Suprainguinal Fascia Iliaca (SIFI) Block Improves Analgesia Following Total Hip Arthroplasty

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1. Protocol Title:

Suprainguinal Fascia Iliaca (SIFI) Block Improves Analgesia Following Total Hip Arthroplasty.

2. Purpose of the Study:

The goal of this prospective randomized double-blind study is to determine if an ultrasound guided suprainguinal fascia iliaca (SIFI) technique is efficacious as an analgesic for total hip arthroplasty. Efficacy will be determined by analyzing post-intervention pain scores (NRS 11), opioid consumption, and functional status including ambulation and dynamometry for quadriceps function. English speaking ASA 1-3 patients ages 18-75 years old undergoing primary total hip arthroplasty will be assessed post-operatively after a general anesthetic. Once pain scores are >5/10, patients will be blocked with either 0.2% ropivacaine or saline, and numerical pain scores and opioid consumption will be evaluated over the following 24 hours. Data will be analyzed on an intent to treat basis using a two-sided t-test (parametric) or Mann-Whitney-Wilcoxson (non-parametric) with a p-value of 0.05 as significant. Patients will assume standard risk associated with nerve blocks, including theoretical risk of nerve damage and local anesthetic systemic toxicity.

3. Background & Significance:

Several regional anesthesia techniques have been implemented to decrease postoperative pain following total hip arthroplasty (THA), with varying success[1,2]. Of these, the fascia iliaca block is commonly utilized nerve block for hip surgery. This block anesthetizes the lateral femoral cutaneous nerve (LFCN), but has a reported 10-37% failure rate[3-5]. To reduce failure, the femoral nerve and the LFCN have been blocked individually utilizing ultrasound guidance. The LFCN, if blocked individually, has traditionally been approached below the inguinal ligament[3-8] and has been shown to be useful in patients with chronic pain. In chronic pain, desired sensory block of the LFCN while avoiding motor block is important, leading to deposition of local anesthetic distal to the inguinal ligament.

Anterior approaches for total hip arthroplasty have led to careful cadaveric examination of the course of the LFCN[9-11] following reports of LFCN damage caused by the anterior approach[8,9]. The LFCN has an unreliable course with variable branching below the inguinal ligament. The branching is variable such that one or more branches may course above, through, or below the inguinal ligament. The branches may cross *sartorius* laterally anywhere from 0-9 cm below the inguinal crease[9-11]. In contrast, the LFCN has a reliable course above the inguinal ligament and conserved course superficial to *iliacus* muscle and immediately below the fascia iliaca in the pelvis[8].

Swenson, *et al*.[12], described injection of local anesthetic under the fascia iliaca at the level of the inguinal ligament with subsequent distal compression to advance the local anesthetic in a retrocaudal direction with MRI confirmation of distribution using dye. Sensory deficit in the distribution of the LFCN was demonstrated in all patients although local anesthetic was up to 2.2 cm laterally from the ASIS in 40% of their subjects. This technique, however, causes a significant motor block since local anesthetic is injected near the femoral nerve.

Hebbard, *et al*.[13], described an infrainguinal approach for suprainguinal needle placement in cadavers and demonstrated dye surrounding LFCN in the pelvis by advancing the needle in a cephalad direction underneath the inguinal ligament[13]. Despite the potential advantages of the suprainguinal needle placement, the long needle entry path and difficulty imaging the correct fascial plane, particularly in obese patients, can

make this approach challenging. As such, this approach has not been widely studied in the several years since its description.

Similarly, Kumar, *et al*.[14], described a modified suprainguinal approach using a landmark based technique during which the needle was placed 1 cm above the inguinal ligament and 1/3 of the distance medially from the ASIS to the pubic tubercle. With this technique, decreased VAS pain scores were seen, as was less morphine consumption and less post-operative nausea and vomiting than patients receiving traditional infrainguinal fascia iliaca blocks, showing a benefit for suprainguinal injection.

Our recent case series comprised of 5 patients described the novel ultrasound guided out-of-plane suprainguinal fascia iliaca (SIFI) plane block[15]. The approach described requires new probe positioning and new sonographic landmarks for combined LFCN and femoral nerve analgesic block. Pain scores were slightly lower in the block group, however, opioid consumption was decreased. Gross motor function was preserved despite local anesthetic tracking down to femoral nerve, however no qualitative measures were taken. Overall, the ultrasound guided SIFI approach to anesthetizing the LFCN showed promise, but has not been adequately evaluated for efficacy in a prospective study.

