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Ultrasound-Guided (Needle In-Plane) Perineural Catheter Insertion: The Effect of Catheter Insertion Distance on Postoperative Analgesia

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Abstract

Background—When using ultrasound guidance to place a perineural catheter for a continuous peripheral nerve block, keeping the needle-in plane and nerve in short-axis results in a

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perpendicular needle-to-nerve orientation. Many have opined that when placing a perineural catheter *via* the needle, the acute angle may result in the catheter bypassing the target nerve when advanced beyond the needle tip. Theoretically, greater catheter tip-to-nerve distances result in less local anesthetic-to-nerve contact during the subsequent perineural infusion, leading to inferior analgesia. While a potential solution may appear obvious—advancing the catheter tip only to the tip of the needle, leaving the catheter tip at the target nerve—this technique has not been prospectively evaluated. We therefore hypothesized that during needle in-plane ultrasound-guided perineural catheter placement, inserting the catheter a minimum distance (0-1 cm) past the needle tip is associated with improved postoperative analgesia compared with inserting the catheter a more-traditional 5-6 cm past the needle tip.

Methods—Preoperatively, subjects received a popliteal-sciatic perineural catheter for foot or ankle surgery using ultrasound guidance exclusively. Subjects were randomly assigned to have a single-orifice, flexible catheter inserted either 0-1 (n=50) or 5-6 cm (n=50) past the needle tip. All subjects received a single-injection mepivacaine (40 mL of 1.5% with epinephrine) nerve block *via* the needle, followed by catheter insertion and a ropivacaine 0.2% infusion (basal 6 mL/h, bolus 4 mL, 30 min lockout), through at least the day following surgery. The primary end point was average surgical pain as measured with a 0-10 numeric rating scale the day following surgery. Secondary end points included time for catheter insertion, incidence of catheter dislodgement, maximum ("worst") pain scores, opioid requirements, fluid leakage at the catheter site, and the subjective degree of an insensate extremity.

Results—Average pain scores the day following surgery for subjects of the 0-1 cm group was a median (interquartile) of **2.5** (0.0-5.0), compared with **2.0** (0.0-4.0) for subjects of the 5-6 cm group (**p=0.42**). Similarly, among the secondary end points, no statistically significant differences were found between the two treatment groups. There was a trend of more catheter dislodgements in the minimum-insertion group (5 vs. 1; p=0.20).

Conclusions—This study did not find evidence to support the hypothesis that for popliteal-sciatic perineural catheters placed using ultrasound guidance and a needle in-plane technique, inserting the catheter a minimum distance (0-1 cm) past the needle tip improves (or worsens) postoperative analgesia compared with inserting the catheter a more-traditional distance (5-6 cm). Caution is warranted if extrapolating these results to other catheter designs, ultrasound approaches, or anatomic insertion sites.

Introduction

The previous decade has produced an abundance of research involving continuous peripheral nerve blocks, or "perineural local anesthetic infusion". However, the overwhelming majority of these reports involve the use of electrical stimulation to guide nerve localization and subsequent catheter insertion, to the near-exclusion of ultrasound-guidance.1 A recent comparison of these two techniques suggests that while ultrasound guidance may result in a higher catheter insertion success rate in certain circumstances, the use of electrical current to guide a stimulating catheter results in improved analgesia—for successfully placed catheters—during the subsequent perineural local anesthetic infusion.2 One theory proposed to explain the inferior postoperative analgesia observed in the ultrasound group involves the needle-nerve orientation during ultrasound-guided perineural catheter insertion.

