Reduction of Hip Arthroscopy Post-operative Pain Using Ultrasound-guided Fascia-iliaca Block

Investigators & personnel

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Protocol Summary

Title of Study:	Reduction of Hip Arthroscopy Post-operative Pain Using Ultrasound-guided Fascia-iliaca Block
Study Type:	Postmarket
Primary Investigator:	Eugene Kim, MD
Primary Endpoint:	Quantify the difference in pain in patients who have received a pre-operative FI block versus those receiving no block
Secondary & Tertiary Endpoints:	• Secondary endpoint: Quantify the difference in opioid consumption in patients who have received a pre-operative FI block versus those receiving no block (local anesthetic/Noropin (30cc of 0.5%) joint injection only). • Tertiary endpoints: Assess differences in episodes of PONV, time in PACU, and proportion of unplanned admissions
Design:	Prospective, randomized, two-arm, single-blind study
Length of Study:	3M follow-up
Sample Size:	95 subjects

Schedule of Events

	BL	Proc	2W	6W	3M
Informed Consent	√	-	-	-	-
Inclusion/Exclusion	√	-	-	-	-
Surgical Details	-	√	-	-	-
Physical Exam-ROM	√	-	√	√	√
Visual Analogue Scale (VAS)	√	-	√	√	√
Adverse Event Assessment	-	√	√	√	√

Abbreviations and Acronyms

FI = fascia iliaca
US = ultrasound
PONV = post-operative nausea and vomiting
PDNV = post-discharge nausea and vomiting
PACU = post-anesthesia care unit

Introduction / Background

Hip arthroscopy can be a very painful procedure causing patients distress in the immediate post-operative period and beyond. As more and more procedures are planned on an outpatient basis, the pain associated with hip arthroscopy can result in unplanned admission of a patient who expected to be discharged home after their procedure. Currently, opioids are the mainstay of treatment for pain control after hip arthroscopy. Various adjuncts have been tried in the past including multimodal analgesia, hip joint injections, and peripheral nerve blocks typically involving the lumbar plexus and the femoral nerve. Studies of blocks of the lumbar plexus using the posterior approach have shown good results with reduction in patients' pain scores and opioid consumption. However, because of the invasiveness and possible complications of the posterior approach to the lumbar plexus, the anterior approach called the fascia iliaca (FI) block is an attractive alternative. Furthermore, earlier studies of the FI block were performed without benefit of visual guidance for needle insertion. With the advent of ultrasound guidance, the FI block may be placed with a greater degree of success than in previous years when ultrasound guidance was not utilized during the placement of FI block. The aim of the present study is to determine if ultrasound guided FI blocks can reduce the pain scores and opioid consumption of hip arthroscopy compared to an opioid-only regimen using a randomized controlled trial comparing these outcomes in patients getting preoperatively placed FI blocks versus patients not receiving a block. A significant improvement in pain control and opioid consumption in FI patients compared to controls could provide a basis for increased utilization of FI blocks for this procedure with the attendant benefits. Other outcomes assessed include unplanned admission, PONV and PDNV from decreased narcotic usage, and decreased time in the PACU.

- Primary objectives: Quantify the difference in pain score and opioid consumption in patients who have received a pre-operative FI block versus those receiving no block (local anesthetic joint injection only).
    - Secondary objectives: Assess differences in episodes of PONV, time in PACU, and proportion of unplanned admissions compared to patients with joint injection only
- Hypothesis: Pre-operative placement of an ultrasound-guided fascia iliaca block in patients undergoing hip arthroscopy will result in reduced pain scores and opioid consumption compared to patients receiving an opioid-only regimen.
    - Secondary hypothesis: Pre-operative placement of an ultrasound-guided fascia iliaca block in patients undergoing hip arthroscopy will result in fewer episodes of PONV, reduced time in PACU, and lower rates of unplanned admissions compared to patients receiving an opioid-only regimen.

Study Methodology

- Study Description

- Design: Randomized controlled trial
- Blinding:
- Blinded: Data analyst
- Unblinded: patient, surgeon and anesthesiologist
- Location: Greenville Health System (Patewood Outpatient Hospital and Hillcrest Memorial Hospital)
- Sample size: Sample size estimates are based on the assumptions of a large clinical effect size (>.40) seen at 5 follow up points for the primary outcome measure of pain. Using a fixed effects, special, main and interactions, analysis of variance testing (ANOVA) with a power of 0.80 and an alpha of 0.05, we estimate the need for 86 subjects to achieve statistical significance. To account for loss of follow up, we will target 10% more subjects, thus 95 total participants.

- **Study population**
  - Subjects
    - Recruitment: Consecutive patients undergoing hip arthroscopy will be enrolled in the study
    - Inclusion criteria:
      - Scheduled for outpatient hip arthroscopy by Dr. Folk
      - ASA 1-3
      - Ages 18-65
    - Exclusion criteria:
      - Prior surgery on ipsilateral hip
      - ASA 4-6
      - Chronic narcotic usage over 6 months or more than the equivalent of 20mg of morphine per day
      - Current or prior placement of a spinal cord stimulator or intrathecal pump for pain control purposes
      - Allergy to amide local anesthetics
      - Contraindication to regional anesthesia
      - BMI > 40
      - Females who are pregnant or plan to get pregnant during the course of the study

- **Study procedure**

At the pre-operative clinic appointment, patients will be recruited into the study. Informed consent will be obtained from the patient by the study doctor. The nature of the experiment will be explained, specifically that the patient agrees to be randomized to receive a block prior to the operation or to receive the joint injection at the conclusion of the surgery as an adjunct to general anesthesia. If the patient agrees to enter into the study, the patient will be randomized by use of a computer generated randomization program at the time of enrollment in the clinic. Currently, the standard of care at the Steadman Hawkins Clinic of the Carolinas is to offer surgical patients a block as an analgesic option. FI blocks are not ordered by the doctor without a request by the patient. If patients do not receive a FI block, they will receive a local anesthetic intraoperatively by the surgeon at the close of the procedure, which is also currently the standard of care for hip surgery.

