STUDY TITLE: Volume versus concentration: A prospective, double blind, parallel study to compare the clinical effectiveness of single shot quadratus lumborum block using either a high volume / low concentration or low volume / high concentration injectate for total hip arthroplasty

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NCT #: **04259645**

IRB ID: STUDY19090192

STUDY PROTOCOL

DOCUMENT APPROVAL DATE: **01/16/2020**

Our sample size in based on a previous study by Yousef NK. Where the total dose of morphine/patient was used to calculate sample size. The sample size was found to be 28 patients in each group assuming a standard deviation of 3.9 mg of morphine as rescue analgesic (from the pilot study), α error of 0.05, β error of 0.2, and a power of 80%. We intended to include 30 patients in each group to compensate for excluded patients

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Protocol title: Volume versus concentration: A prospective, double blind, parallel study to compare the clinical effectiveness of single shot quadratus lumborum block using either a high volume/low concentration or low volumen/high concentration injectate for total hip arthroplasty

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Background

The Quadratus Lumborum Block (QLB) was originally described by Blanco in 2007 (1) as a posterior variation of the Tranversus Abdominis Plane block. It is now, however, recognized as a unique, alternative, and separate interfascial plane block. The QLB has been studied and compared with other types of blocks and it may offer several advantages such as simplicity, safety, and avoidance of hypotension. Additionally, dermatomal coverage may be greater than for other types of blocks.(2) In cadaveric studies the paravertebral spread of dye was found from T7-L5 (3), although an vivo study in healthy volunteers showed the paravertebral spread of the contrast solution only between T10-L1 at 1 hour after the block. (4) It is noted that while these anatomical studies invariably show the spread of contrast or dye extending to the paravertebral space that spread may be limited in degree. Thus follows a point of significant controversy as to whether the paravertebral space is in fact the block's primary site of action or whether it acts primarily on nerves, radicular and sympathetic, situated in the thoracolumbar fascia. Questions of mechanism and site of action notwithstanding, the safety and clinical efficacy of this block has been clearly demonstrated in multiple types of surgeries including abdominal laparoscopic (5), open laparotomy (6), urologic (7,8), and general surgery (9) with analgesia lasting roughly 24 hours, decreased consumption of opioids, decreased time to ambulation, and decreased hospital length of stay. In recent studies, QL block employment was shown to produce a significant reduction in length of stay during hip surgery as well as similar analgesia to Lumbar Plexus blockade.

The quadratus lumborum block has since 2016 become standard of care for abdominal and hip surgeries at our institution, replacing paravertebral and lumbar plexus blocks respectively, and as part of a broader multimodal analgesia institutional ERAS (Enhanced Recovery After Surgery) protocol. Coincident with its implementation we have seen significant reductions in opiate and PCA use as well as hospital length of stay. Similar results have been reported by other institutions.(10)

Since the first description of this technique, several approaches to and anatomic targets within the quadratus lumborum plane have been described although their mechanism of action, spread, and relative clinical effectiveness remain areas of some debate. There remain many unanswered questions regarding this block and its subtypes. It is, for example, unknown if one technique would be better than another for different types of surgery. Likewise little is known of the relative importance of local anesthetic concentration and injectate volume - the principal question addressed by this proposed study.

Specific Aims

1. This study will prospectively investigate the efficacy of two different volumes of preoperative single shot local anesthetic solution injected using the QLB lateral approach (Quadratus Lumborum Block type I; QLB I) in patients undergoing total hip arthroplasty. The primary outcome will be consumption of opioids during the first 24 hours after surgery.

2. Secondary outcomes will include:
    - Pain measurement through VAS (Visual Analogue Score) at rest and with movement at 3, 6, 12, and 24 hours after surgery hours after surgery
    - Consumption of non narcotic medication during the first 24 hours after surgery.
    - Time to ambulation after surgery (ability to walk 100 feet).
    - Hospital length of stay.
    - Time to consumption of the first opioid after surgery.
    - Patient satisfaction 24 hours after surgery.
    - Presence of any adverse effect related with analgesic technique

Hypothesis

There will be a significant difference between the higher and lower volumes on opioid consumption during the first 24 hours after surgery.

Study Design

The study will be conducted as a prospective, randomized, double blinded, parallel trial at the University of Pittsburgh Medical Center (UPMC) Shadyside Hospital. Institutional Review Board approval will be obteined before elegible patients are recruited and consented. Trial will be registered at www.Clinicaltrials.gov before beginning recruitment.

Recruitment

Potential subjects will be recruited in the preoperative area of Shadyside hospital on the day of their scheduled nephrectomy. Patients who agree to participate in the trial will be asked to sign an IRB approved informed consent form. 60 patients are expected be enrolled in this trial with 30 in each group.