4. Design & Procedures:

Preoperatively, patients will be given standard of care premedications: 975mg acetaminophen and 300mg gabapentin by mouth prior to surgery. These medications may be altered or not given depending on patient comorbidities or other extenuating factors such as allergy/intolerance. Furthermore, a spinal anesthetic will be placed in the preoperative area.

Patients will be taken to the operating room and sedated using IV propofol to a bispectral index (BIS) of 60-80, indicating adequate sedation. Once sedated, patients will be given a 0.5mg/kg ketamine bolus (based on ideal body weight) and 10mg dexamethasone will be given prior to incision. The orthopedic surgery attending will determine the degree of preoperative knee extension prior to the procedure and inform the anesthesia team. At conclusion of the case sedation will be stopped and patient will be taken to the post-operative care unit (PACU).

Post-operatively study interventions will begin. Patients will be assessed from arrival in PACU to determine their level of pain as well as nausea/vomiting. Once the patient reported pain score in the recovery area is $\geq$5/10 on a 0-10 numerical pain scale study personnel will initiate intervention. Patients will be given a one time IV bolus of 15mg ketorolac.

Patients will be randomized into either SIFI block or sham group with an online randomization program by the study PI (WMB) prior to any patient enrollment. Patients will be given a number (1-40), and the randomized numbers will be given to key study personnel member that will be unblinded. The intervention drug, either 30mL 0.2% ropivacaine or sham block, consisting of 30mL saline, will be drawn up by this key personnel member of the study team who is unblinded and will not be involved in the SIFI block or post-operative analysis. This person will supply the regional anesthesiologist with the intervention, however, both the regional anesthesiologist performing the block and the patient will be blind as to the contents of the syringe.

At the completion of the intervention, verbally reported pain scores (NRS 11) and opioid consumption (IV morphine equivalents) will be measured by a blinded observer starting at time zero and monitored every 10 minutes for 1 hour (+/- 5 minutes). Verbal pain scores will then be recorded each hour for first 4 hours, 6 hours and 24 hours (+/- 10 minutes). Patients will have post-operative orders for supplementary pain control that

include 25mcg IV fentanyl for pain scores 5-7 and 50mcg IV fentanyl for pain scores 8-10.

Subjects' verbal pain scores and opioid consumption will be recorded hourly for the first four hours, at 6 hours, and at 24 hours. Dynamometry will be utilized 2 hours post intervention on POD0 to determine the extent of quadriceps weakness achieved by SIFI injection as compared to unblocked leg. Ambulation distance in feet will be measured POD0 and POD1 by physical therapy. These results will be recorded as will hospital length of stay.

5. Selection of Subjects:

ASA 1-3 patients aged 18-75 years old undergoing primary hip arthroplasty will be enrolled. Patients will be identified preoperatively in either preoperative screening clinic or the night prior to surgery depending on method of preoperative screening. Patients in the study will be ASA 1-3 patients, many will be screened by phone instead of a clinic visit. Patients not seen in preoperative screening clinic will be contacted by telephone by primary investigator (WMB) to confirm eligibility and, if eligible and interested, the study will be explained. Patients will be given the opportunity to ask initial questions about the study over the phone. Patients interested in participating will be again have the protocol fully explained and written informed consent will be obtained on the day of surgery prior to receiving any sedation

Inclusion

Patients that will be included in the study are English speaking 18-75 year old ASA 1-3 patients undergoing primary total hip arthroplasty.

Exclusion

Patients will be excluded from the study if they meet one or more of the following Criteria:

1) ASA 4 or 5
2) Revision hip arthroplasty
3) Diagnosis of chronic pain
4) Daily chronic opioid use (over 3 months of continuous opioid use).
5) Inability to communicate pain scores or need for analgesia.
6) Acute hip fracture
7) Infection at the site of block placement
8) Age under 18 years old or greater than 75 years old
9) Pregnant women (as determined by standard of care day-of surgery urine bHCG)
10) Intolerance/allergy to local anesthetics
11) Weight <50 kg
12) Suspected or known addiction to or abuse of illicit drug(s), prescription medicine(s), or alcohol within the past 2 years.
13) Uncontrolled anxiety, schizophrenia, or other psychiatric disorder that, in the opinion of the investigator, may interfere with study assessments or compliance.
14) Current or historical evidence of any clinically significant disease or condition that, in the opinion of the investigator, may increase the risk of surgery or complicate the subject's postoperative course.

