

**Randomized controlled trial evaluating postoperative analgesia and muscle strength between single versus continuous adductor canal block for ambulatory ACL reconstruction.**

**Version Date: 08/23/2017**

**NCT02584452**

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## 1. Background

Adequate analgesia with maintained functionality is crucial to recovery for patients undergoing outpatient anterior cruciate ligament reconstruction. Perioperative peripheral nerve blocks have been utilized in these procedures to maximize postoperative pain, minimize side effects from IV analgesics, and facilitate discharge from PACU. The gold standard of peripheral nerve blocks for ACL reconstruction has been the femoral nerve block<sup>1</sup>; however, this block has shown to have deleterious side effects such as quadriceps weakness, which has been associated with increased risk of falls and prolonged recovery postoperatively<sup>2-4, 15</sup>. Previous studies have focused on sparing the motor function of the quadriceps by performing adductor canal block and targeting the saphenous nerve, which is a predominantly a sensory nerve<sup>5</sup>. Studies comparing efficacy of femoral nerve blocks compared to adductor canal blocks in total knee arthroplasty have shown equal analgesic action with significant sparing of quadriceps strength in the adductor canal group<sup>6-9</sup>. Utilization of adductor canal blocks for ACL reconstruction have yielded varying results in terms of significant postoperative analgesia over non-regional based postoperative pain control<sup>10-12</sup>. However, postoperative pain control seems to be equivalent in femoral versus adductor canal blocks in ACL reconstruction<sup>13</sup>. Despite the apparent multifaceted benefit in differentiating blockade sites and duration of nerve blockade, the efficacy of continuous adductor canal blockade utilized specifically in ACL reconstruction has not been extensively studied. Studies comparing single bolus femoral nerve blocks to continuous adductor canal catheters are ongoing. The efficacy of continuous adductor canal blockade utilized specifically in ACL reconstruction compared to single bolus adductor canal blockade has yet to be determined.

## **2. Rationale and Specific Aims**

We will conduct a randomized controlled trial evaluating the efficacy of two different regional techniques in patients undergoing ACL reconstruction. The primary goal will be to determine the differences in postoperative pain on POD 2 when comparing preoperative femoral nerve block with mepivacaine plus postoperative continuous adductor canal nerve catheter with bupivacaine compared to preoperative femoral nerve block with mepivacaine plus postoperative saphenous nerve block with ropivacaine and dexamethasone. Primary outcome will be pain scores at 48hrs after PACU discharge. Secondary outcomes will include pain scores on POD 0, 1 & 3, opioid utilization on POD 0, 1, 2 & 3, and quadriceps strength on operative leg at rehab session on POD 1.

### **Hypothesis**

The use of the adductor canal continuous nerve catheter will result in lower subjective pain scores on postoperative day 2 and improved quadriceps strength on postoperative day 1.

### **Primary Aim**

1. Determine the subjective postoperative pain scores at POD 2 of preoperative femoral nerve block plus postoperative continuous adductor canal nerve catheter compared to preoperative femoral nerve block plus postoperative saphenous nerve block at 48 hours after discharge from PACU.
2. Determine the quadriceps strength of on POD 1 of preoperative femoral nerve block plus postoperative continuous adductor canal nerve catheter compared to preoperative femoral nerve block plus postoperative saphenous nerve block at 48 hours after discharge from PACU straight leg raise and knee extension tests.

### **Exploratory Aims**

1. Determine the subjective postoperative pain scores on POD 1, 2 and 3 of patients receiving (1) preoperative femoral nerve block plus postoperative continuous adductor canal nerve catheter compared to (2) preoperative femoral nerve block plus postoperative saphenous nerve block.
2. Determine the total postoperative opioid consumption on POD 1, 2 and 3 of patients receiving (1) preoperative femoral nerve block plus postoperative continuous adductor canal nerve catheter compared to (2) preoperative femoral nerve block plus postoperative saphenous nerve block.
3. Determine physical therapy participation with a validated assessment tool on POD 1.
4. Determine operative leg strength and pain at 6 weeks post-op.

## **3. Inclusion Criteria**

- A. Age 14 and older
- B. Patients who are scheduled to undergo an ACL reconstruction with patella or allograft
- C. Patient does not have a contraindication to receiving regional anesthesia

#### **4. Exclusion Criteria**

- A. Allergy to local anesthetics, dexamethasone, or adhesive tape
- B. Patients undergoing hamstring graft for ACL
- C. Preexisting infection at site of needle insertion
- D. Immunocompromised patients
- E. Preexisting sensory or motor deficit in operative extremity
- F. Patient on chronic opioid treatment.
- G. Patient having a revision of previous ACL reconstruction.
- H. Pregnancy and lactating women

#### **5. Enrollment**

We will enroll 100 patients undergoing ACL reconstruction with patella or allograft who meet the inclusion criteria stated above.

