Official Title: A Prospective, Randomized, Double-Blind, Active-Comparator, Non-Inferiority study to observe relative efficacy of Ultrasound-Guided Supra-iliac Transmuscular Quadratus Lumborum block (QL 3) vs. classic Lumbar Plexus block in managing post-operative pain following total hip replacement surgery.

ClinicalTrials.gov ID (NCT number): NCT03801265

Document Date: June 5th, 2019

Background

The Lumbar Plexus (LP) block is a well-established and widely studied regional analgesia procedure proven to provide postoperative pain management after primary hip replacement surgery (1). However, the technique of LP block is considered by those with limited experience as complex and associated with potentially serious side effects, including nerve injury, major bleeding, retroperitoneal hematoma, and intrathecal injection of local anesthetic (2). Also, the LP block, when preformed with a concentrated local anesthetic solution, may lead to motor blockade, interfering with early ambulation and delaying initiation of physical therapy before transferring the patient to floor from PACU (3). Despite this, the very skilled Acute and Interventional Perioperative Pain Service (AIPPS) has safely administered over 10,000 LP blocks in this institution, and therefore the LP block is considered the standard of care for hip replacement surgery at Shadyside Hospital. The LP block is currently a part of an approved Enhanced Recovery After Surgery protocol (ERAS) which uses multimodal analgesia, restricted goal directed fluids in intraoperative period, and minimal invasive surgical technique, which are all directed towards getting patient ready for successful outcome and early discharge.

In the past few years, consideration has been given to inter-facial administration of local anesthetic to avoid theoretical nerve injury, bleeding and intrathecal anesthetic administration associated with the direct interaction between the nerve and the nerve block needle. Thus, the use of inter-fascial blocks represents an attractive alternative to traditional peripheral nerve blocks to provide regional analgesia utilizing local anesthetics as part of multimodal analgesic protocol. There are several case reports of Quadratus Lumborum inter-fascial block giving adequate pain relief after total hip replacement surgery and this QL3 block is preformed routinely in this institution 4-6. Several of early case reports were published in many peer review journals from our own institution, although randomized control studies

are yet to be conducted. The inter-facial block is theoretically easier to preform and presents less risk to the patient, as the local anesthetic is deposited further away from the nerve plexus. The purpose of this study is to show that inter-facial block is non-inferior to the standard-of-care lumbar plexus block, and should be used more regularly in hip replacement surgery.

Specific Aims

1. This study will prospectively investigate the efficacy of Quadratus Lumborum block (QL 3) versus Classic Lumbar Plexus block for post-operative pain management in subjects undergoing primary, unilateral hip replacement surgery. Primary outcome measures include pain with movement and total narcotic consumption in 24 or until discharge.

2. To prospectively compare Quadratus Lumborum block (QL 3) versus Classic Lumbar Plexus block in time to mobilization and physical therapy response

Hypothesis

There will be no difference in efficacy between 2 groups.

Study Design

The study will be conducted as a prospective, randomized, double-blind, non-inferiority, active-comparator trial at the University of Pittsburgh Medical Center (UPMC) Shadyside Hospital. Institutional review board approval will be obtained before eligible patients are recruited and consented. Trial will be registered at www.clinicaltrial.gov before beginning recruitment.

Recruitment

Potential subjects will be recruited in the pre-operative area of Shadyside hospital on the day of their scheduled hip replacement surgery. Patients who agree to participate in the trial will sign an IRB

approved Informed Consent Form. Forty patients are expected be enrolled in this trial, with twenty in each group.

Randomization Process

Participating patients will be randomized by computer generated random numbers to either the Quadratus Lumborum block (QL 3) or the Classic Lumbar Plexus group, which is the standard of car in this institution for hip replacement surgery.

Inclusion Criteria:

1. Patients 18-90 years old
2. Primary unilateral total hip arthroplasty
3. BMI 20 – 36
4. Male and Female
5. All races

Exclusion Criteria:

1. Patient refusal
2. ASA class< or = 4
3. Pregnancy
4. Any condition precluding patient going home with in 24 hours of surgery
5. Non-English speaking or inability to participate in the study
6. Patients with coagulopathy or on therapeutic anticoagulation
7. Chronic Steroid Use
8. Narcotic Addiction

Treatment Groups

Group 1: 20 Subjects randomized to Group 1 will have a classic lumbar plexus block with 20mg 0.5% ropivacaine, which is standard of care.

LP Block Approach: Patient will be positioned in lateral decubitus position with side to be blocked facing upwards. Midline will be identified by palpating the spinous process. Intercristal line will be drawn connecting iliac crests. The point of needle insertion will be 4 cm lateral to the intersection of both lines. The transverse process will first contact with a finder needle. Subsequently an 18 gauge 10 cm insulated needle will be used and advanced until it contacted the transverse process. Needle will then be redirected cephalad or causdad and advanced 1 cm, until the quadriceps femoris twitch is obtained as described by Winnie et al. 8 Local anesthetic will then be injected after confirming a motor response between 0.3-0.5 milli amperes.

Group 2: 20 **s**ubjects randomized to Group 2 will have a Quadratus Lumborum block (QL 3) using 20mg of 0.5% ropivacaine

QL3 Approach: Patient will be placed in a lateral position with the side to be blocked facing up. A low frequency transducer will be used to identify three layers of abdominal musculature, probe will be then moved posteriorly till the transverse abdominus aponeurosis is visualized, the QL muscle is then identified by tracing the aponeurosis posteriorly. The transducer is then moved more posteriorly to visualize the shadow of transverse process and the origin of QL muscle. Psoas muscle is then identified lying anterior to the QL muscle. A 22 gauge 8 cm is inserted in plane posterior to the probe and advanced intramuscularly through the QL to interfacial plane between QL and psoas major as described by Børglum, Jens, et al 7 and local anesthetic is deposited.

Anesthetic Management

Participants in both treatment groups will receive standard ERAS multi-modal analgesics pre-operatively (Celebrex 200 mg PO and Acetaminophen 1000 mg PO) and will receive the standard ERAS anesthetic technique intraoperatively (Spinal neuraxial block with hyperbaric bupivacaine in standard doses (1.4 –

1.6 mg), intraoperative propofol infusion (50-100 mcg/kg/min), intravenous dexmetetomidine (12-20 mcg) infusion, and intravenous Ketamine (20 mg)). Participants will also follow ERAS protocol for fluid management intraoperatively. Post-operative pain management will also follow standard ERAS protocol, using IV hydromorphone (0.2 mg) and PO oxycodone (5-10 mg) on request by patient for moderate to severe pain (VAS >5).

Data Collection and Outcome Measures

Once the patient has signed the informed consent document they will be randomized to receive with the LP block or the QL3 block. Only the person administering the block will be unblinded, both the patient and the outcome assessors will be blinded to the treatment group allocation**.** Primary outcome measures include pain with movement at 6 hours after surgery, time for 1st request for pain medication, total pain medications (narcotics and non-narcotic analgesics) given in 24 hours or till time to discharge. If patient is discharged within 24 hours, the time of participant's ability to walk 100 feet as recorded by physical therapist will be collected.

References

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