A Pilot Study Comparing Anterior Femoral Cutaneous Nerve Blocks to Adductor Canal Blocks in Pediatric Ambulatory Knee Surgeries

FUNDER: Anesthesiology Research Department

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PROTOCOL SYNOPSIS

Protocol Title:	A Pilot Study Comparing Anterior Femoral Cutaneous Nerve Blocks to Adductor Canal Blocks in Pediatric Ambulatory Knee Surgeries
Protocol Number:	2024-0582
Protocol Date:	6/14/2024
Sponsor:	Anesthesiology Research Department
Principal Investigator:	Kathryn DelPizzo
Products:	N/A
Objective:	The goal of this pilot study is to collect information on the effects of the Anterior Femoral Cutaneous Nerve Block (AFCNB) compared to the Adductor Canal Block (ACB) in adolescent patients undergoing ambulatory knee surgery at the Hospital for Special Surgery.
Study Design:	A double-blinded, pilot parallel group-randomized trial (GRT)
Enrollment:	60 subjects
Subject Criteria:	1. 8-18 years old at the time of surgery
	2. Patients 40kg and above
	3. ACL repair of MPFL reconstruction surgery with participating surgeons
Study Duration:	1. 3 years (anticipated)
Data Collection:	• Demographics, patient-reported outcomes, pain and satisfaction survey/questionnaires
Outcome Parameters:	• Postoperative function (motor strength in quadriceps)
	• Opioid consumption, NRS pain at rest & with ambulation, pain expectation scale, satisfaction with pain management, postoperative sensation, postoperative function
Data Evaluation:	PACU, post operative 6 hrs, 24 hrs, 48 hrs, 7 days, 14 days, 6 weeks, 6 months
Statistical Analysis:	For this pilot study, we are incorporating the “rule of 12” for continuous outcome in our sample size. A sample size of n=15 per treatment group, to account for potential attrition, for a total of 60 patients.

1.0 INTRODUCTION

The current focus and trend of pediatric postoperative pain management research involves increased opioid stewardship and regional anesthesia use [1-3]. Previous studies have highlighted the importance of regional anesthesia during knee surgery such as ACL reconstruction, suggesting that perioperative adductor canal block is safe [4] for pediatric patients, and beneficial for reducing pain and minimizing muscle weakness in the immediate postoperative in adult patients [5-10]. Controversy remains on the potential residual effects on functional outcomes with adult patients receiving ACBs, and there is limited data on outcomes in younger patients. A study by Christensen et al suggested that there is prolonged postoperative quadriceps weakness after ACL reconstructions in adults who received an ACB [11]. In a recent retrospective study evaluating quadriceps and hamstring strength in adolescent patients who underwent primary unilateral ACL between July 2008 and January 2018 at a single institution, isokinetic quadriceps deficits were measured at 4-8 months postoperatively in patients who received either a femoral nerve block (n = 36), ACB (n = 31) or no block. The authors found no significant difference in isokinetic quadriceps function among the three groups (@ 5.61 ± 2 months), though they identified a trend towards more negative value in the ACB group suggesting of greater muscle weakness.

There was, however, a significantly lower knee flexion peak torque in the hamstring of patients who received the ACB compared to FNB group. Limitations include the retrospective nature of the study, procedures limited to hamstring autografts, inclusion of patients who did or did not have meniscal repairs, variations in anesthetic technique and doses, as well as in postoperative physical therapy approaches.

Targeting the anterior femoral cutaneous nerve (AFCNB) is a motor sparing technique that provides incisional pain relief but also targets the fascia lata which is integral to the knee and surgically traumatized during knee surgeries. The entire kneecap is blocked when targeting the AFCN in the medial thigh.[13, 14]

No prospective randomized controlled studies have been conducted in pediatric ACL and MPFL reconstruction patients that compare pain intensity levels, opioid consumption and muscle strength in the acute perioperative period and later time points with different peripheral nerve blocks. To our knowledge, this will be the first pediatric study to prospectively collect data from patients receiving AFCNB vs. ACB.

2.0 OBJECTIVE OF CLINICAL STUDY

There is scant literature on the efficacy of peripheral nerve blocks or the comparative effectiveness of anesthesia and analgesia techniques in pediatric/adolescent patients undergoing orthopedic procedures, particularly ambulatory knee procedures such as anterior cruciate ligament (ACL) reconstruction. The Pediatric Regional Anesthesia Network, PRAN, to which the study team has contributed information, has focused on safety, rather than efficacy, of regional techniques. The efficacy of these regional techniques in this demographic has not been investigated and therefore represents a vital knowledge gap.

Moreover, there is practice variation at HSS with regard to how patients are blocked for ACL reconstruction surgery. While most surgeons request an adductor canal block (ACB), others do not, citing concerns with potential immediate and persistent functional motor deficits. Given the innervation to the knee and concern with residual functional impairment,

the goal of our pilot study is to collect preliminary information comparing the AFCNB vs ACB, in the hopes of using this data to power a larger randomized controlled trial to rigorously study this clinical question.