#### **6. Study Method**

Patients undergoing ACL reconstruction at Vanderbilt Bone and Joint Surgery Center by Dr. Scott Arthur will be identified at surgical scheduling and conveyed to anesthesia team for inclusion into study. The assigned in-room providers will be educated on the protocol and randomization process.

After written informed consent is obtained by either the patient or the designated surrogate decision maker, patients will be randomized to 2 groups: (1) continuous adductor canal nerve catheter or (2) long-acting single bolus adductor canal nerve block.

Following random selection via random envelope selection patients will receive the following procedures. Both groups will receive ultrasound guided femoral nerve block with 20cc of 2% mepivacaine <20 minutes prior to in room time.

Intraoperative patients will undergo initiation of general anesthesia under the care of the attending anesthesiologist assigned to the patient. Induction will include a propofol bolus and placement of laryngeal mask airway. Intraoperative opioid should be limited to no more than 150mcg of fentanyl. Upon completion of wound closure, appropriate dressing placement, emergence from anesthesia and removal of LMA, patients to be taken to PACU. Once adequately awake and alert, Group 1 patients will receive ultrasound guided adductor canal continuous nerve catheter using normal saline as bolus for placement, followed by initiation of 1/8% bupivacaine infusion through catheter at 8cc/h. Group 2 will receive ultrasound guided adductor canal nerve block with 10cc of 0.5% ropivacaine + 2mg dexamethasone (0.5cc), keeping total injectate at 10.5cc to spare significant proximal spread to femoral nerve<sup>14</sup>. After adequate instruction including catheter education (if applicable) patients are to be discharged home.

The following data will be collected by evaluation by study investigators via phone calls:

- Subjective Numeric Rating Pain Scale score (NRPS) at discharge from PACU

- Subjective Numeric Rating Pain Scale score (NRPS) 48 hours following discharge from PACU.
- PONV score on POD 1 following discharge from PACU
- Subjective Numeric Rating Pain Scale score (NRPS) on POD 1 and 3.
- Opioid utilization based on number of pain pills (standardized dose) on POD 1, 2, and 3.
- Quadriceps strength in operative leg utilizing “Straight Leg Raise” Test, 0-5/5 scale.
- Quadriceps strength in operative leg utilizing knee extension, 0-5/5 scale.
- Physical Therapy participation on POD 1.
- Patient will follow up with surgeon at 6 weeks. He will do an evaluation of each patient's strength in operative leg and functional capacity in terms of ability to ambulate, as well as presence/severity of pain. Strength to be assessed by straight leg, knee extension, knee flexion on 5 point scale. Pain score on 10 point numerical scale. Ambulation: independently vs assistance, with or without pain, with or without gait abnormality

#### **7. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others**

Information regarding AEs is to be obtained and documented by the surgery center anesthesia attending and/or the investigator performing the data collection and by questioning or examining the patient. All new complaints and symptoms (i.e., those not existing prior to signing of informed consent) will be recorded on the AE CRF. All AEs will be characterized in terms of their start and stop dates, start and stop times, intensity, action taken, relationship to research study, subject outcome and whether or not the AE led to an SAE.

#### **8. Statistical Considerations**

Power calculations based on using 2 groups to detect a 2-point reduction in pain on numerical pain scale yields an 88% power. All individual data (including any relevant derived variables) will be stored in a password protected electronic database (REDCAP).

#### **9. Privacy/Confidentiality Issues**

All reasonable efforts will be made to keep a patient's protected health information (PHI) private and confidential. There will be limited access to medical records and de-identification of all records. Federal privacy guidelines will be followed when using or sharing any protected health information.

#### **10. Follow-up and Record Retention**

The study will be completed after the participation of 100 patients. This data will be used to draw conclusions about the superiority of a continuous adductor canal nerve

catheter or long-acting saphenous nerve block versus single shot femoral nerve block. This information could, potentially serve as standard of care for postoperative analgesia for ACL reconstructions by maximizing analgesia and participation in rehab.

The investigators will keep a record (i.e., Master Subject Log) relating the names of the subjects, date informed consent was signed, subject status, and date when subject completed the trial.

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