Title: Effects of Catheter Location on Postoperative Analgesia for Continuous Adductor Canal and Popliteal-Sciatic Nerve Blocks

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RESEARCH DESIGN AND METHODS

This will be a single-center (UCSD), randomized, controlled investigation.

Enrollment. Consenting adults undergoing knee arthroplasty or foot/ankle surgery with a planned adductor canal or popliteal perineural catheter, respectively, will be offered enrollment. Study inclusion will be proposed to eligible patients prior to surgery. If a patient desires study participation, written, informed consent will be obtained using a current UCSD IRB-approved ICF. Selection for inclusion will not be based on gender, race, or socioeconomic status. Inclusion and exclusion criteria are listed in section #10 below.

Preoperative Procedures. Following written, informed consent, we will record baseline anthropomorphic information (age, sex, height, and weight) that is already provided by all patients having surgery. All subjects will have a peripheral intravenous (IV) catheter inserted, standard noninvasive monitors applied, supplemental oxygen administered via a nasal cannula or face mask, and positioned supine (adductor canal) or prone (popliteal-sciatic). Midazolam and fentanyl (IV) will be titrated for patient comfort, while ensuring that patients remain responsive to verbal cues. The area that will be subsequently covered by the catheter dressing will be clipped of hair, if necessary. The ultrasound will be placed to visualize the short axis (cross-section) of the adductor canal or popliteal regional at both proximal and distal locations. If both sites are acceptable for catheter insertion, the subject will be randomized using a computer-generated list (blocks of 8) to one of two treatment groups in a 1:1 ratio using sealed, opaque, consecutively numbered envelopes stratified by catheter type (adductor canal vs. popliteal-sciatic): (1) proximal vs (2) distal insertion.

Catheter insertion. Catheter insertion will adhere to current UCSD standard-of-care. The only difference for subjects participating in the study (vs those not participating) will be that the specific catheter insertion location—both currently standard-of-care and used daily at UCSD because of clinical equipoise—will be determined randomly, instead of the physician simply choosing him/herself. All catheters will be placed by a regional anesthesia fellow or resident under the direct supervision and guidance of a regional anesthesia attending (or by the attending him/herself). All catheters will be placed using standard UCSD perineural catheter techniques, nerve in short-axis, ultrasound-guidance.

The area of insertion will be cleaned with chlorhexidine gluconate and isopropyl alcohol (ChloraPrep One-Step, Medi-Flex Hospital Products, Inc., Overland Park, KS, USA), and a clear, sterile, fenestrated drape applied. The ultrasound probe will be placed to visualize the short-axis (cross-section) of the target nerve(s). A skin wheal will be raised at the catheter-placement needle's anticipated point of entry (proximal or distal location). A 17 gauge needle (FlexTip, Teleflex Medical, Triangle Research Park, NC, USA) will be used to place all perineural catheters. The catheter-placement needle will be inserted through the skin wheal, advanced in-plane beneath the US transducer and directed to the target nerve as described below:

Adductor canal.

Proximal: Inserted as described by Jæger et al., 2013:6
"…we performed an ultrasound survey at the medial part of the thigh, halfway between the superior anterior iliac spine and the [superior border of the] patella. In a short axis view, we identified the femoral artery underneath the sartorius muscle, with the vein just inferior and the saphenous nerve just lateral to the artery."

Distal: Inserted as described by Manickam et al. 2009:7
"The transducer was initially placed on the medial aspect of the distal third of the thigh to identify the femoral artery immediately deep to the sartorius muscle. The transducer was then moved caudally along the long axis of the thigh until the femoral artery was seen diving deep and moving away from the anterior muscle plane (sartorius and vastus medialis muscles), toward the posterior aspect of the thigh where it becomes the popliteal artery. This area was identified as the adductor hiatus, and the block location was selected 2 to 3 cm proximally to this area, in the
distal adductor canal."

Saline (10 mL) will be administered via the needle to dilate the space where the catheter is to be inserted. A flexible non-stimulating perineural catheter (FlexTip, Arrow International, Reading, PA, USA) will be inserted 3-5 cm past the needle tip; and the needle withdrawn over the catheter. A 30 mL bolus of lidocaine 2% with 1:400,000 of epinephrine will then be administered though the catheter. A "successful" catheter insertion will be defined as decreased sensation to cold within the distribution of the saphenous nerve.

