Genicular Nerve Blocks for Arthroscopic Anterior Cruciate Knee Surgery: A Randomized Controlled Trial

FUNDER: Department of Anesthesiology

PROTOCOL NO.: 2022-1962

VERSION & DATE: 11/25/2024

TABLE OF CONTENTS

PROTOCOL SYNOPSIS

Protocol Title:	Genicular Nerve Blocks for Arthroscopic Anterior Cruciate Knee Surgery: A Randomized Controlled Trial
Protocol Number:	2022-1962
Protocol Date:	11/21/2022
Sponsor:	Department of Anesthesiology
Principal Investigator:	David H. Kim, MD
Products:	N/A
Objective:	The intervention to be studied is to see if the addition of the genicular nerve block (GEN) to our current peripheral nerve block regimen of adductor canal block (ACB) and infiltration between the popliteal artery and capsule of the posterior knee (IPACK) significantly reduces opioid consumption in first 24 hours after an anterior cruciate ligament repair with bone tendon bone autograft surgery.
Study Design:	Randomized Study
Enrollment:	192
Subject Criteria:	Inclusion: • Ambulatory arthroscopic unilateral anterior cruciate ligament repair surgery with bone tendon bone autograft • English-speaking • ASA I-III • BMI < 35 Exclusion: • History of chronic pain syndromes • Chronic opioid use (daily morphine milligram equivalents > 30 mg for at least 3 months) • Contraindication to peripheral nerve blocks • Contraindication to neuraxial anesthesia • History of peripheral neuropathy or pre-existing neurological deficits • Psychiatric or cognitive disorder that prohibit patient from following study protocol • Allergy to local anesthetic or study medications • Multiligament surgery • History of substance abuse • Infection at the site of injection • diagnoses of Type I or Type II diabetes
Study Duration:	2 years
Data Collection:	**Sources:** EPIC, Medical Records, and Patient Reported. **Variables:** Name, MRN, DOB, Race, Ethnicity, Gender, Height, Weight, BMI, ASA class, email address, phone number, level of

	education, co-morbidities (diabetes, high blood pressure, cholesterol, rheumatological conditions, allergies), medications to manage pre-existing conditions (opioids and non-opioids), surgery details (surgeon, anesthesiologist, surgery type, tourniquet use, duration), anesthesia details, DVT prophylaxis medications ordered and/or administered, length of PACU stay, time to meet discharge criteria, opioid consumption, IV PCA ordered, NRS pain scores, nerve block success, duration of blocks, ACB assessment, brief pain inventory, patient satisfaction.
Statistical Analysis:	1. **Proposed analysis (e.g., student's t-test, ANOVA, chi-square, regression, etc.):** two-sample t-test (one sided-alternative hypothesis OME reduction 0-24 hours mean (gen block) < mean (control) 2. **Interim analysis planned?:** No 3. **Alpha level:** 0.05 4. **Beta or power level:** 0.8 5. **Primary outcome variable estimate (mean +/- s.d. for continuous outcome, frequency/percentage for categorical variable):** 28.2 +/- 23.34 mg oral morphine equivalents 6. **Number of groups being compared (use 1 for paired analysis within the same subjects):** 2 7. **Effect size or change expected between groups:** 33% reduction in opioid consumption 0-24 hours after block time (9.31) 8. **Resulting number per group:** 96 9. **Total sample size required:** 192 (10% attrition added to 174 needed for statistical significance)

1.0 INTRODUCTION

Genicular nerve blocks have been shown to provide effective analgesia for chronic osteoarthritis knee pain [1]. There are several publications supporting its use for chronic knee pain but there is a scarcity of literature in its use in the perioperative period. Recently, it has been shown to provide effective analgesia for total knee arthroplasty [2]. This will be a novel application for it to be used for anterior cruciate ligament surgery. There are only a couple of prospective and retrospective studies that showed promising analgesic benefits for anterior cruciate ligament repairs [3][4]. There are currently no randomized controlled trials published investigating the use of genicular nerve blocks for anterior cruciate ligament surgery.

