Quadratus Lumborum Block for Analgesia Following Hip Arthroscopy

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PROTOCOL TITLE: Utilization of quadratus lumborum block for postoperative analgesia following hip arthroscopy: A prospective, randomized clinical trial.

PRINCIPAL INVESTIGATOR: Sylvia H. Wilson, MD

1.0 Objectives / Specific Aims

- Purpose: Evaluate difference in postoperative opioid consumption when patients do or do not receive a quadratus lumborum block preoperatively for hip arthroscopy.
- Hypothesis: Preoperative quadratus lumborum block placement with result in decreased postoperative opioid consumption following hip arthroscopy.

2.0 Background

The number of hip arthroscopy cases has surged with over a 200% increased experienced between 2007 and 2011 [1-3]. This increased number of cases is due to both improved techniques and an increased number of indications [4-5]. As with most newer operative techniques, the optimal method of perioperative pain control is still emerging and past publications indicate that the majority of patients experience moderate to severe pain postoperative pain [6-8]. In the wake of a national opioid epidemic, consistent and reliable implementation of non-opioid analgesic strategies is exceedingly important and regional anesthesia often plays a key role in postoperative pain management.

Although quadratus lumborum blocks were first described in 2007 as an truncal block, numerous publications have recently highlighted its effectiveness as an analgesic technique for hip fracture and hip arthroplasty [9-15] and possibly the ideal regional technique for hip arthroscopy [16]. Unfortunately, prospective randomized studies are lacking. This prospective study would randomize patient to receive or not receive a quadratus plane block prior to surgery. The primary end point would be opioid consumption in the postoperative anesthesia care unit. Our hypothesis is that quadratus lumborum blocks will decrease postoperative opioid consumption.

3.0 Intervention to be studied (if applicable)

The quadratus lumborum blocks is fascial plane block. Originally described for abdominal surgery, numerous case reports and editorial publications have highlighted the effectiveness of quadratus lumborum blocks as an analgesic technique for hip fracture and hip arthroplasty [1-9] and possibly the ideal regional technique for hip arthroscopy [16]. Unfortunately, prospective randomized studies are lacking.

The anterior approach to the quadratus lumborum block is performed by injecting local anesthetic deep to the transversus abdominus abdominus apnoneurosis and superficial to the fascia transversalis with direct ultrasound guidance. After completing consent, placing monitors and providing mild sedation, the patient is positioned laterally and the muscular anatomy (external oblique, internal oblique, transverse abdominis, quadratus lumborum and latissimus dorsi muscles) identified. After placing a subcutaneous skin wheel with lidiocaine, a blunt regional anesthesia needle is inserted using in-plane ultrasound guidance. Local anesthetic

is deposited incrementally with frequent aspiration in the anterolateral border of the quadratus lumborum muscle at the junction of the transversalis fascia, outside the anterior layer of the thoracolumbar fascia and superficial to the fascia transversalis.

Risks of anterior approach to the quadratus lumborum block are similar to most truncal blocks and include infection, bleeding, bowel perforation or local anesthethetic toxicity (LAST). Infection risk is minimized by utilizing appropriate antiseptic and sterile technique as is standard for any regional procedure. Risk of a retroperitoneal hematoma is increased with the posterior approach to the quadratus lumborum block because of its transmuscular approach and likelihood of abdominal branches of lumbar arteries in the path of the needle. For this reason, the posterior approach to the quadratus lumborum block will not be used for this study. The risk of LAST is a risk with any regional procedure and is minimized by frequent aspiration, incremental local anesthetic injection and vital signs monitoring throughout.

The quadratus lumborum block is already a block utilized daily at MUSC for a variety of surgical procedures to decrease postoperative pain. Additionally, the block has been offered at MUSC to patients with uncontrolled postoperative pain following hip arthroscopy with excellent resulting analgesia. Unfortunately, whether a patient undergoing hip arthroscopy at MUSC is offered a quadratus lumborum block for postoperative pain is currently highly provider dependent. We hypothesize that preoperative quadratus lumborum blocks will reduce opioid consumption following elective hip arthroscopy.