3.0 STUDY HYPOTHESES

As this is a pilot study, no formal hypothesis testing will be performed.

4.0 STUDY DESIGN

A double-blinded, pilot parallel group-randomized trial (GRT)

4.1 Study Duration

Approximately 3 years

4.2 Endpoints

Primary and secondary outcomes

4.2.1 Primary outcome

- Postoperative function (motor strength in quadriceps)

4.2.2 Secondary outcome(s)

- Cumulative opioid consumption
- NRS at rest & with ambulation
- Pain expectation scale
- Satisfaction with Pain Management
- Postoperative sensation
- Postoperative function

4.3 Study Sites

Hospital for Special Surgery, New York, New York

5.0 STUDY POPULATION

5.1 Number of Subjects

60

5.2 Inclusion Criteria

Subjects of either gender will be included if they:

1. 8-18 years old at the time of surgery
2. Patients 40kg and above
3. ACL repair of MPFL reconstruction surgery with participating surgeons
4.

5.3 Exclusion Criteria

Subjects will be excluded from the study if they:

1. Revision surgery
2. Bilateral surgery
3. General anesthesia
4. Contraindications to any part of the study protocol
5. Relevant pre-existing neurological deficit
6. Chronic pain

5.4 Randomization

30 ACL subjects, randomized to either Adductor Canal Block (15) or Anterior Femoral Cutaneous Nerve Block (15).

30 MPFL subjects, randomized to either Adductor Canal Block (15) or Anterior Femoral Cutaneous Nerve Block (15).

6.0 PROCEDURES

6.1 Surgical Procedure

Anterior Cruciate Ligament (ACL
Medial Patellofemoral Ligament (MPFL)

6.2 Medical Record Requirements

Basic demographic variables: Name, MRN, DOB, Race, Sex, Ethnicity, Height, Weight, BMI

6.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

- basic demographic data
- patient weight & height, BMI
- NRS pain at rest & with ambulation

Surgical procedure

- date of surgery
- type of surgery

Follow-up visits (PACU, POD 1-4, 7, 2 wks, 6 wks, 3 mo, & 6 mo)

- NRS pain at rest & with ambulation
- Opioid consumption
- Patient satisfaction with pain management
- Pain expectation
- Postoperative sensation
- Quadriceps strength (dynamometer)

- Range of motion (goniometer)
- PROMIS-10: physical function score

6.4 Schedule of Assessments

Procedures	Before DOS	Pre-op (Holding area)	POD 0	POD 1-2	POD 7	POD 14	2 weeks, 6 weeks, 3 mo, 6 mo, 1 yr
Informed Consent & Eligibility Review	X						
Obtain Assent from minor patient and Consent from parent or guardian		X					
Randomization		X					
NRS Pain Scores (rest & ambulation)		X	X	X*	X	X	
Opioid consumption			X	X*	X	X	
Patient satisfaction w/pain management					X		
Pain expectation			X	X*	X	X	
Measure of sensation						X	X*
Measure of function						X	X*

*=Patient will be re-evaluated by the investigator as per standard follow-up post-operatively at the following intervals

7.0 STATISTICAL ANALYSIS

For this pilot study, we are incorporating the “rule of 12” for continuous outcome in our sample size.
A sample size of n=15 per treatment group, to account for potential attrition, for a total of 60 patients.

8.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report. Definitions for Adverse Event (AE) used in this study are listed below and are based on FDA and international guidelines:

8.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product.

8.2 Serious Adverse Events (SAE)

The event is serious and should be reported to FDA when the patient outcome is:

Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Congenital Anomaly/Birth Defect, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events).

8.3 Adverse Event Relationship

Relationship to study: definitely, probably, possibly, not related.

8.4 Adverse Event Recording

All adverse events will be recorded in the adverse event log by the research coordinator.

8.5 Adverse Event Reporting

All adverse event reports will be made to the institutional review board as they come up/occur.

9.0 INVESTIGATOR RESPONSIBILITIES, RECORD AND REPORTS

9.1 Subject Consent and Information

Research assistants will screen the co-investigating surgeons' patients undergoing ACL and MPFL surgeries. Screening will involve reviewing the patient's EPIC chart to ensure

that they meet the inclusion criteria and are not excluded due to any of the exclusion criteria listed. Patients who meet the inclusion criteria will be identified as potential study participants. After the investigating anesthesiologists have confirmed the eligibility of all potential participants, one of the investigating anesthesiologists will approach the potential patients in the pre-operative holding area, explain the rationale for the study, and ask if the patient is interested in participating.

9.2 Subject Data Protection

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the Research Director and accessible only to the principal investigator, in addition to other IRB-approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e., name, medical record number, date of birth, registry number) will be maintained in a different password-protected database maintained by Research Director, to which only the primary investigator will have access.

9.3 Staff Information

Primary Investigator: Kathryn DelPizzo, MD
Research Coordinator: Pa Thor, PhD, 646-797-8535

9.4 Protocol Reviews

Study protocol reviewed and approved by:

- Anesthesiology CRP
- Hospital for Special Surgery Institutional Review Board

10.0 REFERENCES

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