Study Title: Pilot Study on Pain and Sensation after Regional Anesthesia for Total Hip Arthroplasty

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Background, Rationale and Context

Total hip arthroplasty (THA) remains one of the most successful orthopedic procedures in that it can effectively relieve pain and restore function in patients with end stage osteoarthritis[1]. In an attempt to accelerate recovery, many orthopedic surgeons have opted to utilize a direct anterior approach (DAA) as opposed to the more traditional posterolateral approach (PLA). The literature supports that DAA is superior to PLA with regard to lower blood loss, less pain, shorter hospital stay, and faster rehabilitation. The DAA technique involves dissection of muscular planes for insertion of components resulting in less tissue damage as compared to PLA[2]. For this reason, we are seeing more DAA total hip arthroplasty procedures performed at our institution.

Traditionally, we perform Lumbar Plexus blocks (LPB) in a manner consistent with that described by Capdevila et. al[3] to provide post-operative analgesia for total hip arthroplasty. This technique works well for the traditionally performed PLA in that the hip joint and incision site are within the analgesic distribution of the LPB. Conversely, the DAA utilizes an anterior incision that overlies the L1 and L2 dermatomes as opposed to the lower lumbar dermatomes of the PLA incision. The incision runs proximal to distal starting 3cm distal to and 3cm lateral to the anterior superior iliac spine.[4] When performing LPB, it has been our clinical experience that it is rare to achieve analgesia in the proximal distribution of the lumbar plexus resulting in apparent sparing of the L1 and L2 nerve root distributions.

The Quadratus Lumborum block (QLB) is a newer regional analgesic technique that may be as effective as LPB at providing pain control following DAA hip arthroplasty. The QLB as described by Børglum is thought to provide analgesia by blocking both the lateral and anterior cutaneous branches of T7 through L4.[5] This degree of dermatomal coverage suggests that QLB could be an efficacious alternative to LPB for DAA hip arthroplasty. To the best of the authors' knowledge, there has been no investigation comparing the efficacy, with regards to post-operative pain management, between LPB and QLB.

Analgesic modalities commonly employ primarily opioid therapy, however there is increased attention in the literature that supports minimizing opioid related adverse effects using multimodal analgesic therapies and avoiding an increase in the use of known agents that contribute substantially to adverse effects, including post-operative nausea and vomiting, hypoxia, and urinary retention. In contrast, analgesia provided by regional anesthesia results in a decreased risk of the aforementioned complications.[6] It is therefore postulated that, at minimum, analgesic efficacy would be comparable, and potentially improved for DAA procedures through the use of a QLB versus LPB.

In order to compare a QLB to a LPB, we must first assess patient pain scores 6 hours after receiving a LPB and spinal anesthetic (both are considered a practice standard for our institution) for DAA procedures. We also want to test the presence or absence of pin prick sensation at the base of the 1st toe (L5 dermatome) and the base of the 5th toe (S1 dermatome) 6 hours postoperatively. This will allow us to assess for spinal resolution below the level of the lumbar plexus. Intact sensation at L5 and/or S1 in addition to a demonstrable lumbar plexus block would indicate that the pain scores obtained at 6hrs would represent analgesia provided by the lumbar plexus block alone.

Objectives

The purpose of this study is to collect pilot data to help the design of a future randomized study, comparing a QLB to a LPB for DAA procedures. We will collect pain scores measured on a visual analog scale at 6hrs. Additionally, we will assess for spinal resolution below the level of L5/S1 by assessing the presence of absence of pin prick sensation at these levels. This will help determine if pain scores collected at 6hrs reflect analgesia provided by the preoperative LPB alone or if the data is confounded by the presence of spinal anesthesia. This data will help us determine if 6hrs is a feasible primary endpoint to assess pain scores. Additionally, assuming that spinal regression is complete by 6hrs, the VAS pain scores obtained will then be used to perform a power analysis to determine the necessary study size when comparing QLB to LPB for DAA hip arthroplasty.

Methods

Study staff will visit 10 patients, at their hospital rooms, 6 hours after a LPB and spinal block are performed for their DAA hip surgeries. Patients will be asked to verbally rate their pain, on a scale from 0 to 10, when resting and when they sit up in bed. Study staff will use a blunt needle to touch the base of the 1st toe (L5) and the base of the 5th toe (S1), without breaking the skin. Patients will be asked if they can feel "pinprick," touch, pressure, or nothing.

Setting

All participating patients will receive their surgeries at Davie Medical Center of Wake Forest Baptist Health.

Subject Selection

Inclusion

Patients will be eligible for inclusion in the study if they are at or over the age of 18 years old and have elective total hip arthroplasty with DAA at Davie Medical Center.

Exclusion

Patients will be excluded if they do not receive a lumbar plexus block and spinal anesthesia and/or if they have peripheral neuropathy effecting their feet.

Interventions

Interventions are limited to a pin prick sensation testing at the base of the 1st toe and of the 5th toe.

Outcomes:

Outcomes will include patient pain scores (rest and with activity) and the presence or absence of pin prick sensation 6 hours post LPB placement.

Human Subject Protection

Informed Consent

No informed consent will be obtained as patients will not be prospectively enrolled in this study, and no patient information will be obtained or otherwise collected.

Confidentiality and Privacy

The only information taken for this study will be pain scores and presence or absence of sensation. No patient identification numbers or characteristics will be collected. Patients will be referred to by a simple number (numbers 1 through 10).

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

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