Evaluation of utility of ultrasound guided iPACK block for knee extension after total knee arthroplasty

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Purpose of the Study

This prospective double-blind study aims to evaluate the functional benefit of the interspace between the popliteal artery and the capsule of the knee (iPACK) block for postoperative physical therapy (PT) following total knee arthroplasty (TKA). English speaking ASA 1-3 patients ages 18-75 years old undergoing primary TKA will be randomized into 2 groups, one receiving 20mL 0.2% ropivacaine with 1:400,000K epinephrine as part of our standard TKA protocol and the other group 20 mL 0.9% saline. The primary outcome will be difference in knee extension within the first 8 hours after surgery as evaluated by our physical therapists. Secondary outcomes include numerical pain scores and opioid consumption over 24 hours, other PT measures, and hospital length of stay. Participants will assume standard risk associated with nerve blocks, including theoretical risk of nerve damage and local anesthetic systemic toxicity.

Background & Significance

Postoperative pain following total knee arthroplasty (TKA) continues to persist despite a wide variety of methods available for analgesia. The knee joint receives innervation from the 3 major nerves of the lower extremity, the femoral, obturator, and sciatic nerves. Current practices incorporate femoral nerve blockade as part of the analgesic regimen for the anterior skin and within the joint itself1. The posterior knee receives branches from the tibial and common peroneal nerves.

The ideal analgesic regimen would provide adequate analgesia with minimal effect on motor function. Currently, analgesic regimens for TKA include regional anesthesia for components of femoral and sciatic nerves. Achieving complete analgesia by blocking the femoral and sciatic nerves would provide excellent analgesia, however would not allow the patient to participate in PT and may delay discharge. Likewise, pain after TKA not only causes patient dissatisfaction, but can limit postoperative rehabilitation, prolong hospital discharge, increase opioid consumption, and increase cost.

A recent randomized-controlled trial has demonstrated that sciatic nerve blocks reduce pain compared with placebo2. In addition to pain control, sciatic nerve blockade also inhibits motor fibers, which limit participation in rehabilitation. In order to decrease motor blockade, Sinha and colleagues described a field block in the interspace between the popliteal artery and capsule of the knee (iPACK)3. This technique anesthetizes the nerves supplying the posterior part of the knee, specifically the posterior articular nerve and geniculate nerves. This block become part of our comprehensive multimodal analgesic regimen for TKA. While some research has shown not shown efficacy from the iPACK block4, emerging data has shown benefit including improved participation in PT and decrease time to discharge5,6. No current studies, however, have been performed utilizing our comprehensive analgesic protocol, including multimodal analgesia, adductor canal catheter, and iPACK single shot block to show improvement in post-operative PT outcomes, specifically knee extension. Proper knee extension is a key component in acute post-operative rehabilitation, allowing the patient to fully participate in PT. Participation in PT improves both long- and short-term outcomes, including ambulation and knee flexion and extension7-9. The goal of this prospective double-blind study aims to evaluate the benefit of the iPACK block as part of a comprehensive perioperative analgesic pathway for TKA in order to evaluate its effects on PT outcomes. The main outcome our study will address is knee hyperextension.

Design & Procedures

ASA 1-3 patients aged 18-75 years old undergoing primary TKA will be enrolled. Patients will be identified preoperatively and contacted by telephone by primary investigator (WMB) or study personnel. The study will be explained in full detail, after which patients will be given the opportunity to ask questions about the study. If patients are interested in participating, they will be again explained the protocol and informed consent will be obtained the day of surgery.

Patients will be given the standard of care at Duke University Hospital per our TKA protocol with the exception of the study intervention. Preoperatively, patients will be given 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 followed by the iPACK intervention.

Patients will be randomized to either iPACK block group or sham group. Prior to patient enrollment, group allocations will be determined by an online randomization program used by the study PI (WMB). To ensure blinding, randomizations will be sealed in envelopes numbered 1-50. Upon enrollment, patients will be given a number (1-52) and the corresponding envelope will be given to a key unblinded study personnel member (JG), who will not be involved in the iPACK intervention nor in post-operative analysis. This key member will supply the regional anesthesiologist performing the intervention with the study drug -- either 30mL 0.2% ropivacaine or sham block, consisting of 30mL saline. Both the regional anesthesiologist performing the intervention and the patient will be blind as to the contents of the syringe.

Following the intervention, 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, patients will be assessed on arrival to determine level of pain as well as nausea/vomiting and for return of sensation. Prior to return of sensation, an adductor canal catheter will be placed as part of the TKA protocol. In addition to catheter placement, patients will have post-operative orders for pain control that include 0.2mg IV hydromorphone for pain scores 5-7 and 0.4mg IV hydromorphone for pain scores 8-10. If patient has pain, site of pain will be determined, specifically inquiring about posterior knee pain. Finally, per the protocol, a one-time dose of 15mg IV ketorolac will be given prior to discharge from PACU.

Range of motion, specifically knee extension, will be measured with a goniometer in the first PT evaluation within the first 8 hours after surgery. Additional measures include knee flexion, distance ambulated, and timed-up-and-go (TUG) test. Furthermore, pain scores and cumulative opioid administration (in IV morphine equivalents) will be recorded for the first 4 hours, at 8 hours, and at 24 hours following surgery. Complications and hospital length of stay will also be recorded.

Selection of Subjects

Inclusion Criteria:

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

Exclusion Criteria:

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

1) ASA 4 or 5
2) Revision knee 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) Infection at the site of block placement
7) Age under 18 years old or greater than 75 years old
8)Pregnant women (as determined by point-of-care serum bHCG)
9) Intolerance/allergy to local anesthetics
10) Weight <50 kg
11) Suspected, or known addiction to or abuse of illicit drug(s), prescription medicine(s), or alcohol within the past 2 years.
12) Uncontrolled anxiety, schizophrenia, or other psychiatric disorder that, in the opinion of the investigator, may interfere with study assessments or compliance.
13) 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.

Risk/Benefit Assessment

Patients will not incur any added risk to standard risks incurred with both general and 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. Patients will have analgesic medications available for pain if needed including 0.2mg hydromorphone for pain score 5-7/10 and 0.4mg hydromorphone for pain scores 8-10/10. These medications will be given every 8 minutes as needed based on pain score.

Benefits include contributing to general knowledge base to improve future patient care. This includes potential confirmation of better range of motion postoperatively, increased participation in PT, analgesic benefit, decreased pain scores, and improved patient satisfaction. Conversely, this study may show no benefit of the block, thereby changing patient care by decreasing amount of total local anesthetic given, fewer needle punctures, and decreased cost.

Data Analysis & Statistical Considerations

A double blinded randomized (1:1) trial assuming a rate of hyperextension of 20% in the placebo group, will provide 91% power to detect a 50% increase in the rate of hyperextension in the treatment

group in a chi-square test at alpha level 0.05. Sample size and power calculations were performed using PASS v15 (NCSS, LLC. Kaysville, Utah).

Patient and surgical characteristics will be summarized by standard descriptive statistics and will be compared between groups using t-tests, Wilcoxon rank sum tests, chi-square tests, or Fisher exact tests as appropriate. A chi-square test and logistic regression models will be used to assess the effect of treatment on rate of hyperextension. We will report odds ratios, 95% confidence intervals, and p-values to assess significance and clinical importance of the observed treatment effect. Additional measures of treatment efficacy (range of motion, pain scores, and opioid consumption) will be summarized overall and between groups to further characterize the treatment effect in this population. Randomization schedules will be prepared using mixed block sizes in nQuery and significance will be set at 0.05 for all analyses.

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.