Comparative evaluation of lumbar plexus and suprainguinal fascia iliaca compartment block for pain management after orthopedic surgical procedures involving hip and femur in pediatrics

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PROTOCOL TITLE:

Comparative evaluation of lumbar plexus and suprainguinal fascia iliaca compartment block for pain management after orthopedic surgical procedures involving hip and femur in pediatrics.

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VERSION NUMBER/DATE:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
2	13Mar2019	Adding coinvestigators, adding exclusion criteria, minor changes to methods.	No
3	06May2019	Changing the procedures regarding the neuromuscular blocking agents and the postoperative analgesia.	No

1.0 Study Summary

Study Title	Comparative evaluation of lumbar plexus and suprainguinal fascia iliaca compartment block for pain management after orthopedic surgical procedures involving hip and femur in pediatrics.
Study Design	Prospective study
Primary Objective	The primary objective will be to measure total time to perform the regional anesthesia technique.
Secondary Objective(s)	The secondary objectives are opioid consumption during the first 24 and 48 postoperative hours, pain scores during the first 24 and 48 hours, and hospital length of stay.
Research Intervention(s)/ Investigational Agent(s)	Lumbar plexus block or fascia iliaca compartment block with ropivacaine 0.5% with 1:200,000 epinephrine.
IND/IDE #	N/A
Study Population	Patients undergoing elective orthopedic surgical procedures involving the hip and upper thigh.
Sample Size	70
Study Duration for individual participants	Time of surgery to discharge home - ~ 48 hours
Study Specific Abbreviations/ Definitions	LPB – lumbar plexus block FICB – fascia iliaca compartment block

2.0 Objectives

2.1 The primary objective will be to measure total time to perform the regional anesthesia technique. The secondary objectives are opioid consumption during the first 24 and 48 postoperative hours, pain scores during the first 24 and 48 hours, and hospital length of stay.

2.2 The hypothesis is that the two techniques will be equally effective in providing analgesia following hip and femur surgery in the pediatric population; however, the time to perform the FICB will be shorter than the lumbar plexus block.

3.0 Background

3.1 Regional anesthesia techniques including peripheral nerve blockade in children undergoing orthopedic procedures provide effective postoperative analgesia, reduce opioid consumption, decrease the time to discharge, and minimize the exposure to general anesthetic agents.[1-3] Increased use of regional anesthesia in infants, children, and adolescents has significantly improved the scope of pediatric pain management. Epidural analgesia was formerly the gold standard for

pain treatment following orthopedic procedures involving the lower extremities despite the potential for adverse effects including hypotension and urinary retention. Additionally, epidural analgesia provides bilateral sensory blockade for what may be a unilateral procedure. Lumbar plexus blockade (LPB) has recently seen increased use as an adjunct to decrease opioid consumption for procedures involving the hip and thigh.[3,4] However, the technique is complex, time-consuming, and is associated with potential complications including needle advancement into the peritoneum or retroperitoneum, which may result in a renal hematoma, vascular puncture (retroperitoneal hematoma), or even bowel puncture.

Alternatively, fascia iliaca compartment block (FICB) provides an easy and safe technique to anesthetize the femoral, lateral femoral cutaneous, and obturator nerves in a superficial fascial plane avoiding the potential risks of lumbar plexus block.[5] FICB reduces opioid consumption in adult patients after total hip arthroplasty. Desmet et al. demonstrated that a supra-inguinal FICB reduced opioid consumption by 46% in the first 24 hours and 45% over 48 hours in adult patients following total hip arthroplasty thus offering another regional anesthetic technique to provide postoperative pain management following procedures on the hip and upper thigh.[6] To our knowledge, there are no studies comparing lumbar plexus block to fascia iliaca block for pain management after orthopedic procedures involving the hip and femur in the pediatric population.

3.2 We aim to compare the use of a suprainguinal FICB vs lumbar plexus block as an adjunct to general anesthesia in pediatric patients undergoing orthopedic procedures involving the hip or upper femur. This study will help determine the efficacy of the two techniques and their advantages when compared to each other including time to perform the block, opioid consumption reduction, effects on postoperative pain, and the length of stay. If the FICB technique is equally effective, it would offer a safer alternative to lumbar plexus block, which may be accomplished in a more expeditious manner.

4.0 Study Endpoints

4.1 Time to perform each block.

4.2 Pain scores and opioid consumption during the first 24 and 48 hours post-op.

5.0 Study Intervention/Investigational Agent

5.1 Study subjects will receive either a LPB or a suprainguinal FICB under ultrasound guidance. Either block will be achieved with 3 mg/kg (0.6 mL/kg) of ropivacaine 0.5% with 1:200,000 epinephrine.

5.2 Both of these blocks are considered standard of care and patients could receive either one without participating in this study.

6.0 **Procedures Involved***

6.1 This will be a double-blinded, randomized, prospective study involving patients, ranging in age between 2 and 18 years of age, ASA grade I-III, undergoing elective orthopedic surgical procedures involving the hip and upper thigh. Patients will be randomly divided into 2 groups: Group LP and Group FICB. The block (LP or FICB) will be performed by one of the study investigators. The team providing intraoperative care will step out of the room during the regional block and care will be provided by the research team including an attending anesthesiologist. Once the primary anesthesia team finishes the induction phase, the study team will perform the regional anesthesia time-out. Measurement of the time to complete the block will start when the time-out is completed and end when the need is withdrawn and the patient is positioned in the surgical positioning. The perioperative care teams will be blinded to the type of the block by using two dressings in all the patients. The first dressing will be placed at the actual site of needle insertion and the second dressing at the site where needle would have been inserted if the patient were to receive the other type of block (in the back for the LP block and groin for the FICB).