When using ultrasound guidance, it is most-common to visualize the target nerve in cross-section, or "short-axis," which allows for easier differentiation of the nerve from surrounding tissue.3 The needle is then often inserted within the ultrasound plane (needle "in-plane"), permitting real-time needle tip visualization and identification of its location relative to the target nerve. Subsequent local anesthetic injection and perineural spread may

be visualized and evaluated, with needle repositioning and local anesthetic reinjection, as necessary. However, unlike nearly all reports of electrical stimulation-guided perineural catheter insertion with the long axis of the needle advanced *parallel* to the longitudinal axis of the target nerve, needle in-plane ultrasound guidance results in a *perpendicular* nerve-to-needle orientation. When placing a perineural catheter *via* the needle, it is conceivable that the acute angle may result in the catheter bypassing the target nerve when advanced beyond the needle tip.4 Theoretically (although currently unexamined and unproven), greater catheter tip-to-nerve distances result in less local anesthetic-to-nerve contact during the subsequent perineural infusion,5 leading to inferior analgesia.2

While a potential solution may appear obvious—advancing the catheter tip only to the tip of the needle, leaving the catheter tip at the target nerve—this technique was not used in the overwhelming majority of continuous peripheral nerve block reports of the past few decades. The reason for advancing the catheter beyond the needle tip was rarely addressed, but was probably an attempt to decrease catheter tip dislodgement during or after insertion. The analgesic effects, if any, of leaving the catheter tip at the needle tip (and thus target nerve) remain unknown. As ultrasound-guided regional anesthesia becomes more common,6 ultrasound-guided perineural catheter insertion will doubtlessly follow. It is important that postoperative analgesia not suffer due to a change in insertion technique (electrical stimulation to ultrasound guidance).2 Thus, it is critical to determine strategies to optimize ultrasound-guided perineural catheter insertion.

We therefore tested the hypothesis that during needle in-plane, nerve in short-axis ultrasound-guided perineural catheter placement, inserting the catheter a minimum distance (0-1 cm) past the needle tip is associated with improved postoperative analgesia compared with inserting the catheter a more-traditional 5-6 cm past the needle tip.

Materials and Methods

The Institutional Review Board (University of California, San Diego School of Medicine, San Diego, CA, USA) approved the protocol and oversaw the study through data analysis. The trial was prospectively registered at clinicaltrials.gov (NCT00997867). All subjects provided written, informed consent prior to any study procedures. Patients offered enrollment included adults (≥ 18 years) scheduled for at least moderately painful orthopedic surgery of the foot and/or ankle who desired, and were approved for, a continuous popliteal-sciatic nerve block for postoperative analgesia. Exclusion criteria included known neuropathy of any etiology in the surgical extremity; pregnancy; incarceration; current chronic opioid use [daily opioid consumption for more than the previous four weeks of >10 mg oxycodone equivalent]; history of opioid abuse; and inability to communicate with the investigators and hospital staff.

Randomization

Subjects were randomized to one of two treatment groups using a computer-generated randomization table based in a secure, password-protected, encrypted central server (www.PAINfRE.com, Clinical and Translational Science Institute, Gainesville, FL, USA). The treatment groups defined the distance that the catheter tip would be inserted past the needle tip: 0-1 cm or 5-6 cm.

All subjects had a peripheral intravenous catheter inserted, standard noninvasive monitors applied, supplemental oxygen administered *via* a face mask, and placed in the prone position. Intravenous midazolam and fentanyl were titrated for patient comfort, while ensuring that patients remained responsive to verbal cues. Any hair that would be subsequently covered by the catheter dressing was removed with a surgical clipper. The

popliteal fossa area was cleansed with chlorhexidine gluconate and isopropyl alcohol (ChloraPrep One-Step, Medi-Flex Hospital Products, Overland Park, KS), and a clear, sterile, fenestrated drape applied.

All subjects had their target nerve located using ultrasound guidance. With a high-frequency linear array transducer (HFL38, SonoSite M-Turbo, Bothell, WA, USA) in a sterile sleeve, the sciatic nerve was identified in a transverse cross-sectional view at the apex of the popliteal fossa. Once the optimal image of the sciatic nerve cephalad to the bifurcation was obtained, a local anesthetic skin wheal was raised lateral to the ultrasound transducer. An 8.9 cm, 17 gauge, Tuohy-tip needle (FlexTip, Arrow International, Reading, PA, USA) was inserted through the skin wheal in-plane beneath the ultrasound transducer and directed medially toward the sciatic nerve. Local anesthetic solution (40 ml, mepivacaine 1.5% with epinephrine 2.5 μg/ml) was injected in divided doses circumferentially around the target nerve *via* the needle. The needle tip was returned to a position immediately anterolateral to the sciatic nerve to standardize the insertion protocol among all study subjects.

