Comparison of postoperative analgesic efficacy of adductor canal block with IPACK versus adductor canal and popliteal sciatic nerve block in patients undergoing arthroscopic anterior cruciate ligament reconstruction

NCT03983941

March 15, 2021

PROTOCOL TITLE:

Comparison of postoperative analgesic efficacy of adductor canal block with IPACK versus adductor canal and popliteal sciatic nerve block in patients undergoing arthroscopic anterior cruciate ligament reconstruction.

PRINCIPAL INVESTIGATOR:

Name: Sujana Dontukurthy, MD
Department/Center: Anesthesiology & Pain Medicine
Telephone Number: 614-722-4200
Email Address: Sujana.Dontukurthy@nationwidechildrens.org

VERSION NUMBER/DATE:

Version 6 / March 15, 2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/13/2019	Changing block meds to what is currently standard of care.	No
2	9/3/2019	Adding 0.2 mg/ml of dexamethasone to the sciatic & IPACK, which was missed in the last revision.	No
3	9/17/2019	Adding epinephrine 1:200,000 to the sciatic & IPACK, which was missed in the last revision.	No
4	9/27/2019	Changing femoral nerve block via the adductor canal to just femoral nerve block, removing acetaminophen at the end of surgery, and removing the motor and sensory evaluations in the PACU.	Yes
5	3/15/2021	Adding information about obtaining signature of 2nd parent in section 22.3.	No

1.0 Study Summary

Study Title	Comparison of postoperative analgesic efficacy of femoral nerve block with IPACK versus femoral and popliteal sciatic nerve block in patients undergoing arthroscopic anterior cruciate ligament reconstruction.
Study Design	Prospective study
Primary Objective	The primary objective of the study is to compare the analgesic efficacy of FNB with IPACK versus FNB with sciatic nerve block in patients undergoing ACL repair by monitoring postoperative pain scores.
Secondary Objective(s)	The secondary objective is to show a decreased incidence of adverse effects including motor blockade with IPACK compared to sciatic nerve block and to demonstrate that it is technically less challenging by showing a decreased time required for performance of the block.
Research Intervention(s)/ Investigational Agent(s)	Patients will receive up to 20 mL of 0.5 % ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for FNB-AC and up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for sciatic nerve block or posterior knee capsular infiltration.
IND/IDE #	N/A
Study Population	Patients undergoing elective anterior cruciate ligament reconstruction.
Sample Size	50
Study Duration for individual participants	Total of 2 weeks.
Study Specific Abbreviations/ Definitions	IPACK – infiltration of the posterior knee capsule FNB - Femoral nerve block PACU – post-anesthesia care unit POD – post-op day

2.0 Objectives

2.1 The primary objective of the study is to compare the analgesic efficacy of FNB with IPACK versus FNB with sciatic nerve block in patients undergoing ACL repair by monitoring postoperative pain scores.

2.2 The secondary objective is to show a decreased incidence of adverse effects including motor blockade with IPACK compared to sciatic nerve block and to demonstrate that it is technically less challenging by showing a decreased time required for performance of the block.

2.3 We hypothesize that FNB with IPACK provides the same analgesic efficacy as FNB with sciatic block while avoiding the motor blockade associated with sciatic nerve block.

3.0 Background

3.1 Anterior cruciate ligament reconstruction is one of the most common orthopedic surgical procedures performed on an outpatient basis.1 The ability to effectively discharge these patients is primarily determined by the efficacy of postoperative pain control. Regional anesthetic techniques are commonly used to provide postoperative analgesia as they provider superior analgesia when compared to opioids and have also been shown to facilitate same day, outpatient discharge home.2 Various regional techniques have been used, generally combining blockade of the femoral and sciatic nerve to provide analgesia of the knee and surrounding structures. Performance of the sciatic nerve block can be technically challenging and time consuming. One alternative to sciatic nerve block is infiltration of the posterior knee capsule (IPACK) under ultrasound guidance. Results with IPACK in adults for posterior knee joint analgesia in patients undergoing total knee arthroplasty have been comparable to sciatic nerve block. Furthermore, IPACK is technically less challenging as it is only infiltration of the knee capsule below the division of the sciatic nerve, without targeting for nerves, and is not associated with motor block.3

3.2 The aim of the current study is to determine if the analgesic efficacy of IPACK is similar to sciatic nerve block thereby reducing the side effects involved with sciatic nerve block as well as the technical challenges of performing the block.

