Study Protocol Cover Sheet

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A Comparative Evaluation of Quadratus Lumborum Block Versus Fascia Iliaca Nerve Block for Patients Undergoing Elective Total Hip Replacement Under Spinal Anaesthesia

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A COMPARATIVE EVALUATION OF QUADRATUS LUMBORUM BLOCK VERSUS FASCIA ILIACA NERVE BLOCK FOR PATIENTS UNDERGOING ELECTIVE TOTAL HIP REPLACEMENT UNDER SPINAL ANAESTHESIA
INTRODUCTION

Total hip replacement is a commonly performed surgical procedure with up to 4,500 procedures performed annually in Ireland and up to 400,000 per year in the United States.\(^1\) Most of the patients experience moderate to severe pain in the initial post-operative period.\(^2\) Multimodal analgesia with peripheral nerve blockade is recommended as gold standard for management of lower limb joint replacements. The limitations with peripheral nerve blocks include limited duration of effect with single shot injections and associated motor block which can delay rehabilitation.

Transmuscular Quadratus lumborum (TQL) block has been described recently as an effective option for post-operative analgesia in patients undergoing total hip replacements with single injection providing analgesia for up to 24 hours.\(^3,4\) We hypothesise that a single injection TQL block when compared to single injection fascia iliaca block (FIB) will provide better analgesia and less motor block in the initial 24 hour period.

METHODS

This prospective, randomised controlled trial will be conducted in patients undergoing total hip replacement surgeries under spinal anaesthesia. Ethical committee approval has been obtained from the Research Ethics Committee (REC) in Tallaght hospital and the study will be registered in Clinicaltrials.gov database. All patients scheduled for elective total hip replacement surgery will be contacted up to 24 hours prior to the surgery by telephone. Information about the nature and purpose of the study will be provided to them by Anaesthetic trainees who are part of the study team. Informed written consent will be obtained from all consenting patients prior to participation in the study.

Randomisation will be carried out by computer generated random numbers and allocation will be enclosed in sealed envelopes. Patients and Outcome assessors will be blinded to the study group. The following are the inclusion and exclusion criteria.

**Inclusion Criteria**

Patients undergoing elective total hip replacements under spinal anaesthesia

ASA 1-3

Age > 18 yrs.
Written informed consent

**Exclusion Criteria**

Local infection

Allergy to local anaesthetics

Severe coagulopathy

**Primary Outcome Measure:**

24 hour morphine consumption between the two groups

**Secondary outcome**

Motor block assessed by the Modified Bromage Scale

Numerical Rating Scale (NRS) score for pain

**Detailed description**

Consenting patients will be randomised to undergo either Transmuscular Quadratus Lumborum block (TQL) or Fascia Iliaca Block (FIB).

On arrival to the anesthesia induction room baseline monitoring (non-invasive blood pressure, pulse oximetry and 3 lead ECG) and intravenous access will be established. Patients in both groups will then be positioned sitting on a level trolley with feet resting on a foot rest. They will be given a pillow to hug and requested to maintain an arched back posture with an assistant holding the patient to aid positioning. No sedation will be given prior to or during administration of spinal anesthesia.

Spinal anaesthesia will be performed under strict aseptic precautions (Chlorhexidine 0.5% for skin decontamination with anaesthetist performing the procedure scrubbed wearing sterile gown, cap and sterile gloves). 25G Whitacre needle will be used and 3.2ml 0.5% plain bupivacaine will be administered.

**Tranmsuscular Quadratus Lumborum Block (TQL):**

Following the administration of spinal anaesthetic, the patient will be positioned laterally with the operating side as the non dependant side. Skin decontamination of the block site will be done with 2% Chlorhexidine (Chloraprep 3 ml applicator, CareFusion Corporation, San Diego, CA 92130,USA). Under strict aseptic precautions (cap, mask, sterile gloves, sterile probe cover
and sterile ultrasound gel), a 100 mm (Stimuplex® Ultra 360® 22 gauge insulated echogenic needle with 30° bevel and extension set) needle will be used to perform TQL block. A curvilinear low frequency probe (2-5 MHz) will be placed above the iliac crest and the following structures will be identified i) Transverse process ii) Erector spinae muscle iii) Quadratus lumbarum muscle iv) Psoas major muscle. The needle will be advanced by in-plane technique and local anaesthetic will be deposited between psoas major and quadratus lumbarum muscles. 20 ml of 0.25% bupivacaine will be administered under USG guidance following careful intermittent aspiration.

**Fascia Iliaca Block (FIB):**

Following the administration of spinal anaesthetic, the patient will be positioned supine. Skin decontamination of the block site will be done with 2% Chlorhexidine (Chloraprep 3 ml applicator, CareFusion Corporation, San Diego, CA 92130, USA). Under strict aseptic precautions (cap, mask, sterile gloves, sterile probe cover and sterile ultrasound gel), a 80 mm (Stimuplex® Ultra 360® 22 gauge insulated echogenic needle with 30° bevel and extension set) needle will be used to perform FIB. A linear high frequency probe (8-13 MHz) will be placed along the inguinal crease to identify the femoral artery, femoral nerve and Iliacus fascia. The needle will be advanced by in-plane technique and local anaesthetic will be deposited under the fascial iliaca. 20 ml of 0.25% bupivacaine will be administered under USG guidance following careful intermittent aspiration.

All patients (unless contraindicated) will receive intra-operative intravenous medication viz: paracetamol 1 gm, Parecoxib 40 mg, tranexamic acid 1 gm and antibiotics as per local guidelines. Perioperative sedation will be left to the discretion of the anaesthetist.

Postoperatively:

Following transfer to recovery unit, if patient reports pain score by numerical rating score >3, morphine 2 mg increments will be given intravenously by the recovery staff. This will be repeated every 5 minutes till the pain score is <4. In patients needing more than 10 mg of morphine in the recovery, anaesthetist will be requested to review the patient. Post-operatively, in the absence of contraindications, all patients will be prescribed regular paracetamol 1 g every 6 hourly and celecoxib 200 mg, 12 hourly. Anti-emetics (ondansetron 4 mg, 8 hourly and Cyclizine 50 mg, 8 hourly) will be prescribed for all patients to be administered as required. All patients will receive morphine PCA in post-operative period. All patients will be reviewed at 6 hours and 24 hours to assess the pain scores and motor block.
Statistics:
A sample size of 46 patients (23 per group) is estimated based on 50% reduction in morphine consumption with power of 80% and alfa error of 0.05%. To allow for the drop outs, we aim to recruit 50 patients in total.