Fascia Iliaca Block versus Lumbar Plexus Block after Hip Arthroscopy:

A non-inferiority study

June2016

Ignacio Badiola MD

Abstract

Hip arthroscopy results in moderate to severe pain after surgery. These procedures are frequently done in an outpatient setting and thus it is critical that an analgesic solution be available to treat this pain with minimal side effects. Options include systemic medications (IV, oral etc.) as well as regional anesthetic techniques. There are many studies looking at various techniques to block the sensory innervation to the hip after arthroscopy. These include fascia iliaca block (FIB), femoral nerve blocks and lumbar plexus blocks. There are studies looking at the efficacy of these techniques compared to systemic analgesia showing that in isolation they tend to improve postoperative analgesia. However, there have been no head-to-head comparisons of various anesthetic techniques. The FIB is an easy to perform block with minimal adverse events or side effects. It provides excellent analgesia after hip arthroscopy. Studies have also shown lumbar plexus blocks to produce excellent analgesia after hip arthroscopy. Which block is performed depends on the practitioners' preference/past training and the institution's culture. This prospective, randomized trial will explore the question: Are fascia iliaca blocks just as good (non-inferior) as lumbar plexus blocks in providing analgesia after outpatient hip arthroscopy?

The Overall Objectives of this study are:

1. Compare the immediate (PACU) analgesic response to either a fascia iliaca block or lumbar plexus block
2. Compare discharge times between the fascia iliaca block and lumbar plexus block after hip arthroscopy
3. Compare the analgesic efficacy of both techniques as demonstrated by pain scores, opioid requirements, and an APS/quality of recovery questionnaire in 24 hours
4. Compare adverse events/side effects between the fascia iliaca block and lumbar plexus block
5. Compare patient satisfaction scores between the two blocks
6. Compare length of times each block takes to perform
7. Compare analgesia time for each block.

The primary outcome variable is the pain scores in the PACU following the regional anesthetic.

Secondary outcome variables: opioid consumption first 24 hours postop, adverse effects from the blocks, PACU discharge times, and block performance time, patient satisfaction scores

Background

The neural innervation to the hip joint is very complex with branches from multiple nerves innervating various areas of the hip. In a cadaveric study, Birnbaum et al noted that the hip capsule is innervated by branches from the obturator nerve, femoral nerve, sciatic nerve, superior gluteal nerve. [1] Because of this complex innervation, postoperative pain management following hip arthroscopy is tenuous and multimodal forms of analgesia must be used

Various nerve blocks and regional anesthesia techniques have been proposed for hip surgery including: femoral nerve blocks, obturator nerve blocks, , lateral femoral cutaneous nerve block (i.e. 3 in 1 block), sciatic nerve blocks [6] lumbar plexus block and fascia iliaca block. Unlike regional anesthesia blocks of single nerves, the fascia iliaca block and lumbar plexus block are particularly interesting options. They are considered "compartment blocks" with the goal being to inject high volume local anesthetic into a closed compartment so that it diffuses to multiple nerves. In the case of the fascia iliaca block and lumbar plexus block spread is to the lateral femoral cutaneous nerve, femoral nerve, and obturator nerve

Both blocks are easy to perform and various techniques have been described for each. The fascia iliaca block is usually performed using ultrasound guidance. The fascia iliaca is a fascial layer overlying the iliacus muscle. Both

the femoral nerve and lateral femoral cutaneous nerve lie under the fascia iliaca in their intrapelvic course.[2] As it passes under the inguial ligament it moves to occupy a position between the fascia iliaca and fascia lata. Classically, (without ultrasound) a needle is advanced through two distinctive “pops” as it pierces first the more superficial fascia lata followed by the deeper fascia illiaca. These two “pops” are also what are used to determine correct needle placement when this block is done without ultrasound. 30-40 ml of local anesthetic is then injected and visualized to spread toward the femoral nerve.

The lumbar plexus block is classically performed without ultrasound. Confirmation of correct needle placement is done with stimulation of the plexus leading to quadriceps contraction. 30-40cc of local anesthetic is injected with the goal of spread in the fascial plane within the posterior aspect of the psoas major muscle. [3]

Studies have looked at both of these blocks as methods of postoperative analgesia after hip arthroscopy. Krych et al noted that “the quality of early post-operative analgesia provided by the fascia iliaca block was excellent and resulted in low opioid consumption, high quality of pain relief and high overall patient satisfaction” [4] A prospective randomized controlled trial by Yadeau et al noted significant reductions in PACU resting pain after hip arthroscopy following lumbar plexus block[5]

Each of these regional anesthetic techniques carries their own risk, although fascia iliaca blocks are traditionally thought to be “less risky”. The location of this block makes intravascular injection of local anesthetic or nerve damage unlikely. Like all injections of local anesthetic, there are risks of local anesthetic toxicity and infection, but these are thought to be very rare. Lumbar plexus blocks have a possibility of leading to epidural spread of local anesthetic, however this is not common. Traditional postop analgesia (IV or PO opioids) are not a panacea and carry significant risks including respiratory depression and increased risk of nausea and vomiting. Given the importance of postoperative pain management (not only as it relates to patient satisfaction but also as it relates to progression to chronic pain states) it is imperative to find the best combination of low risk, high efficacy analgesia.