Catheter insertion

A 19 g catheter (FlexTip, Arrow International, Reading, PA, USA) was then placed through the length of the needle and advanced either 0-1 cm or 5-6 cm beyond the needle tip, determined by their randomization group described previously. The needle was then withdrawn over the stationary catheter at least 3 cm. The needle was held stationary and 2-3 cm of catheter inserted to create “slack” between the nerve and skin exit point. Finally, the needle was withdrawn over the remaining catheter. The injection port was attached to the catheter and the catheter secured with sterile liquid adhesive, an occlusive dressing, and an anchoring device. Any difficulty with catheter insertion was recorded, as well as the time for placement (first needle insertion until final needle withdrawal).

Fifteen minutes post-injection, block onset was evaluated and scored in the affirmative if patients exhibited decreased plantar- and dorsi-flexion at the ankle and experienced decreased sensory perception to light touch on the dorsal and plantar surfaces of the foot compared to the contralateral limb. Subjects with a successful surgical block were retained in the study. Also noted was placement of a femoral or saphenous nerve block.

Postoperatively, each perineural catheter was attached to an electronic, portable infusion pump (Pain Pump 2, Stryker Instruments, Kalamazoo, MI, USA; or ambIT Preset, Summit Medical, Salt Lake City, UT, USA) set to deliver 0.2% ropivacaine (basal rate of 6 ml/h; patient-controlled bolus of 4 ml; 30 min lockout interval). For postoperative surgical pain, subjects were instructed to self-administer a local anesthetic bolus dose, wait 15 minutes, and only then use oral opioids (oxycodone 5 mg tablets), if desired.

Outcome measurements

The primary end point was the average pain in the three hours prior to a data-collection phone call the morning following surgery as measured on a 0-10 numeric rating scale (0: no pain; 10: worst imaginable pain). Secondary end points included time for catheter insertion (Tuohy needle insertion until final withdrawal), incidence of catheter dislodgement during the perineural infusion, maximum (“worst”) pain scores during the same three-hour period prior to the data-collection phone call, opioid requirements, fluid leakage at the catheter site, and the subjective degree of an insensate extremity (0: no numbness; 10: completely insensate to touch).

Statistical analysis

The sample size estimate was centered around the primary hypothesis that when inserting a perineural catheter for a continuous popliteal-sciatic nerve block using an ultrasound-guided, needle in-plane technique, inserting the catheter 0-1 cm past the needle tip is associated with decreased postoperative pain compared with inserting the catheter 5-6 cm past the needle tip. We considered a difference of 1.5 on the NRS to be clinically relevant. Based on a standard deviation of each group of 2.5,2 and assuming a two-sided type I error protection of 0.05 and a power of 0.80, approximately 45 patients in each group were required (StatMate 2.0, GraphPad Software, San Diego, CA, USA). To account for a possible increased standard deviation, we enrolled 50 subjects in each treatment group.

Normality of distribution was determined using the Kolmogorov-Smirnov test (GraphPad InStat, GraphPad Software, San Diego, CA, USA). For normally-distributed data, comparisons of independent samples were performed using a t-test. Additional analyses included the Fisher's exact test for categorical variables, and the Mann-Whitney U for comparisons of nonparametric continuous variables. A two-sided $P<0.05$ was considered statistically-significant for the primary end point. Continuous data are summarized with mean (SD) and two-sample t-test p-values. In cases where Kolomogorov-Smirnov tests indicate violation of the normality assumption, we present median (interquartile) and Mann-Whitney U test p-values. For purposes of analysis, each of these subjects was retained in their respective treatment group per the intention-to-treat principle.7

Results

Of 100 subjects enrolled, 50 were randomized to each treatment group. Demographic, anthropometric, and surgical characteristics were similar between groups (Tables 1 and 2). All subjects had a successful catheter placement; and all exhibited nerve block onset as defined by the study protocol. No catheter appeared dislodged during Tuohy needle withdrawal over the perineural catheter (judging from the length of catheter noted at the skin).