Popliteal-sciatic. Using an ultrasound, the bifurcation of the sciatic nerve will be identified in short axis and marked at a point immediately distal at which point the two main branches of the sciatic nerve are separate and a hypoechoic area can be viewed between the two. This level will be marked on the skin.

Proximal: The needle will be inserted to intersect the sciatic nerve 6-7 cm proximal to the mark on the skin (therefore, proximal to the sciatic bifurcation) and injection with saline used to ensure subepimyseal spread.

Distal: The needle tip will be inserted into the hypoechoic area between the two branches of the sciatic nerve immediately distal to the sciatic nerve bifurcation between the paraneurium and epineurium (the subparaneural space/compartment).8 As described by Tran et al:9 "An adequate position was defined as the presence of circular expansion of the paraneural sheath... Once circular expansion was obtained, we injected. During the injection process, the Tuohy needle was kept stationary and care was taken to ensure that neural swelling did not occur. The latter was defined as an increase in the cross-sectional surface of the nerve.6 If neural swelling was detected by US, the needle was carefully withdrawn before resuming the injection."

A 40 mL bolus of normal saline or lidocaine 2% with 1:400,000 of epinephrine will then be given though the needle. A flexible non-stimulating perineural catheter (FlexTip, Arrow International, Reading, PA, USA) will be inserted 3-5 cm past the needle tip; and the needle withdrawn over the catheter. If saline was administered pre-operatively, then the 40 mL of lidocaine 2% with 1:400,000 of epinephrine will be administered through the catheter following surgery. A "successful" catheter insertion will be defined as decrease in cutaneous sensation to cold on the plantar aspect of the foot.

Intraop: Patients may receive a general and/or neuraxial anesthetic that would be determined by the intraoperative anesthesia provider. Additional boluses of 10 mL 2% lidocaine with epinephrine may be given, if needed, via the perineural catheter.

Perineural infusion: An infusion pump will be attached to each subject's perineural catheter. The pump will provide ropivacaine 0.2% at 8 mL/h (adductor) or 6 mL/h (popliteal) basal rate infusion and a 4 mL patient-controlled bolus with a 30 minute lockout (all standard at UCSD).

Data collection: All data collection will be through standard UCSD nursing/therapy EPIC notes (adductor canal) or postoperative phone calls (popliteal) for the day following surgery.

Primary endpoint: The primary endpoint will be the average pain on post operative day 1 following surgery as measured on a numeric rating scale (0-10, 0=no pain, 10=worst imaginable pain) during the time periods of 08:00-24:00 (adductor) or the two hours preceding the data-collection phone call (popliteal).

Secondary endpoints: Popliteal subjects will be called the day following surgery to collect information regarding surgical pain (Numeric Rating Scale of 0 to 10, with "0" being no pain and "10" being the worst pain ever experienced), analgesic use (oral, IV, and infusion boluses), infusion side effects, and distance ambulated (adductor catheters only). Popliteal subjects will be called one week (+/- 1 day) following surgery to inquire about possible block-related complications.

Sample size estimates:

Adductor canal. The primary analysis will utilize the Wilcoxon Rank Sum test. The figure below shows the estimated density of post-op day 1 pain scores following Proximal insertion (mean = 4.12, SD = 1.74) based on published data.10 To simulate power, we used the truncated Gaussian distribution with range 0 to 10; SD=1.74; Proximal group mean = 4.12; and Distal group means = 5, 5.5, 6, 6.5, 7, 6.5, and 8.

Under these assumptions and two-sided a = 5%, we simulated 10,000 trials with sample size of 25 per group with a primary end point measurement.

We found the simulated power to be as plotted below.

So we have 80% power to detect group differences in pain as small as about 1.52.

Popliteal-sciatic. Using an expected NRS mean=2.6 and SD=2.1 of average pain on postoperative day 1 (based on unpublished data from IRB study #101282), approximately 31 subjects in each treatment arm with a primary end point measurement will be required to detect a difference between treatment group means of 1.5. This is with a 2-sided alpha=0.05, beta=0.2, and power=0.8 (ClinCalc.com accessed June 28, 2015). We will employ a t-test for parametric data and Wilcoxon Rank Sum test for non-parametric data.

With the two locations combined, we will need 112 subjects with a primary end point measurement; and, we will enroll up to 150 subjects to account for drop-outs and subjects without a primary end point measurement.