This study was designed to test the hypothesis that a fascia iliaca block is not inferior to a lumbar plexus block in providing postoperative analgesia following hip arthroscopy. We believe the fascia iliaca block will lead to similar patient satisfaction compared to the lumbar plexus block and comparable postoperative analgesia use over the first 24 hours

Characteristics of the Study Population

The target population will be patients 18 years old or older presenting for a hip arthroscopy to one expert surgeon at the University of Pennsylvania Penn Medicine University City (PMUC). Patients will be contacted about the study at the preoperative surgery clinic of the orthopedic surgeon or will be contacted via telephone ahead of time (once scheduled for surgery). The discussion will highlight the aims of the study, answer any questions they may have about the study and procedures, and discuss the informed consent in detail. Patients will be consented for the study in person in clinic or in preoperative waiting area if contacted by phone by one of the study investigators or the research coordinator.

Inclusion Criteria: Adult patients 18 years old or older scheduled for a primary hip arthroscopy that are eligible to receive either a postoperative fascia iliaca block or lumbar plexus block. They must be ASA I-III. All subjects must have the ability to follow the study protocol, read, write and speak English

Exclusion Criteria: chronic opioid use (use of any opioid daily or on most days of the week for more than 3 months), diagnosed peripheral neuropathy in the surgical lower extremity, allergy to study medications, BMI >42

Group Assignments

The standard of care at PMUC is for hip arthroscopy patients to undergo general anesthesia followed by postoperative regional anesthesia if PACU pain scores are moderate to severe (4/10-10/10 on the NRS) and the patient has consented to regional anesthesia preoperatively. The patient usually consents to regional anesthesia during the preoperative visit. If they do not wish to have regional anesthesia postoperative pain management is

attempted using IV/PO medications. The choice of regional anesthesia depends on the attending regional anesthesiologist. This is discussed with the patient prior to surgery.

THIS STUDY WILL NOT DEPRIVE ANY PATIENT OF RECEIVING STANDARD ANESTHESIA CARE.

For the purposes of this study, if patients have consented to postoperative regional anesthesia they will be assessed in the PACU. If pain is greater than or equal to 4/10 on the NRS they will be randomized into the lumbar plexus block group or the fascia iliaca block group.

Randomization Process

A randomization table will be generated at the initiation of the study. Patients will be randomized in blocks of 10 patients each. The group assignment of each number will be placed in a sealed envelope. The sealed envelope will be kept in a secure location in the anesthesia research office. Upon the successful recruiting of a participant the sealed envelope will be opened, and the indicated block will be performed.

Recruitment

All patients will be screened initially either at the preoperative surgical clinic visit or prior to the day of surgery via telephone once they are scheduled for surgery. If they meet all criteria they will have all their questions answered and the study procedure will be described in depth. It is common practice at the PMUC that all patients receive general information on the day of surgery about the types of anesthesia to be used including general anesthesia and regional anesthesia.

Blinding: The research assistant responsible for postoperative data collection will be blinded to subject group assignments.

Procedures

All prospective patients will be given a copy of the informed consent, which explains in detail the purpose and execution details of the study. If the patient is willing to participate and signs the consent, he/she will be randomized to receive either a postoperative fascia iliaca block or a postoperative lumbar plexus block if a block is done in the PACU

The patient will undergo general anesthesia as by the attending anesthesiologist assigned to the case. No intraoperative restrictions will be required for this study. Once in the PACU, the patient will be assessed and if their pain score is ≥ 4 on the NRS, the patient will be randomized to a lumbar plexus block or fascia iliaca block.

The fascia iliaca block will be performed in a standard fashion as described[2]. The patient will be placed in a supine position. The ipsilateral groin will be prepped and cleaned with chlorhexidine. An ultrasound machine with a linear transducer covered with a sterile tegaderm will be utilized. The transducer is placed inferior to the inguinal ligament until the femoral artery is located. The probe is then moved laterally until the Sartorius muscle is seen. A skin wheal with 3ml of 1% lidocaine is made and a 2-inch blunt tip needle is inserted in plane. The needle is seen to pierce the fascia iliaca and 1-2 ml of 0.25% Preservative Free bupivacaine with 1:200,000 epinephrine is injected to confirm correct needle placement between the fascia iliaca and iliopsoas muscle. An injection will be deemed adequate if local anesthetic is seen to separate these two layers in a medial to lateral direction. A total of 30ml of the above solution will be injected