Average pain scores the day following surgery for subjects of the 0-1 cm group was a median (interquartile) of **2.5** (0.0-5.0), compared with **2.0** (0.0-4.0) for subjects of the 5-6 cm group (**p=0.42**). Worst pain scores during the same time period for subjects of the 0-1 cm group was a median (interquartile) of **6.0** (3.0-9.0), compared with **7.0** (3.0-8.0) for subjects of the 5-6 cm group (**p=0.37**). Similarly, among the secondary end points, no statistically significant differences were found between the two treatment groups (Table 3).

Discussion

This study did not find evidence to support the hypothesis that, for popliteal-sciatic perineural catheters placed using ultrasound guidance and a needle in-plane technique, inserting the catheter a minimum distance (0-1 cm) past the needle tip improves postoperative analgesia compared with inserting the catheter a more-traditional distance (5-6 cm). While there were no definitive drawbacks to using a minimum insertion distance, there was a trend of more catheter dislodgements in the 0-1 cm group (5 vs. 1; p=0.20). It remains unknown whether this trend was simply due to a chance finding in an secondary end point, or a true difference exists but did not reach the level of statistical significance as the investigation was not powered to detect small differences in secondary end points.

Historical context

No clinical trial evolves within a vacuum; and, the reasoning behind the current trial deserves comment. As with most investigators prior to five years ago,8 our group used nerve

stimulation to localize a target nerve, followed by blind insertion of a nonstimulating perineural catheter to provide a continuous popliteal-sciatic nerve block.9 We then gravitated to stimulating catheters as they became widely available,10 with the suspicion that they provided a more-reliable catheter insertion and higher-quality postoperative analgesia.11 After adopting ultrasound-guidance for nerve localization we did not perceive our success rate to change noticeably;12 and so our first controlled study involving ultrasound compared the insertion times for stimulating catheters placed using electrical current and non-stimulating catheters placed using ultrasound guidance.13 However, secondary end points included average and worst pain scores, both of which suggested a non-statistically significant trend towards inferior analgesia with ultrasound-guided placement. Given the study was powered only for the primary end point of placement time, no definitive conclusions could be drawn.

We therefore redid the trial with a primary end point of average pain the day following surgery, and doubled the sample size.2 This second study found a statistically- and clinically-significant difference between the two treatment groups, with subjects who had an ultrasound-guided catheter insertion reporting a median (interquartile) average pain score of 5.0 (3.0-6.0) compared with 3.0 (1.0-4.8) for those who received a stimulating catheter (on a 0-10 numeric rating scale of pain; p=0.03). We suspected that our insertion technique—derived from a decade of published research—of passing the catheter tip 5 cm past the needle tip led to a less-accurate catheter tip placement for the ultrasound group, on average, than when we had employed a more parallel needle-to-nerve trajectory using electrical stimulation for nerve identification. It was for this reason that we designed and executed the current study. However, the negative results of the current study do not lend credence to this theory.

Catheter design

The catheters used for this study are relatively flexible and have a single orifice at the tip. We, as well as other investigators,4;14 have suspected (without objective evidence) that a more-rigid catheter often overshoots the target nerve using a needle in-plane, nerve in short-axis ultrasound technique. Thus, we have preferred flexible catheters when employing ultrasound guidance to place a perineural catheter.12 The results of the current study may not necessarily be applied to other catheter designs. Similarly, if a multiport catheter is not inserted past the needle tip, leaving the catheter tip at the location of the target nerve, local anesthetic exiting from the proximal orifice(s) may not provide similar analgesia as single-orifice catheters of the current study.15 And previous investigations suggest that while a bolus dose administered under relatively high pressure will equally exit all orifices, a relatively low-pressure basal infusion will exit primarily the proximal orifice.15

Infusion pumps

Following enrollment of the first 80 subjects, Stryker Instruments recalled the portable infusion pumps we had been using. We therefore completed the study using Summit Medical's ambIT infusion pump. These electronic, programmable pumps infuse at nearly identical degrees of precision.16;17 The same proportion of subjects from each treatment group received each of these devices.