6. Subject Recruitment & Compensation:

Only patients who are having total hip arthroplasty are eligible for this study. We will not bias any demographic groups in identifying patients eligible for this study. A total of 40 patients will be consented from Duke University Medical Center. An IRB approved phone script may be used to discuss the study with eligible patients missed at their Pre-Op screening visit. Patients will not receive any additional compensation for enrollment in this study.

7. Consent Process

A patient's permission to be approached for research will be obtained by the primary care team involved with the patient. The consent process will be conducted by the research personnel or one of the physicians involved in the study. The consent process will take place in the pre-operative screening or the surgical clinics. Throughout the consent process, measures will be taken to maintain privacy, such as by conducting face-to-face conversations in private rooms. As much time as necessary will be spent with each potential subject to sufficiently explain and answer all questions, and address all concerns they may have in regard to the study and/or consent process. Under HIPAA waiver, the study team will identify potential subjects from clinic schedules, OR schedules and Maestro Care.

8. Subject's Capacity to Give Legally Effective Consent:

Patients who do not have the capacity to give legally effective consent will not be approached for participation in this study.

9. Study Interventions:

See 4 above.

10. Risk/Benefit Assessment:

Patients will not incur any added risk to standard risks incurred with regional anesthesia. These standards risks are:

- Regional anesthesia - minor pain or discomfort, injury to arteries, veins or nerves affecting the arms or legs, residual numbness or weakness or paralysis, headache, muscle soreness, infection, allergy or adverse drug reaction, intravascular injection of local anesthetic causing seizure or cardiac arrest.

Patients will be monitored in the post-operative care unit by nurses assigned to their care. Once pain scores $\geq$5, the study team will be notified and the intervention will be performed. Patients will have post-operative analgesics available for pain control that include 25mcg IV fentanyl for pain scores 5-7 and 50mcg IV fentanyl for pain scores 8-10. Fentanyl will not be administered prior to intervention unless intervention cannot be performed within 5 minutes of notification by PACU nurse.

Benefits include contributing to general knowledge base to improve future patient care. This includes potential confirmation of analgesic benefit, decreased pain scores, and improved patient satisfaction. Conversely, this study may show no benefit of the block, thereby invalidating the technique.

11. Costs to the Subject:

Subjects will not incur any additional costs to participate in the study. A MaestroCare build will be created to ensure that any subjects are not charged for researched related procedures, equipment, or medications.

12. Data Analysis & Statistical Considerations:

The primary hypothesis, that there is a difference in numeric pain score at 4 hours postoperatively between the intervention groups, will be assessed with a two-sided 2 group t-test or Mann-Whitney-Wilcoxson test as appropriate. We will perform a secondary repeated measures ANOVA or non-parametric Friedman test to assess difference in numeric pain score over the full 24-hour period. If there is evidence of a difference in numeric pain score during the 24-hour period, we will perform post-hoc pair-wise multiple comparison corrected tests to identify the time-points where the intervention groups differ on pain score. Additional secondary analyses will assess differences in cumulative opioid consumption in IV morphine equivalents and motor strength for both tibial and common peroneal nerves with parametric or non-parametric tests as appropriate. Statisticians employed by the Department of Anesthesiology will conduct these analyses.

A total of 40 participants will be enrolled in the study, randomized equally between study (n=20) and placebo (n=20) groups based on sample size calculation for a non-parametric Mann-Whitney Test with α=0.05, β=0.8, difference in means=2, and effect size of 1.0. The sample size required for a non-parametric test will provide greater than 80% power if the data meet requirements for a parametric t-test.

13. Data & Safety Monitoring:

In accordance with federal regulations the PI will monitor for, review, and promptly report to the IRB, appropriate institutional officials, sponsor, coordinating center and the appropriate regulatory agency head all unanticipated problems involving risks to subjects or others that occur in the course of a subject's participation in a research study (45 CFR 46.103(b)(5)(i) and 21 CFR 56.108(b)(1)), all AE reports will be reported per the DUHS IRB policies. PI will be monitoring all AEs and submitting reports to the IRB per DUHS IRB policy.

14. Privacy, Data Storage & Confidentiality

Potential subjects and their families will be approached private rooms. Any guests not involved in the consent process will be asked to leave the room during any such communications, unless the patient allows them to be present. Efforts to maintain subject confidentiality will include following Federal Privacy Regulations which provide safeguards for privacy, security, and authorized access. Except when required by law, subjects will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). Subjects will not be revealed in any reports or publications resulting from this study. For records disclosed outside of DUHS, subjects will be assigned a unique code number. The paper and electronic data will be stored as per the RDSP.

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