4.0 Study Endpoints

4.1 The time for performance of the block (FNB plus sciatic versus FNB plus IPACK).

4.2 Intraoperative opioid (fentanyl) and inhalational anesthetic agent (sevoflurane) requirements.

4.3 Pain scores and opioid requirements in the PACU.

4.4 Degree of sensory and motor block in phase I (PACU) and phase 2 recovery.

4.5 Post-discharge opioid requirements and pain scores (pain diary).

4.6 Duration of subjective postoperative sensory and motor blockade.

5.0 Study Intervention/Investigational Agent

5.1 Study subjects will receive up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for FNB and up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for sciatic nerve block under ultrasound guidance or posterior knee capsular infiltration under ultrasound guidance (IPACK), the total dose not to exceed 3 mg/kg of ropivacaine.

5.2 Both the FNB and sciatic nerve blocks are considered standard of care at NCH. The IPACK is not currently performed at NCH.

6.0 Procedures Involved*

6.1 Following informed consent, patients will be randomized into one of the two groups. Intraoperative anesthetic care will not vary from our usual practice. Patients requiring preoperative anxiolysis will receive oral midazolam (0.3-0.5 mg/kg, maximum 20 mg) 30 minutes prior surgery or intravenous midazolam (0.05 mg/kg, maximum 2 mg) prior to transport to the operating room. Standard American Society of Anesthesiologists' monitors will be placed. Once in the operating room, anesthesia will be induced by the intravenous or inhalational route as clinically indicated. All subjects will receive propofol (2-3 mg/kg) and fentanyl (2μg/kg). Following the induction of anesthesia, an appropriately sized laryngeal mask airway (LMA) will be placed. After the regional anesthesia time out, patients will receive the block based on the group assigned from a randomization list created by www.sealedenvelope.com. The time from the initiation of the time-out for the block until the patient has been returned to the surgical position will be noted.

6.2 The following demographic and surgical parameters will also be collected and recorded: patient age, gender, race/ethnicity, height, weight, ASA status, primary diagnosis, list of comorbidities, procedure date and duration, admission status, intraoperative medications and postoperative medications, PACU arrival and discharge times, discharge destination, pain scores (including recorded time), regional anesthetic time and dose, postoperative opioids consumed and time of hospital admission and discharge.

6.3 Group 1: Patients will receive up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for FNB and up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for sciatic nerve block under ultrasound guidance, the total dose not to exceed 3 mg/kg of ropivacaine (total volume 1.5 mL/kg of 0.2% ropivacaine). For patients who weigh less than 30 kg, the volume of the local anesthetic will be reduced to keep the total dose at ≤ 3 mg/kg.

Group 2: Patients will receive up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for FNB and up to 20 mL of 0.5% ropivacaine with epinephrine 1:200,000 and 0.2 mg/ml of dexamethasone for posterior knee capsular infiltration under ultrasound guidance (IPACK), the total dose not to exceed 3 mg/kg of ropivacaine. For patients who weigh less than 30 kg, the volume of the local anesthetic will be reduced as needed to keep the total dose at ≤ 3 mg/kg.

6.4 For intraoperative increases in heart rate or systolic blood pressure ≥ 20% above the baseline, fentanyl (1 μg/kg) will be administered every 5 minutes until the heart rate is below this threshold. Prophylaxis for postoperative nausea and vomiting will include ondansetron (0.1-0.15, maximum 4 mg). At the conclusion of the procedure, all patients will receive ketorolac (0.5 mg/kg, maximum 30 mg).

6.5 Patients experiencing severe pain with VAS scores >7 at the surgical site will be considered as failed FNB or sciatic nerve block and will be withdrawn from the study. In the postoperative care unit, the nursing staff will be blinded to which group the patient was assigned to, reducing bias. Fentanyl (1 μg/kg, maximum 50 μg) will be administered every 5-10 minutes as needed until the patient's visual analogue score (VAS) score is ≤ 4. VAS will be evaluated every hour until discharge. When the patients are ready for discharge and tolerating oral intake, analgesia will be changed to hydrocodone with acetaminophen, 1 tablet by mouth if needed, prior to discharge home.

6.6 Patients will be discharged home with postoperative pain medication to include hydrocodone with acetaminophen. Parents will be instructed to administer one tablet every 4 hours as needed when the VAS score is greater than 4. If the patient does not tolerate hydrocodone, the patient will be given the option for ibuprofen 10 mg/kg every 6 hours. Caregivers will be given a diary to record the amount of pain medication consumed, pain scores (every 4-6 hours), and the duration of motor block as reported by the patient. On postoperative day 1(or 2 for a later discharge), a member of the study team will call to collect the information for a total of 24 hours following hospital discharge. The study investigator will also contact the patients 2 weeks after the procedure to assess for any adverse events not detected during the initial data collection.