Comparative-effectiveness research

This investigation was a comparative-effectiveness study which provides relevant information to practitioners on optimizing patient care by directly comparing two current treatments.18 Historically, comparative-effectiveness research has been neglected, and is therefore being newly promoted by the National Institutes of Health19 and Institute of Medicine.20 A possible criticism of the present study design is that local anesthetic was

injected through the needle first followed by catheter insertion, resulting in a catheter tip that was not immediately adjacent to the target nerve.11 While there are ways to estimate catheter tip location using ultrasound,21 to date there are no studies providing the positive and negative predictive value of any technique.1 Regardless, even if it was possible to accurately estimate catheter tip location, this would be a surrogate end point—it is irrelevant to patients where the tip appears to be relative to the target nerve. The end point of interest to patients (and providers) is the degree of analgesia provided by the perineural infusion. It is for this reason that we used postoperative analgesia as the primary end point of this study. Our goal was not to compare catheter tip location specifically, but rather to provide practitioners with relevant clinical information directly comparing two currently-utilized perineural catheter-insertion distances. Clinicians require prospectively-collected data from a randomized study to help determine their relative risks and benefits.

Study limitations

While the comparative-effectiveness research design we employed offers many advantages —especially for clinicians—one limitation is a relative lack of information regarding mechanisms for the observed outcome(s). For example, although our results suggest that catheter insertion distance correlates poorly with postoperative pain scores, it remains unknown if subjects of one treatment group self-administered more bolus doses, resulting in the similar pain scores. Given that an increased dose presumably results in increased motor block—an end point not measured in our investigation—the relative number of self-administered bolus doses may be clinically relevant. Thus, further investigation is warranted.

In addition, this study was unmasked, although it is doubtful that subjects or the research coordinator making data-collection phone calls had a bias towards one technique. The results of the present study apply specifically to the needle in-plane, nerve in short-axis ultrasound-guided catheter insertion technique, and should not be extrapolated to all ultrasound-guided approaches.1 Lastly, the results of this study may not be applicable for insertion sites other than the popliteal-sciatic location since perineural anatomy directly affects infusion characteristics.22;23

In summary, this randomized, controlled study found no evidence that catheter insertion distance is associated with an improvement or detriment in postoperative analagesia for popliteal-sciatic perineural catheters placed using ultrasound guidance and a needle in-plane, nerve in short-axis technique. Caution is warranted if extrapolating these results to other catheter designs, ultrasound approaches, or anatomic insertion sites.

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Table 1

Population data and procedural information

	Group 0-1 cm (n=50)	Group 5-6 cm (n=50)
Age (yr)	45 (16)	47 (17)
Sex (female)	32	31
Height (cm)	168 (10)	171 (12)
Weight (kg)	76 (15)	81 (20)
Body Mass Index (kg/m^2)	27 (4)	28 (6)

Values are reported as mean (SD) or number of subjects, as indicated

Table 2

Primary surgical procedures

	Group 0-1 cm (n=50)	Group 5-6 cm (n=50)
Achilles tendon repair	5	5
Foot osteotomy or ORIF	26	24
Foot/ankle arthrodesis	4	3
Ankle arthroplasty or ORIF	7	10
Ankle ligament/tendon repair	5	3
Ankle arthrotomy, synovectomy and/or debridement	3	5

Values are reported as number of subjects

ORIF: open reduction, internal fixation

Table 3

Secondary end points

	Group 0-1 cm (n=50)	Group 5-6 cm (n=50)	*P*-Value
Catheter insertion time (min)	5.0 (3.3-6.0)	6.0 (4.0-7.0)	0.68
Oral morphine equivalents (mg)	23 (10-30)	15 (8-30)	0.33
Catheter site fluid leakage (#)	10	16	0.25
Degree of an insensate extremity (0: no numbness; 10: completely insensate)	7.0 (3.5-8.5)	7.0 (3.0-8.0)	0.40
Catheter dislodged during infusion (#)	5	1	0.20

Values are reported as median (interquartile) or the number of subjects, as indicated.