Researching novel innovative motor-sparing and opioid-sparing peripheral nerve blocks for have been the focus of our research team. We have investigated the motor sparing benefits of the adductor canal block [5], the effective analgesic benefits of the IPACK block [6], the phrenic sparing benefits of the superior trunk block [7], and the analgesic benefits of the pericapsular nerve group block and lateral femoral cutaneous nerve [8]. Genicular nerve blocks would be a potential additive block that may further enhance the recovery of our knee surgeries, including unicondylar, total knee and anterior cruciate ligament repair patients.

2.0 OBJECTIVE OF CLINICAL STUDY

Since 2021, we have performed genicular nerve blocks on our patients at HSS and anecdotally seen immediate benefit in the patients via reduction of opioid consumption and earlier discharge. Recently, genicular nerve blocks have demonstrated significant and clinically meaningful reduction in opioid consumption in total knee arthroplasty patients. The purpose of the study is to perform a randomized controlled trial on the patients who underwent anterior cruciate ligament repairs comparing our current standard regimen of peripheral nerve blocks, which includes an adductor canal block (ACB) and interspace between the popliteal artery and capsule of the posterior knee block (IPACK), to a new regimen that includes the addition of genicular nerve blocks.

3.0 STUDY HYPOTHESES

Genicular nerve blocks will significantly and clinically meaningfully reduce mean opioid consumption (in oral morphine equivalents) by 33% in the first 24 hours compared to the standard peripheral nerve block regimen. Genicular nerve blocks will significantly reduce mean NRS pain scores in the first 24 hours. Genicular nerve blocks will significantly reduce discharge times. Genicular nerve blocks will reduce opioid consumption and NRS pain scores in first 48 hours. Genicular nerve blocks will have better scores on the brief pain inventory questionnaire and higher patient satisfaction.

4.0 STUDY DESIGN

4.1 Study Duration

January 2023 – November 2024

4.2 Endpoints

4.2.1 Primary Endpoint

- **Mean opioid consumption at 24 hours**

4.2.2 Secondary Endpoints

- **Opioid consumption at PACU, 48, 72,96, 168 hrs:** PACU (PACU arrival to removal from board), 48,72,96,168 hours after time zero (PACU arrival time)
- **NRS pain scores at PACU, 24, 48, 72, 96, 168 hrs:** PACU (discharge ready time = recovery complete time), 24,48,72,96,168 hours after time zero (PACU arrival time)
- **Cumulative opioid consumption at 48, 72, 96 hours:** sum of opioid used from 0-48 hours, and 0-72 hours, and 0-96 hours.
- **Brief pain inventory (short form):** Preoperatively, 24,48,72,96,168 hours
- **Patient satisfaction with pain treatment:** PACU, 24, 48 hours
- **Duration of analgesic block**: RA scripted phone call at 24 hours after block placement (or 48 hours if block still in place). Patients will be asked "When did your pain relief from the block completely"
- **Success of ACB:** numbness in the saphenous distribution will be assessed in the PACU by an anesthesiologist or RA
- **Time of readiness for pacu discharge:** from pacu arrival time to recovery complete time.
- **Length of PACU stay:** from pacu arrival time to patient removed from board time
- **Adverse events:** Incidence of neuropraxia (neurological symptoms over 3 days), LAST, and infection

4.3 Study Sites

This study will take place at the Hospital for Special Surgery (HSS) West Side Ambulatory Surgery Center.

5.0 STUDY POPULATION

5.1 Number of Subjects

192

5.2 Inclusion Criteria

Subjects of either gender will be included if they:

- Ambulatory arthroscopic unilateral anterior cruciate ligament repair surgery with bone tendon bone autograft
- English-speaking
- ASA I-III
- BMI < 35

5.3 Exclusion Criteria

Subjects will be excluded from the study if they:

- History of chronic pain syndromes
- Chronic opioid use (daily morphine milligram equivalents > 30 mg for at least 3 months)

