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Title
Continuous Popliteal Sciatic Blocks

Permalink
https://escholarship.org/uc/item/6v72t8gg

Journal
Anesthesia & Analgesia, 122(5)

ISSN
0003-2999

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Publication Date
2016-05-01

DOI
10.1213/ane.0000000000001211

Peer reviewed

Continuous Popliteal Sciatic Blocks: Does Varying Perineural Catheter Location Relative to the Sciatic Bifurcation Influence Block Effects? A Dual-Center, Randomized, Subject-Masked, Controlled Clinical Trial

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BACKGROUND: Multiple studies have demonstrated that, for single-injection popliteal sciatic nerve blocks, block characteristics are dependent upon local anesthetic injection relative to the sciatic nerve bifurcation. In contrast, this relation remains unexamined for continuous popliteal sciatic nerve blocks. We, therefore, tested the hypothesis that postoperative analgesia is improved with the perineural catheter tip at the level of the bifurcation compared with 5 cm proximal to the bifurcation.

METHODS: Preoperatively, subjects having moderately painful foot or ankle surgery were randomly assigned to receive an ultrasound-guided subepimyseal perineural catheter inserted either at or 5 cm proximal to the sciatic nerve bifurcation. Subjects received a single injection of mepivacaine 1.5% either via the insertion needle preoperatively or the perineural catheter postoperatively, followed by an infusion of ropivacaine 0.2% (6 mL/h basal, 4 mL bolus, and 30-min lockout) for the study duration. The primary end point was the average pain measured on a numeric rating scale (0–10) in the 3 hours before a data collection telephone call the morning after surgery.

RESULTS: The average numeric rating scale of subjects with a catheter inserted at the sciatic nerve bifurcation (n = 64) was a median (10th, 25th to 75th, and 90th quartiles) of 3.0 (0.0, 2.4–5.0, and 7.0) vs 2.0 (0.0, 1.0–4.0, and 5.0) for subjects with a catheter inserted proximal to the bifurcation (n = 64; P = 0.008). Similarly, maximum pain scores were greater in the group at the bifurcation: 6.0 (3.0, 4.4–8.0, and 9.0) vs 5.0 (0.0, 3.0–8.0, and 10.0) (P = 0.019). Differences between the groups for catheter insertion time, opioid rescue dose, degree of numbness in the foot/toes, catheter dislodgement, and fluid leakage did not reach statistical significance.

CONCLUSIONS: For continuous popliteal sciatic nerve blocks, a catheter inserted 5 cm proximal to the sciatic nerve bifurcation provides superior postoperative analgesia in subjects having moderately painful foot or ankle surgery compared with catheters located at the bifurcation. This is in marked contrast with single-injection popliteal sciatic nerve blocks for which benefits are afforded to local anesthetic injection distal, rather than proximal, to the bifurcation.   (Anesth Analg 2016;122:1689–95)

Continuous popliteal sciatic nerve blocks provide postoperative analgesia after surgical procedures of the foot and ankle.[1] The sciatic nerve courses down the posterior thigh and bifurcates just above or within the popliteal fossa into 2 branches: the tibial and common peroneal nerves. Cadaver studies have confirmed the location of this bifurcation to range from approximately 0 to 11 cm proximal to popliteal crease, most commonly 5 to 7 cm above the crease.[2,3] Using ultrasound guidance, practitioners can target a precise location along the sciatic nerve relative to the sciatic bifurcation for deposition of local anesthetic.[4–6]

Previous randomized studies document that depositing an initial bolus of local anesthetic via a needle distal to the sciatic bifurcation—compared with proximal to the bifurcation—results in decreased time to onset of sensory and motor block and at times an increased surgical-quality block success rate.[4–6] This suggests that deposition of local anesthetic at various locations along the sciatic nerve can influence block characteristics. However, findings from studies involving single-injection nerve blocks have not always been replicated when investigated in relation to continuous peripheral nerve blocks.[7–12] Whether the perineural catheter location relative to the sciatic nerve bifurcation influences

the quality of analgesia provided by a postoperative perineural local anesthetic infusion remains unexamined.

We, therefore, conducted this dual-center, randomized, subject-masked, controlled, parallel-arm clinical trial to test the hypothesis that during a *continuous* popliteal sciatic nerve block, postoperative analgesia will be improved with the perineural catheter tip at the level of the sciatic nerve bifurcation compared with when the catheter tip is 5 cm cephalad/proximal to the bifurcation. The primary end point was the average pain measured on a numeric rating scale (NRS: 0–10) in the 3 hours before a data collection telephone call the morning after surgery.

METHODS
Enrollment
This study adhered to Good Clinical Practice quality standards and ethical guidelines defined by the Declaration of Helsinki. It was prospectively registered at ClinicalTrials.gov (NCT01229696) before enrollment initiation. Study protocol approval as well as data and safety oversight was conducted by the University of California San Diego IRB (San Diego, California). Written informed consent was obtained from all participating subjects.