7.0 Data and Specimen Banking*

N/A

8.0 Sharing of Results with Subjects*

8.1 Results will not be shared.

9.0 Study Timelines*

- An individual study subject's participation in the study should last approximately 2 weeks total.
- All study subjects should be enrolled within 2 years of study start.
- The study should be completed within 3 years of study start.

10.0 Inclusion and Exclusion Criteria*

10.1 Potential subjects will be identified by reviewing the surgery schedule in Epic and will be recruited from the Surgery Unit pre-op area prior to their surgery.

10.2 Inclusion criteria: Patients 10 - 21 years of age, with American Society of Anesthesiologists physical status I and II, undergoing elective anterior cruciate ligament reconstruction.

10.3 Exclusion criteria: Patients will not participate in the study if any of the following apply to them:

- They are unable or unwilling to take part in the study
- History of allergy to any of the medications administered for the nerve block
- Contraindication to peripheral nerve block
- Patients who are unable to understand instructions or questions related to the study or the families required language interpretation.
- Patients who consume opioid medications for more than three days per week for more than a month prior to surgery.

10.4 We are including children, and will not include:

- Adults unable to consent
- Pregnant women
- Prisoners

11.0 Vulnerable Populations*

11.1 This study presents no more than minimal risk as it involves regional nerve blocks which are used routinely as standard of care by the anesthesiologists at this institution.

12.0 Local Number of Subjects

12.1 50

12.2 Sample size will be determined according to previous studies in adults. Abdallah et al. described the non-inferiority of the IPACK block over 24 hours postoperatively, while Kim et al. described superiority of IPACK with respect to pain scores at rest and ambulation, as well as opioid consumption, over postoperative days 0-1. With the greatest pain observed on POD0, our study will be powered for comparing the maximal pain score on POD0 between the 2 groups. Based on the data presented by Abdallah et al., we anticipate that pain scores over POD0 would differ by no more than 1 point between the groups, on a 0-10 scale. Based on the data presented by Kim et al., we hypothesize a standard deviation of pain scores of 1.1. Following Abdallah et al, our study will be powered for a test of IPACK non-inferiority, such that the null hypothesis will

be rejected if pain scores in the IPACK group are >1 point greater than in the control group. Under these assumptions, an unpaired one-tailed t-test would attain 90% power for rejecting the null hypothesis at a 95% confidence level when at least 22 patients are enrolled in each group. We propose enrolling a total of 50 patients to account for non-normal distribution of the primary outcome; protocol violations resulting in subject exclusion; and missing data.

13.0 Recruitment Methods

13.1 Subjects will be recruited from the surgery unit pre-op area. They will be identified by reviewing OR schedules in Epic.

14.0 Withdrawal of Subjects*

14.1 Patients experiencing severe pain with VAS scores >7 at the surgical site will be considered as failed FNB or sciatic nerve block and will be withdrawn from the study.

15.0 Risks to Subjects*

15.1 The common side effects of ropivacaine (the numbing medication used in the nerve blocks) are injection site burning or pain and prickly feeling as the block wears off. Occasional side effects of ropivacaine are ear ringing, metallic taste, and drowsiness. Rare side effects of ropivacaine are seizures, unconsciousness, respiratory arrest, low blood pressure, irregular heartbeat, cardiac arrest, and allergic reactions including anaphylaxis. There is also potential risk for loss of confidentiality.

15.2 Subjects and their families will be approached about the study and consented in a private room in the pre-op area by a member of the research team. The information collected will be limited to that which is required to achieve the objectives of the study and will not be shared with anyone not directly involved in the study. Subjects will be informed of their right to refuse to participate. Subject PHI will be stored in a locked cabinet, and will be stored and maintained in password protected computer files.

16.0 Potential Benefits to Subjects*

16.1 No direct benefit to the subject.

17.0 Data Management* and Confidentiality

17.1 Continuous outcomes will be compared between groups using 2-sample t-test or rank-sum tests according to the normality of the distribution (checked by the Shapiro-Wilk test). Categorical outcomes will be compared between groups using Chi-square or Fisher's exact tests, according to cell size.

17.2 Research records will be stored in a locked cabinet and password protected computer. Only certified research personnel will be given access to identifiable subject information

17.3 Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 The study will only be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subjects and their families will be approached about the study and consented in a private room in the pre-op area by a member of the research team. The information collected will be limited to that which is required to achieve the objectives of the study and will not be shared with anyone not directly involved in the study. Subjects will be informed of their right to refuse to participate.