4.0 Study Endpoints (if applicable)

- Our primary outcome is opioid consumption including intraoperative consumption exceeding 100μg of fentanyl and all postoperative opioid consumption in the postoperative anesthesia care unit (PACU).
- Secondary outcomes include visual analog pain scaled on PACU arrival and discharge, PACU duration, patient satisfaction, block duration and opioid related side effects.

5.0 Inclusion and Exclusion Criteria/ Study Population

Inclusion Criteria

- Age greater than or equal to 18 years-old
- Undergoing elective hip arthroscopy.

Exclusion Criteria

- Local anesthetic allergy
- Chlorhexidine allergy
- Patient weight < 40kg
- Patient is currently pregnant
- Patient is unable or chooses not to give informed consent

- Emergency surgery
- Known preoperative substance abuse
- Preoperative opioid use for over three months

6.0 Number of Subjects

46

*Sample size was determined using G*Power version 3.1.9.2 software. Using preliminary data, we estimate that we will need 19 subjects in each group (N=38) to have sufficient power (80%) at alpha=0.05 to test the hypothesis of a 30% decrease in IV ME opioid consumption in patients having a QL block vs. those with no block. Accounting for a possible 20% withdrawal, we anticipate the need to enroll 46 total subjects.*

7.0 Setting

- MUSC perioperative areas.

Study Sites

- There will not be any sites outside of MUSC.

8.0 Recruitment Methods

- Patients will be invited to participate by a study team member that is IRB approved, CITI certified and trained on the protocol. Eligibility will be determined by screening the operating room schedule for patients undergoing hip arthroscopy.
- Recruitment: Patients will be enrolled on the day of surgery in the preoperative holding area. After discussion with surgeons, patients will be educated on the role of regional anesthesia in postoperative analgesia and a quadratus lumborum block described.

9.0 Consent Process

During pre-operative appointments the surgeons will notify potential participants that they may be invited to participate in this study on the day of surgery. The surgeon will provide potential participants with the consent document to review prior to day of surgery. After discussion in the preoperative holding area regarding risks and benefits of the study and the quadratus lumborum block, patients will be consented if they choose to participate. Consent will be obtained from patient by an IRB approved CITI certified study team member that has been trained on the protocol. Copies of all documents will be provided to the patients. Once patients are consented, they will be assigned a two digit enrollment number. Prior to patient enrollment, randomization will done by a statistician and randomized group (no block (current practice) or quadratus lumborum block) assigned based on the patient enrollment number.

10.0 Study Design / Methods

This prospective, single blinded clinical trial will randomize patient to receive or not receive a preoperative quadratus lumborum block prior to elective hip arthroscopy. The consent form will be distributed to patients preoperatively in the surgeon's

office. On the day of surgery in the preoperative holding area, patient undergoing elective hip arthroscopy would be informed about the trial and the block with both the risks and benefits. If they are interested in participating, informed consent would then be completed.

Once patients have signed an informed consent, they would be assigned a two-digit identification number. Numbers would be assigned sequentially with the first enrolled patient receiving "01," the second patient receiving "02," and the last patient receiving number "38." Randomization will be created prior to the study starting by a statistician with half of the research subject number being assigned to receive a nerve block and the other half assigned to not receive a block, which is our current standard of care. The regional anesthesia team will open the envelope labeled with the patient's assigned number to reveal the randomization.

Following informed consent, all patients will be positioned, prepped and sedated for a quadratus lumborum block in the preoperative holding area to blind the patient, surgeon, intraoperative anesthesia team and data collectors. The patient will be positioned in the lateral decubitus position with the operative side up and pulse oximetry and blood pressure cuff placed for monitoring. As part of routine care, the patient will receive sedation for their comfort. The relevant anatomy will then be identified using an ultrasound. The skin will be cleaned with chlorhexidine. If the subject has been randomized to the "no block" group, a subcutaneous saline skin wheel will be placed and the procedure would end at this point. If the subject has been randomized to the block group, a subcutaneous lidocaine skin wheel placed will be placed followed by a quadratus lumborum regional block with 40 ml, 0.25% ropivacaine deposited deep to the transversus abdominus apnoneurosis and superficial to the fascia transversalis with direct ultrasound guidance. Local anesthetic will be injected in 5 ml aliquots with aspiration for blood performed before and after the injection of each aliquot. Local anesthetic injection will also be observed with real time ultrasound guidance.