- Contraindication to peripheral nerve blocks
- Contraindication to neuraxial anesthesia
- History of peripheral neuropathy or pre-existing neurological deficits
- Psychiatric or cognitive disorder that prohibit patient from following study protocol
- Allergy to local anesthetic or study medications
- Multiligament surgery
- History of substance abuse
- Infection at site of injection
- diagnoses of Type I or Type II diabetes

5.4 Randomization

Participants will be assigned at random to one of 2 study groups:

- Group 1 (control): patients receive adductor canal block (ACB) + infiltration between the popliteal artery and capsule of the posterior knee (IPACK)
- Group 2 (genicular nerve block): patient receive ACB + IPACK + GEN

6.0 PROCEDURES

6.1 Surgical Procedure

Arthroscopic anterior cruciate ligament repair

6.2 Medical Record Requirements

Using EPIC, research staff will review the patient's medical history to determine eligibility to participate in the study.

PHI that will be reviewed:

Name, DOB, preferred language, medical history, allergies, current outpatient medication, weight & body mass index

6.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

Name, MRN, DOB, Race, Ethnicity, Gender, Height, Weight, BMI, ASA class, phone number, co-morbidities

Surgical procedure

- Surgery details (date of surgery, surgeon, laterality, duration, tourniquet use)
- Anesthesia details (neuraxial, PNB, medications given)

Follow-up visits (PACU, Post-operative day of surgery (POD) 1, 2, 3, 4, 7)

- Brief Pain Inventory (BPI)
- Analgesic duration
- ACB assessment
- Opioid consumption

- NRS pain score
- Patient satisfaction

7.0 STATISTICAL ANALYSIS

Proposed analysis (e.g., student's t-test, ANOVA, chi-square, regression, etc.): two-sample t-test (one sided- alternative hypothesis OME reduction 0-24 hours mean (gen block) < mean (control)
Interim analysis planned?: No
Alpha level: 0.05
Beta or power level: 0.8
Primary outcome variable estimate (mean +/- s.d. for continuous outcome, frequency/percentage for categorical variable): 28.2 +/- 23.34
Number of groups being compared (use 1 for paired analysis within the same subjects): 2
Effect size or change expected between groups: 33% reduction in opioid consumptions 0-24 hours after block time (9.31)
Resulting number per group: 96
Total sample size required: 192 (10% attrition added to 174 needed for stat. significance)

8.0 ADVERSE EVENT ASSESSMENT

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

9.0 REFERENCES

1. Aaron Conger, DO, et al. Genicular Nerve Radiofrequency Ablation for the Treatment of Painful Knee Osteoarthritis: Current Evidence and Future Directions, Pain Medicine, Volume 22, Issue Supplement_1, July 2021, Pages S20–S23
2. Rambhia M, et al. Ultrasound-guided genicular nerve blocks following total knee arthroplasty: a randomized, double-blind, placebo-controlled trial. Reg Anesth Pain Med. 2021 Oct;46(10):862-866.
3. Caldwell GL Jr, Selepec MA. Reduced Opioid Use After Surgeon-Administered Genicular Nerve Block for Anterior Cruciate Ligament Reconstruction in Adults and Adolescents. HSS J. 2019 Feb;15(1):42-50.
4. Gruskay JA, et al. Surgeon-Administered Anterolateral Geniculate Nerve Block as an Adjunct to Regional Anesthetic for Pain Management Following Anterior Cruciate Ligament Reconstruction. Arthrosc Tech. 2022 Jan 20;11(1):e1-e6.
5. Kim DH, et al. Adductor canal block versus femoral nerve block for total knee arthroplasty: a prospective, randomized, controlled trial. Anesthesiology. 2014 Mar;120(3):540-50.
6. Kim DH, 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. 2019 Aug;129(2):526-535.
7. Kim DH, et al. Superior Trunk Block: A Phrenic-sparing Alternative to the Interscalene Block: A Randomized Controlled Trial. Anesthesiology. 2019 Sep;131(3):521-533
8. Kim DH, et al. Pericapsular nerve group with lateral femoral cutaneous blocks for hip arthroscopy: a retrospective cohort study. ASRA abstract presentation 2022