6.2 Anesthetic care will be standardized in all patients except for type of the regional nerve block. Patients requiring 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 up to 2 mg) prior to transport to the operating room. Once in the operating room, all patients will be monitored as per standard ASA guidelines. Anesthetic induction will be achieved with 70% nitrous oxide in oxygen and sevoflurane or with intravenous propofol. If preoperative midazolam was not administered, intravenous midazolam will be administered (0.05 mg/kg to a maximum of 2 mg). Following loss of consciousness, fentanyl (2 µg/kg) will be administered and the trachea intubated. Administration of neuromuscular blocking agents (NMBA) will be deferred until after regional anesthesia technique has been performed. Rocuronium (0.6-1 mg/kg) will be used according to surgeons request. In case NMBA are needed for tracheal intubation then succinylcholine (1-2mg/kg) will be used. Anesthesia will be maintained with 1-2 MAC of sevoflurane in 50% oxygen/air. Following endotracheal intubation, patients will receive either a LPB or a suprainguinal FICB under ultrasound guidance. Either block will be achieved with 3 mg/kg (0.6 mL/kg) of ropivacaine 0.5% with 1:200,000 epinephrine. Maximum block volume will be 30 mL for both blocks. 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. Additional intraoperative analgesia will be achieved with bolus doses of fentanyl 1 µg/kg to maintain the

heart rate and blood pressure within 20% of baseline. Prophylaxis for postoperative nausea and vomiting will include dexamethasone (0.1-0.15 mg/kg up to 8 mg) and ondansetron (0.1-0.15 mg/kg up to 4 mg). At the conclusion of surgery, residual neuromuscular blockade will be reversed and the patient's trachea extubated.

6.3 Postoperative analgesia will be achieved with IV hydromorphone as needed (PRN) with a dose regimen of 0.02 mg/kg per dose. Depending on patient's use if there is need to escalate treatment a PCA, NCA or CCA will be started. Patients will also receive IV acetaminophen 15 mg/kg every 6 hours and IV ketorolac 0.5 mg/kg every 6 hours (unless contraindicated) during the 48 hour study period. The first dose of these two agents will be administered in the operating room at the completion of the surgical procedure. If the patient is ready to transition from IV to oral pain medications, oxycodone (0.1 mg/kg every 4 hours) will be started and the hydromorphone discontinued. At that time, acetaminophen will be switched to oral and ketorolac switched to oral ibuprofen.

6.4 The following data will be collected:

- Block procedure time (in minutes and seconds)
- Opioid administration intraoperatively.
- Postoperative opioid consumption in the PACU.
- Postoperative opioid consumption for the first 48 hours after surgery (PACU discharge to inpatient ward admission).
- Pain assessment scores (VAS in older children, FACES scales in children between 2-4 and FLACC for non-verbal children) in the PACU (first pain score) and for the first 48 hours (standard pain assessments) on the inpatient ward.
- The duration of the need for intravenous opioid therapy.
- Use of rescue pain medications in the PACU, on the floor, including non-opioids, will also be recorded and analyzed.
- Hospital length of stay.

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, duration, admission status intraoperative medications, PACU arrival and discharge times, discharge destination, pain scores (including recorded time),

regional anesthetic time and dose, and time of hospital admission and discharge.

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 48 hours 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: Aged 2-18 years, ASA grade 1-3, undergoing elective orthopedic surgical procedures involving the hip and upper thigh.

Exclusion criteria: Local anesthetic allergy, skin or localized infection at the site of catheter insertion opioid use within 3 months prior to surgery, history of opioid abuse or dependence, pre-existing motor or sensory deficits, patient or parent refusal.

10.3 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 70

12.2 Sample size will be determined according to a previous study investigating the time taken to perform 2 variations on the lumbar plexus block, with the slower technique taking 334 ± 156 seconds and the faster technique taking 238 ± 74 seconds. We hypothesize that the time difference between the 2 techniques in our study will be

at least as large as the difference between the 2 block types investigated in this prior study. Specifically, assuming that the FICB will be at least 96 seconds faster than the LP block while the pooled standard deviation is 128 seconds, the proposed t-test would have 80% power to confirm a statistically significant difference at a 95% confidence level when at least 29 subjects are enrolled in each group. Therefore, we propose enrolling a total of 70 patients to account for dropout or 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*

N/A

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 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study. 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 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

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.

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. None

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.)
Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

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. Wong J, Marshall S, Chung F, Sinclair D, Song D, Tong D. Spinal anesthesia improves the early recovery profile of patients undergoing ambulatory knee arthroscopy. Can J Anaesth 2001;48:369-74.
2. Rappaport B, Mellon RD, Simone A, Woodcock J. Defining safe use of anesthesia in children. N Engl J Med 2011;364:1387-90.
3. Ross AK, Eck JB, Tobias JD. Pediatric regional anesthesia: Beyond the caudal. Anesth Analg 2000;91:16-26.
4. Dadure C, Raux O, Gaudard P, Sagintaah M, Troncin R, Rochette A, Capdevila X. Continuous psoas compartment blocks after major orthopedic surgery in children: A prospective computed tomographic scan and clinical studies. Anesth Analg 2004;98:623-628.
5. Eastburn E, Hernandez M, Boretsky K, Technical success of the ultrasound-guided supra-inguinal fascia iliaca compartment block in older children and adolescents for hip arthroscopy. Pediatr Anesth 2017;27:1120-1124.
6. Desmet M, Vermeylen K, Van Herreweghe I, et al, A longitudinal supra-inguinal fascia iliaca compartment block reduces morphine consumption after total hip arthroplasty. Reg Anesth Pain Med 2017;42:327-333.