The lumbar plexus block will be performed with the patient placed in a lateral position with the operative side facing up. An ultrasound machine with a curved transducer covered with a sterile tegaderm will be utilized. The ipsilateral hip and knee will be flexed to 90 degrees. The anatomy for the LP block will be localized using a modified transverse scan of the lumbar paravertebral area (PMTS). This technique is well described by Karmarkar et al.[7] The target vertebral level will be identified by locating the lumbosacral junction (the gap of L5-S1) using a paramedian sagittal scan and then counting cranially to locate both the lamina and the transverse process of L3-

L5. The transducer is then placed 4 cm lateral to the midline at the L3-4 level and directed medially to insonate the intervertebral foramen through the lumbar intervertebral space. A skin wheal is made at this site with 1% lidocaine. and a 4 inch blunt tip needle is introduced 4 cm lateral to the midline and just medial of the transducer after connecting it to a nerve stimulator set at 1.00 mA. The needle is slowly advanced under ultrasound guidance until engaged in the psoas compartment and a quadriceps twitch is elicited. The nerve stimulator is turned down until the twitch is abolished at 0.3mA or less. 1-2cmlof 0.25% Preservative free Bupivacaine with 1:200,000 epinephrine is injected slowly after negative aspiration. A total of 30ml will be injected. Spread will be confirmed with ultrasound.

Analysis Plan

After the regional anesthetic, the research assistant (who will be blinded for the entire study) will record PACU pain scores 15 minutes after the block and then every 20-30 minutes until discharge. The fascia illiaca block will first be assessed by checking for decreased sensation to cold temperature along the distribution of the lateral femoral cutaneous nerve compared to sensation immediately prior to the nerve block. The lumbar plexus block will be assessed by checking for a decrease sensation to cold temperature in the anterior lateral thigh compared to sensation prior to the block. Time to discharge and pain at discharge will also be obtained. A diary will be provided to the patient and they will record pain scores every 6 hours for the following 24 hours since time of block along with home analgesic use. Total opioid, analgesic, and anti-nausea medication consumption in the PACU will be recorded. A patient satisfaction questionnaire will be provided and the patient will answer the questionnaire 24 hours after the block. The patient will be contacted 24 hours after the procedure by a research assistant blinded to the nerve block to obtain responses to the above data or they may bring in the surveys at their post op clinical visit

We will assume an alpha of 0.05 and power of 80. The median pain score is 5 with FI, and assume LP at 4 (20-25% difference). The standard deviation is estimated between 1.35 to 2.34. This estimates to 23 patients in the FI group and 23 patients in the LP group. Considering a 10% drop out during followup, we propose to recruit 25 patients per group.

Subject Confidentiality

Individual patients will be de-identified by assigning a numeric code. All personal health information will be stored in a separate database linked to the de-identified study database only by the patient. Once data entry into the study database has been completed, the database containing personal health information will be destroyed. All patient data, including the personal health information database and de-identified study database will be stored in secure files that are accessible only to co-investigators and study personnel. All data will be entered directly into an electronic database on a laptop computer that is designated for the study. Study personnel will have access to the database user interface via secure password logins and the laptop will be stored in a secure, locked location when not in use. At the conclusion of the study, data will be retained by the principle investigator in a secured file.

Potential Study Risks

Procedural risks: There are no additional clinical procedural risks to this study. All medications used in this study are FDA approved and used daily in the delivery of anesthesia. The patient's anesthetic management/monitoring/care plan will not be altered based on this study. The procedures performed are standard of care for postoperative pain management following arthroscopic hip surgery.

Alternatives to Participation

Participation in this study is voluntary. If a patient chooses not to participate in this study he/she will receive the standard anesthetic treatment/monitoring/care per standard protocol for this surgery at PMUC.

1. Birnbaum et al. The sensory innervation of the hip joint-An anatomical study. Surg Radiol Anat (1997) 19; 371-375
2. NYSORA. Ultrasound Guided Fascia Illiaca Block. 19 September 2013. Web 07 April 2015, http://www.nysora.com/updates/3107-ultrasound-guided-fascia-iliaca-block.html
3. NYSORA. Lumbar Plexus Block. 20 September 2013. Web 07 April 2015, http://www.nysora.com/techniques/neuraxial-and-perineuraxial-techniques/landmark-based/3282-lumbar-plexus-block.html
4. Krych A et al. Utility of multimodal analgesia with fascia iliaca blockade for acute pain management following hip arthroscopy. Knee Surg Traumatol Arthrosc (2014) 22: 843-847
5. Yadeau J et al. Lumbar Plexus Blockade Reduces Pain After Hip Arthroscopy: A Prospective Randomized Controlled Trial. Anesthesia and Analgesia (2012) Vol 115 Number 4 968-972
6. Indelli PF et al. Regional Anesthesia in Hip Surgery. Clin Orthop Relat Res (2005) Vol 441:250-255
7. Karmakar M et al. Ultrasound Guided Lumbar Plexus Block Using a Transverse Scan Through the Lumbar Intervertebral Space: A Prospective Case Series. Regional Anesthesia and Pain Medicine (2015) Vol 40: 75-81