatment as necessary. Serious adverse events will be reported to the Institutional Review Board. The data already obtained from a participant who has had a serious adverse event will be analyzed according to intention-to-treat principle.

All data will be collected under the supervision of the primary investigator.

12. Procedures to Maintain Confidentiality:

All patients will be identified by a numerical code such as Case 01, Case 02, Case 03…etc. This code will be used during gathering and reporting the information. Direct patient identifiers

will not be used during data analysis. A key coding system will be created. De-identified study data will be recorded using the secure Redcap database.

Stored electronic data that contains PHI and/or other types of identifiable data will be encrypted and password protected and stored on a secure server. Subject identifiers will not be reused or disclosed to any other person or entity for research unless required by law, for authorized conduct and oversight of the study, or for other IRB-approved research.

All protected health information will be kept in a secure location with limited access.

Following the completion of the analysis and the project, the key to the coding system will be destroyed by shredding the documents so that there is no direct or indirect link to subject identifiers and information.

13. Potential Benefits:

Potential benefits in determining whether the two neurosensory blockade techniques are different include identifying a potential difference in the area of sensory blockade of the thigh, a potential difference in strength as indicated by MVIC, as well as suggesting a potential improvement in analgesia of the thigh and subsequent increase in patient satisfaction, as well as decreased postoperative opioid usage for future patients.

Both neurosensory blockade techniques are very safe, have little or no pain associated with administration, and have the same cost.

14. Biostatistics:

Sample Size Estimation:

There is no prior study to provide basis for a sample size estimation. Thus the study is powered to achieve 70% power with two-sided alpha = 0.05 for testing the equivalence of the two blocking methods. With an equivalence margin of 2 points (two blocking methods will be equivalent if mean score for one blocking method within two points of the other) and assuming a standard deviation of 3 points, the study will have 70% power with n = 34 in each group (total n = 68).

Statistical analyses:

Data will be summarized as mean and standard deviation for continuous variables and frequency and percentages for categorical variables. The equivalence of the two blocking methods will be tested using the two-one-sided-tests (TOST) procedure following Schuirmann (1987). [28] Pain scores and opiate consumption will also be analyzed in subgroups according to the location and type of surgery (foot vs. ankle vs. leg) and presence of concurrent sciatic block.

If non-inferiority between the two neurosensory blockade techniques is significantly detected at 50% enrollment (or enrollment of 34 patients), we will stop the study. We would also stop the study in the event that there is overwhelming statistical evidence at interim analysis that the two blocks are different. In the very small chance that there are multiple

adverse events in our patient population, we would also consider that to be a signal to stop the study.

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