On the day of surgery, all patients will receive multimodal analgesia with an oral preoperative cocktail consisting of acetaminophen 15mg/kg up to a maximum of 1000mg, celebrex 400mg, lyrica 75mg, and oxycontin 10mg unless they are allergic to any of the components. Both block (B) and non-block (NB) patients will receive pre-operative midazolam 1-5 mg as needed for procedural sedation (B) or pre-operative anxiety (NB) respectively.

Patients to be blocked will receive not less than 50 ml and up to 60 mL of 0.35% ropivicaine at a dose of 3 mg/kg (with adjuvants of 100 mcg clonidine [per 60 mL] and epinephrine 1:400,000) placed using a 17 gauge 3.2" B-Braun Tuohy needle under ultrasound guidance using a SonoSite S-Nerve machine with a 15-10 MHz 38 mm probe using a caudad to cephalad in-plane approach. (A 70kg patient would receive all 60 mL of the block solution and 210mg of ropivicaine total). The blocks will be placed exclusively by a selected group of anesthesiologists, who have been trained in the technique.

Patients who are randomized to no-block will receive a single injection of Noropin in the joint space.

General anesthesia will be conducted in a standard fashion for all patients. General anesthesia with an endotracheal tube will be induced with IV fentanyl 2 mcg/kg, lidocaine 50mg, propofol 2 mg/kg, and rocuronium 0.6 mg/kg unless another plan is chosen at the discretion of the attending anesthesiologist. Maintenance of anesthesia will be done with O2:air FIO2 50%, isoflurane end-tidal concentration of 0.7-1.4%, and tidal volumes of 7-10 mL/kg with a respiratory rate to maintain an end-tidal carbon dioxide concentration of 30-40 mmHg. Fentanyl will be given in 25-50 mcg increments for HR or BP greater than 20% over baseline. No long acting intra-operative opioids will be administered and only fentanyl will be used. Ephedrine in 5-10 mg increments or neosynephrine in 80-160 mcg increments will be used to treat hypotension at the anesthesiologist's discretion. A minimum of 20mL/kg of IV crystalloid will be administered during the surgery. Ondansetron 4 mg IV will be administered to all patients approximately 30 minutes prior to emergence for PONV prophylaxis.

Post-operatively in the recovery room, hydromorphone will be used as a first line opioid for pain given in 0.2-0.5 mg increments to an initial maximum of 4 mg. Nausea will be treated in a stepwise fashion with promethazine 6.25 mg IV as a first line agent. Second line will be a repeat dose of promethazine 15 minutes after the first dose, followed by diphenhydramine 6.25 mg IV 15 minutes later PRN. Pain scores will be recorded initially upon arrival to the PACU and thereafter until the patient is discharged from the PACU. All episodes of nausea and vomiting will be tallied. Total recovery time in the PACU will be recorded. If a patient is otherwise ready for discharge but remains in the PACU due to a non-medical issue (i.e. bed hold), the time at which the patient could have otherwise been discharged will be

recorded as the PACU end time for the purposes of the study. Any unplanned admissions will be noted. All opioids administered intraoperatively and in the PACU will be recorded and converted to morphine equivalents.

Patients will be followed in the study surgeon's clinic office per his standard protocol at 2 weeks, 6 weeks, and 3 months post-operatively. Pain scores will be evaluated at this time. Clinical outcome measures and range of motion of the patients' hips will be collected at this time as well. Any adverse reaction from the block will be noted and recorded at all times from the administration of the block and at each clinic follow up. Any signs or symptoms of numbness in the distribution of the fascia iliaca block will be noted.

- Primary endpoint: Quantify the difference in pain in patients who have received a pre-operative FI block versus those receiving no block.
  - Secondary endpoint: Quantify the difference in opioid consumption in patients who have received a pre-operative FI block versus those receiving no block.
  - Tertiary endpoints: Assess differences in episodes of PONV, time in PACU, and proportion of unplanned admissions

- Risks / benefit
  - Risks associated with FI blocks are the following:
    Overall the procedure has a very low risk profile. The location of the injection means the risk of intravascular injection, local anaesthetic toxicity, and mechanical nerve damage is extremely low.
    Good aseptic technique will minimize the risk of infection. The injection of a large volume of local anaesthetic ensures good spread and reduces the risk of failure. The risk of local anaesthetic toxicity is highest within the first 15 minutes after injection, which makes close monitoring mandatory.

  - The potential benefit is improvement in pain control and opioid consumption in FI patients. The knowledge gained from this study will also be used in future patients with this condition.

- **Statistical Analysis**

The study incorporates four dedicated follow up points beyond baseline: a) perioperative (1 to 5 days), b) 2 weeks, c) 6 weeks, and d) 3 months. The primary outcome measure (pain) will be analyzed using a fixed effects, special, main and interactions, analysis of variance testing (ANOVA). Opioid consumption will be analyzed using a Pearson chi square or parametric equivalent (depending on final coding). Tertiary end points will be captured using an ANOVA for continuous measures (once tests of normality are completed), or Kruskal Wallis, whereas re-admission rates will be analyzed using a Pearson Chi-square. A p value of 0.05 will be considered statistically significant for all findings. Intention to treat and last value carried forward will be integrated for all analyses.

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