20.0 Compensation for Research-Related Injury

20.1 None

21.0 Economic Burden to Subjects

21.1 None

22.0 Consent Process

22.1 The consent process will begin in the preoperative surgery unit on the day of surgery, by PI, Sub-Investigators, Study Coordinators, and/or trained research staff.

22.2 The study will be thoroughly explained to the patient and their family. There will be ample time allotted for questions and answers. An explanation of voluntary participation will take place, and the family will be asked if they are interested in participating in the study. If the patient and their parent(s), or legal guardian agrees to participate they will be asked to sign consent and assent forms. The patient will then be enrolled in the study with the understanding that they can elect to stop the study and be withdrawn from the study at any time.

22.3 If the second parent is not with the patient, since this study requires 2 parent signatures, the second parent will be contacted by phone, the study will be explained to him/her, and we will either obtain verbal consent or the document will be scanned, emailed, signed, and emailed back.

23.0 Process to Document Consent in Writing

23.1 We will be following SOP: Written Documentation of Consent (HRP-091).

24.0 Setting

24.1 Subjects will be recruited from Surgery Unit and all study procedures will take place in the OR after the subject has been anesthetized.

25.0 Resources Available

25.1 The department of Anesthesiology and Pain Medicine has 2 research coordinators and 2 research associates that will be enrolling subjects for this study. All study staff will be trained on the study procedures.

26.0 Multi-Site Research*

N/A

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

☒ Name
☐ Complete Address
☐ Telephone or Fax Number
☐ Social Security Number (do not check if only used for ClinCard)
☒ Dates (treatment dates, birth date, date of death)
☐ Email address , IP address or url
☒ Medical Record Number or other account number
☐ Health Plan Beneficiary Identification Number
☐ Full face photographic images and/or any comparable images (x-rays)
☐ Account Numbers
☐ Certificate/License Numbers
☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☒ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)

☐ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)
☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)
☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)
☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

***Find the HIPAA forms in the IRB Website Library, Templates.**

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained?
Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

4.0 Describe any plans to code identifiable information collected about each participant. Subject ID numbers will be used on research related documents such as the subject journals.

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:
☒ Research records will be stored in a locked cabinet in a secure location
☒ Research records will be stored in a password-protected computer file
☐ The list linking the assigned code number to the individual subject will be maintained separately from the other research data
☒ Only certified research personnel will be given access to identifiable subject information

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)
Subjects and their families will be approached about the study and consented in a private room in the pre-op area by a member of the research team. The information collected will be limited to that which is required to achieve the objectives of the study and will not be shared with anyone not directly involved in the study. Subjects will be informed of their right to refuse to participate.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

- ☒ Demographics (age, gender, educational level)
- ☒ Diagnosis
- ☐ Laboratory reports
- ☐ Radiology reports
- ☐ Discharge summaries
- ☒ Procedures/Treatments received
- ☒ Dates related to course of treatment (admission, surgery, discharge)
- ☐ Billing information
- ☒ Names of drugs and/or devices used as part of treatment
- ☐ Location of treatment
- ☐ Name of treatment provider
- ☐ Surgical reports
- ☒ Other information related to course of treatment
- ☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to meet the objectives of the study and to analyze the data.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No

References:

1. Abdallah FW, Whelan DB, Chan VW, Prasad GA, Edersby RY et, al. Adductor canal block provides noninferior analgesia and superior quadriceps strength compared with femoral nerve block in anterior cruciate ligament reconstruction. Anesthesiology 2016;123:1053-1064.
2. Schloss B, Bhalla T, Klingele K, Phillips D, Prestwich B, Tobias JD. A retrospective review of femoral nerve block for postoperative analgesia after knee surgery in the pediatric population. J Pediatr Orthop 2014;34:459-61.
3. Kim DH, Beathe JC, Lin Y, et al. Addition of infiltration between the popliteal artery and the capsule of the posterior knee and adductor canal block to periarticular injection enhances postoperative pain control in total knee arthroplasty: a randomized controlled trial. Anesth Analg 2018 (in press).

4. Amir N. Combined adductor canal and i-PAK blocks is better than combined adductor canal and periarticular injection blocks for painless ACL reconstruction surgery. J Anes Crit Care 2018;10:154-157.
5. Korula S, George GM, Ipe S, Abraham SP. Epidural anesthesia and post-operative analgesia for bilateral inguinal mesh hernioplasty: Comparison of equipotent doses of ropivacaine and bupivacaine. Saudi J Anaesth 2011;5:277-281.