Randomization process

Participating patients will be randomized by computer generated random allocation to have both of the QLBs performed with either Low Volume [ropivacaine 0.75% x 20 mL] or High Volume [ropivacaine 0.375% x 40 mL] injectate. All blocks will have the standard additives of dexmedetomidine 0.4 mcg/kg (max dose 30 mcg for age <70, max dose 20 mcg for age >70) + dexamethasone 4 mg.

Inclusión criteria

- Patients 18-90 years old
- Patients undergoing total hip arthroplasty
- BMI 19-45, >40 kg
- Male and Female
- All races
- ASA I, II, III
- Spinal Anesthesia Provided

Exclusion Criteria

- Patient refusal
- Pregnancy
- Non english speaking or inability to participate in the study
- Patients with coagulopaty or With INR >1,5 the day of the surgery.
- Chronic steroid use
- Chronic pain
- Chronic opiate use

Treatment Groups:

Both groups will receive QLBI as described below:

With the patient in the lateral position and following sterile prep and draping, a low frequency curvilinear ultransound probe with sterile cover is positioned transversely between the iliac crest and the costal margin at the level of the anterior axillary line. The three muscle layers of the lateral abdominal wall (external and internal obliques, transversus abdominis) are identified and traced postero-laterally until the transversus abdominis tapers off into its hyperechoic aponeurosis. At this point the QL muscle is identified deep and lateral to the aponeurosis. The probe is advanced further postero-laterally to position the quadratus muscle mid-screen on the ultrasound. A 22-g Tuohy needle is inserted in plane from anteromedial to posterolateral to position the needle tip at the interfascial plane deep to the thoracolumbar fascia and superficial to the Quadratus Lumborum muscle. The optimal point of injection is determined using hydrodissection (QLB 1).(6)

Group Low Volume: 30 subjects randomized to Low Volume will receive QLBI. Each block of 0,75% ropivacaine x 20 mL + dexmedetomidine 0.4 mcg/kg (max dose 30 mcg for age <70, max dose 20 mcg for age >70) + dexamethasone 4 mg

Group High Volume: 30 subjects randomized to High Volume will receive QLBI. Each block of 0,375% ropivacaine x 40 mL + dexmedetomidine 0.4 mcg/kg (max dose 30 mcg for age <70, max dose 20 mcg for age >70) + dexamethasone 4 mg

Anesthetic management

Participants in both treatment groups will receive standard ERAS multi-modal analgesic pre-operatively (celebrex 200 mg PO and acetaminophen 1000 mg PO) and will receive the estándar ERAS anesthestic technique intraoperatively (spinal neuroaxial block with hyperbaric bupivacaine in estándar doses 1.4-1.6 ml), introperative propofol infusion(50-100 mcg/kg/min) intravenous dexmedetomidine (12-20 mcg) infusion, and intravenous ketamine (20mg).
Patients will receive antiemetic prophylaxis with haloperidol 0.5 – 1.0 mg IV intraoperatively and rescue ondansetron 4 mg IV in PACU. All patients will receive standard ERAS fluid management intraoperatively. Postoperative pain management will also follow standard ERAS protocol to include acetaminophen 1000 mg PO q6h, gabapentin 300 – 600 mg PO qhs, PO ketamine 10-30 mg q8hrs, celecoxib 200 mg PO BID. Rescue analgesic medication will include Oxycodone 5 – 10 mg q4hr PRN, and hydromorphone 0,2 – 0.4 mg IV q1hr for severe pain (VAS>5).

Data collection and Outcome Measures

Once the patient has signed the informed consent document they will be randomly assigned to one of the two study groups as described. Only the persons administering the block will be unblinded to the patient's group assignment. Both the patient and the outcome assesors will be blinded to that assignment.

Primary outcome: VAS pain score at 3, 6, 12, and 24 hours after surgery will documented by one of the Investigator. Patients will also asked to respond on a scale (Liker Type) from 1-5 how would he/she describe the pain management during the first 24 hours after surgery. Other variables such as total opioid consumption, length of hospital stay, consumption of non narcotic analgesics,and time to consumption of the first opioid after surgery will be abstracted from the electronic medical record.

Statistical analysis plan

Continuous patient/procedure variables (age, weight, height, body mass index, duration of surgery, length of stay, morphine equivalent opiate analgesic requirement, visual analog pain scales, time to the first opioid requeriment after surgery) will be analyzed using t test (normally distributed data) or Rank sum test (for not normally distributed data). Dichotomous variables (gender, incidence of complications eg. postoperative nausea and vomiting, and analgesia related complications) will be analyzed by Chi square and Fischer exact test. SPSS and Stata programs will be used for statistical analysis.

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