Comparing Through-the-Needle with Suture-Method Catheter Designs for Popliteal Nerve Blocks

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Research Protocol

This parallel group study adhered to Good Clinical Practice quality standards and ethical guidelines defined by the Declaration of Helsinki. Study protocol approval as well as data and safety oversight were conducted by the University of California San Diego Institutional Review Board (IRB #170834; San Diego, California). Written, informed consent was obtained from all subjects participating in the trial.

Enrollment was offered to all adults who met study criteria undergoing painful unilateral ambulatory foot and/or ankle surgery with a planned popliteal-sciatic perineural catheter for postoperative analgesia at a single institution. Exclusion criteria included:

1. Clinically-apparent neuropathy in the surgical extremity
2. Chronic high-dose opioid use (defined as daily use for more than 4 weeks prior to surgery of at least the equivalent of 20 mg oxycodone);
3. History of opioid misuse
4. Surgery outside of ipsilateral sciatic and saphenous nerve distributions (e.g., iliac crest bone graft)
5. Patients with nerves deeper than 5 cm from the skin surface

6. Pregnancy
7. Inability to communicate with the investigators and hospital staff
8. Incarceration.

Patients eligible for the study were called the night before surgery by one of the investigators to offer enrollment. If not available by telephone, patients were offered enrollment in person by one of the investigators prior to block placement if there was sufficient time to fully discuss the study and answer all questions. Only one patient who was offered enrollment in the study declined.

Pre-operative Procedures. After applying standard ASA monitors, oxygen by facemask, and positioning the patient prone, intravenous midazolam and fentanyl were titrated for patient comfort while ensuring patients remained responsive to verbal cues. A 13 to 6 MHz 38-mm linear array ultrasound transducer (Edge II; SonoSite, Bothell, WA) was used to visualize the sciatic nerve 5 cm proximal to the bifurcation with a short-axis view. After confirming this site was appropriate for catheter insertion, the subjects were randomized using a computer-generated list in opaque, sealed envelopes to one of two treatments groups (1:1 ratio) in blocks of 4:

1. Through-the-needle ["Traditional" group]
2. Suture-catheter ["Suture" group]

The catheter site was sterilely prepped, draped, and the needle entry site anesthetized with lidocaine 1% (3 mL).

***Through-the-needle insertion*:** A 17-guage Tuohy needle (FlexTip Plus; Teleflex Medical, Research Triangle Park, NC) was inserted on the posterior aspect of the leg, from lateral to

medial, using an in-plane, short-axis ultrasound-guided technique. Normal saline (5-10 mL) was used to hydrodissect around the sciatic nerve to facilitate catheter insertion. A 19-guage flexible, single-orifice perineural catheter was inserted under ultrasound guidance. Correct location of the tip was confirmed by injection of normal saline (1-2 mL) with visualization of spread adjacent to the nerve. The catheter was then secured with clear, occlusive dressings. To facilitate tourniquet placement in the operating room, the catheter was taped up the lateral thigh and secured on the lower abdomen.

***Suture-catheter insertion*:** A short-beveled 19-guage suture needle (75 mm radius, 160 mm length) joined to a 19-guage, single-orifice, nylon catheter (Certa Catheter, Ferrosan Medical Devices, Szczecin, Poland) was inserted on the posterior aspect of the leg, from lateral to medial, under ultrasound guidance using an in-plane technique. Normal saline (5-10 mL) injected through the hollow-bore needle was used to hydrodissect below and then above the sciatic nerve to facilitate spread of local anesthetic following catheter insertion. The suture needle was then advanced under ultrasound guidance to an exit point approximately 6-8 cm medial to the entry site. After anesthetizing the skin at the exit point with lidocaine 1% (1-2 mL), the needle was advanced through the skin and then removed. The catheter was subsequently advanced under ultrasound visualization utilizing the echogenic markings to place the orifice directly adjacent to the sciatic nerve. Proper position of the catheter was confirmed by injection of normal saline (1-2 mL) though the catheter and visualizing spread adjacent to the nerve. The excess catheter was then cut, leaving a tail approximately 1 cm long at the exit site. The entry and exit sites were secured with clear, occlusive dressings. To facilitate tourniquet placement in the operating room, the catheter was taped up the lateral thigh and secured on the lower abdomen.

If a postoperative neurologic exam was desired by the surgeon, no local anesthetic was administered pre-operatively. In cases were no post-operative exam was anticipated, 20 mL 2% lidocaine with 5-10 μg/mL epinephrine was injected *via* the catheter immediately following placement. This was done under ultrasound visualization to confirm that the injection produced circumferential spread of the LA around the sciatic nerve. Successful block was defined as a decrease in temperature discrimination to ice after 30 minutes in the tibial nerve distribution. For cases in which the surgeon desired a postoperative exam prior to local anesthetic administration, a bolus with the same lidocaine-epinephrine volume/concentration was performed in the post-anesthesia care unit.

If the planned surgical procedure was anticipated to produce pain in the saphenous nerve distribution, a single-injection saphenous nerve block was performed with 20 mL 0.5% ropivacaine with 5-10 μg/mL epinephrine administered *via* a 17-guage Tuohy needle under direct ultrasound visualization.