Care in the perioperative period will otherwise be standardized. As part of routine care, all patients will receive general anesthesia. After receiving 100µg of fentanyl intraoperatively, hydromorphone or morphine will be administered and titrated by the anesthesia care team for postoperative pain control. In the post-anesthesia care unit (PACU), hydromorphone or morphine would continue to be titrated by the PACU nurse for the patient's comfort. The total opioids administered after the initial 100µg of fentanyl would be compared between groups in order to evaluate the effect of the quadratus lumborum block.

Data collection will begin after informed consent is completed. Data collection will include demographic data, operative date/time, medications administered intraoperative and postoperative, time to meet discharge criteria in PACU and visual analog scores (VAS) for pain and satisfaction. VAS scores for pain will be collected prior to surgery, on PACU arrival (when aware enough to do so) and upon meeting PACU discharge criteria. Patient satisfaction will be recorded upon meeting PACU discharge criteria. Effects of the block (numbness or motor weakness) will be recorded. Opioid side effects including nausea, vomiting, and itching will also be noted. Patients will be called on postoperative day one to assess block duration and satisfaction with care.

12.0 Data Management

Sample size and power.

Our primary hypothesis is that use of a preoperative quadratus lumborum block will decrease opioid consumption, measured in intravenous (IV) morphine equivalents (ME), by 30%.

H_0: $ME_{QL} \neq ME_{no\ block}$
H_A: $ME_{QL} < ME_{no\ block}$

The primary analysis will be a one-sided test of mean IV ME opioid consumption. Preliminary data on IV ME opioid consumption in hip arthroscopy were reviewed. In people with no preoperative block, IV ME opioid consumption averaged 18.0±3.2; people with preoperative block averaged 9.6±8.7.

Sample size was determined using G*Power version 3.1.9.2 software. Using preliminary data, we estimate that we will need 19 subjects in each group (N=38) to have sufficient power (80%) at alpha=0.05 to test the hypothesis of a 30% decrease in IV ME opioid consumption in patients having a QL block vs. those with no block. Accounting for a possible 20% withdrawal, we anticipate the need to enroll 46 total subjects.

Baseline clinical and demographic factors for each group will be collected. Categorical data will be compared across the two groups with Chi-square tests of homogeneity and continuous data will be compared with t-tests for means. Covariables determined to be associated with IV ME opioid consumption will be assessed for inclusion in a multivariate linear model.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Any adverse events related to placement of nerve blocks will be treated according to MUSC Hospital policy and procedures and the practice of the Department of Anesthesia.

The Department of Anesthesia's DSMB will review the study on an annual basis. Any adverse events will be reported in real time and reviewed by the DSMB. Adverse events will be reported to MUSC's IRB per policy.

All data will be kept in a locked office, in a locked cabinet, and electronic data will be stored on a password protected MUSC server. Only CITI certified, IRB approved study team members will have access to data.

14.0 Withdrawal of Subjects

- Subjects may withdrawal from the study at any time.

15.0 Risks to Subjects

- Risks of anterior approach to the quadratus lumborum block are similar to most truncal blocks and include infection, bleeding, local anesthetic systemic toxicity (LAST) and nerve damage. These risks are all less than 1%. Infection risk is minimized by utilizing appropriate antiseptic and sterile

technique as is standard for any regional procedure. Risk of a retroperitoneal hematoma (bleeding) is increased with the posterior approach to the quadratus lumborum block because of its transmuscular approach and likelihood of abdominal branches of lumbar arteries in the path of the needle. For this reason, the posterior approach to the quadratus lumborum block will not be used for this study. The risk of LAST is a risk with any regional procedure and is minimized by frequent aspiration, incremental local anesthetic injection and vital signs monitoring throughout.

- There is also a risk of loss of confidentiality.
- Any puncture of the skin (including the saline skin wheel for the no block group) poses a risk of infection. Prepping the skin with chlorhexidine prior to skin puncture lowers this risk to less than 1%.

16.0 Potential Benefits to Subjects or Others

- The quadratus lumborum block may likely improve postoperative analgesia and thereby decrease opioid consumption.

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