***Intra-operative Procedures*:** Surgical anesthesia was provided with either pre-operative administration of local anesthesia as part of the nerve block combined with propofol sedation, or general anesthesia consisting of inhaled volatile anesthetic with or without nitrous oxide in oxygen with opioids provided, as needed.

***Post-operative Procedures*:** Subjects received a 3-day perineural infusion via electronic pump (ambIT® PreSet, Summit Medical Products Inc, Salt Lake City, UT) of ropivacaine 0.2% (basal

6 mL/hour; 4 mL demand bolus; 30-minute lockout) initiated in the recovery room along with a prescription for oxycodone 5 mg tablets prior to discharge for supplementary analgesia. Subjects were contacted by telephone for 4 days following surgery to collect study outcome measures.

On the third postoperative day, subjects or their caretakers were instructed to remove the perineural catheter. Subjects were instructed to remove the occlusive dressing at the skin entry site and slowly pull out the catheter. Subjects in the suture-catheter group were specifically instructed to leave the distal dressing in place until the catheter was completely removed, thus ensuring that the small tail at the exit site was pulled through the skin prior to sterile dressing removal to avoid contamination of the catheter track.

Outcome Measures: The first four items of the Brief Pain Inventory were collected daily: worst, average, least, and current surgical pain measured using the Numeric Rating Scale (provided verbally to the investigator with specificity to the 0.1 unit). The primary outcome measure was "average" pain score on the first 2 postoperative days. Additional outcomes included daily opioid use, sleep disturbances due to pain (binary), opioid and local anesthetic infusion (e.g. perioral numbness) side effects (binary), local anesthetic leakage (binary), complete catheter dislodgement (binary), degree of sensory block (measured on a 0-10 scale with 0: no deficits and 10: completely insensate), satisfaction with postoperative analgesia (0: very dissatisfied, 10: completely satisfied), and the volume of local anesthetic consumed.

Statistical methods: We assessed the balance of randomized groups on baseline and procedural characteristics using absolute standardized difference, defined as the absolute difference in

means, mean ranks, or proportions divided by the pooled standard deviation. Baseline variables with Absolute Standardized Difference > 0.46 (i.e., $1.96 \times \sqrt{(1/n1 + 1/n2)}$) were considered imbalanced and were adjusted for in all analyses, as appropriate.[9] All analyses used modified intention-to-treat such that all patients randomized and receiving at least some of the study intervention were included.

We tested noninferiority of the suture method to the through-the-needle perineural catheter method on the primary outcome of average pain score and other continuous secondary outcomes in the first 2 days after surgery using a 1-tailed noninferiority t-test at the 0.025 significance level. We used an *a priori* noninferiority delta of 1.25 for each pain score outcome and a ratio of means of 1.2 for the cumulative log-transformed opioid consumption. Noninferiority was claimed if the upper 95% confidence limit for the treatment effect (estimated from analyses described below) was less than the specified noninferiority delta. P-values were obtained from a 1-tailed t-test using a test statistic defined as $T_{NI} = (\hat{\beta} - \delta) / SE(\hat{\beta})$, where ($\beta$) is the estimated treatment effect, $SE(\hat{\beta})$ is the estimated standard error of the treatment effect, and δ is the noninferiority delta. If noninferiority was found, superiority would be tested in the same direction.

We assessed the effect of suture-method to the through-the-needle perineural catheter on each of 4 pain scores in the first 2 postoperative days using a repeated measures linear mixed effects model with an unstructured within-subject correlation structure adjusted for a variable's imbalances at baseline (age was the only imbalanced variable). The heterogeneity of the estimated treatment effect over time was assessed *via* the treatment-by-time interaction at a

significance criterion of $P < 0.15$. A significant interaction suggested that the treatment effect varies over time, in which case we estimated the treatment effect individually for each of 2 time points at the 0.0125 significance level using Bonferroni correction (0.025/2). Treatment effect estimates from these regression models were used to assess noninferiority of the suture versus through-the-needle methods, as described in the preceding paragraph.

For cumulative opioid consumption during the first 2 days after surgery, we first estimated the treatment effect of the suture method versus the through-the-needle method on log-transformed opioid consumption using linear regression and adjusting for age. If a patient did not receive opioids (amount = 0), 0.5 mg was added in order to facilitate the log-transformation.

We originally planned to estimate the effect of the treatment on the side effect of complete catheter dislodgment as a secondary outcome for testing noninferiority. However, we observed no event in the suture method group. Therefore, we simply compared the groups using Fisher's exact test. We also compared the randomized groups on binary outcomes using chi-square or Fisher's exact test, as appropriate.

Sample size and power estimation: The study was designed to have 90% power at the 0.025 significance level to detect noninferiority of the suture method to the through-the-needle perineural catheter on mean "average" pain score on the first 2 days following foot/ankle surgery. Assuming a noninferiority delta of 1.25 points, a standard deviation of 2.2, and a true difference of 0.5 points in the pain score favoring the suture method, a total sample size of 70

patients (35 per group) was required. SAS statistical software (Carey, NC) was used for all analyses.