Enrollment was offered preoperatively to adults (age ≥18 years) undergoing moderately painful unilateral foot and ankle surgery with a preplanned popliteal sciatic perineural catheter for postoperative analgesia. Exclusion criteria included any neurologic deficit of the operative extremity, chronic opioid use (daily use of 20 mg oxycodone equivalent or more for >4 weeks), surgery outside the sciatic and saphenous nerve distributions, history of opioid abuse, inability to communicate with the investigators, pregnancy, and incarceration. The study was conducted at Hillcrest (San Diego, California) and Thornton (La Jolla, California) hospitals, both academic institutions associated with the University of California San Diego Medical Center.

Perineural Catheter Insertion
Subjects were positioned prone with a towel rolled under the ankle to slightly flex the knee. Standard monitors were applied, and oxygen was given by facemask at a rate of 8 L/min. IV midazolam (1–2 mg) and fentanyl (50–100 μg) were administered, titrating for anxiolysis and analgesia with verbal responsiveness maintained at all times. Catheters were placed by regional anesthesia fellows or residents under the direct supervision of an attending regional anesthesiologist or by the attending themselves.

The sciatic nerve bifurcation was identified by using a 13-6 MHz 38-mm linear array ultrasound transducer (M-Turbo; SonoSite, Bothell, WA) in the short-axis view. The bifurcation was defined as the most proximal point at which the tibial and common peroneal nerves had separated. Both the sciatic nerve bifurcation and the area 5 cm proximal to the bifurcation were scanned and identified. Randomization was performed only if both sites were determined to be acceptable for catheter insertion. Allocation to 1 of 2 treatments was achieved by using computer-generated lists in blocks of 8 with a 1:1 ratio, stratified for treatment center. Treatment allocation was concealed by using consecutively numbered, sealed, opaque envelopes that were opened only after confirmation by ultrasound that either insertion site would be acceptable. Treatment allocation was to 1 of 2 groups: (1) at the sciatic nerve bifurcation or (2) 5 cm proximal to the sciatic nerve bifurcation. For subjects within the latter treatment group, the preferred insertion point was 5 cm proximal to the bifurcation but could be inserted up to 8 cm proximal to the bifurcation if the sciatic nerve image was superior in the 5- to 8-cm range. Treatment group assignment was masked to subjects, but not to investigators.

The site was cleaned with chlorhexidine gluconate/isopropyl alcohol solution, a sterile fenestrated drape applied, and a skin wheal raised using 1% lidocaine. A 17-gauge noninsulated Tuohy needle was directed to a subepimyseal extraparaneural location using an in-plane technique under real-time ultrasound guidance, as described in detail previously.[13] Final needle tip positioning was superficial to the paraneurium and deep to the epimysium of the surrounding muscles.[14]

Injectate was administered via the needle to achieve circumferential spread, ensuring that there was no subparaneural or extraepimysial spread. Injectate contents were determined by surgeon's preference: if a postoperative neurologic check in the recovery room was planned, the injectate consisted of normal saline (20 mL); if no neurologic examination was anticipated, the injectate consisted of mepivacaine 1.5% with epinephrine 5 to 10 μg/mL (40 mL).

A 19-gauge catheter (FlexTip Plus; Teleflex/Arrow International, Research Triangle Park, NC) was inserted 1 cm beyond the needle tip, with the Tuohy needle still under ultrasound visualization. The needle was then withdrawn ≥3 cm over the stationary catheter. The needle was held stationary, and 2 to 3 cm of catheter was 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 a small bolus of air (0.5 mL) was injected through the perineural catheter under ultrasound visualization to assess catheter tip location. The catheter was secured with sterile liquid adhesive, an occlusive dressing, and an anchoring device. The time for catheter insertion was measured from the time the Tuohy needle first touched the subject until it was completely withdrawn without reinsertion. For subjects who received a local anesthetic bolus, sensory and motor block onset was determined within 15 minutes after the mepivacaine injection. Sensory onset was determined on the plantar aspect of the foot (toes when a cast was present) and was deemed positive with decreased sensation to light touch from before the local anesthetic bolus. Motor block was determined with plantar flexion (flexion of the toes when a cast was present) and was deemed positive with decreased force from before the local anesthetic bolus. Also noted was any saphenous nerve block administration (ropivacaine 0.5% with epinephrine 5–10 μg/mL).

Intraoperative Protocol
For subjects with a preoperative mepivacaine bolus, their popliteal sciatic block usually provided the primary anesthetic for the surgical procedure. Sedation or a general anesthetic was permitted, and additional boluses of mepivacaine 1.5% and epinephrine could be administered via the catheter, if needed, if a postoperative neurologic examination was not planned.

Postoperative Protocol

For subjects who received normal saline preoperatively, a neurologic check was performed by the surgeon postoperatively. A local anesthetic bolus was subsequently administered via the catheter that was identical to subjects who had a preoperative bolus via the needle (mepivacaine 1.5% with epinephrine 5–10 µg/mL, 40 mL). A successful catheter insertion was defined as sensory and motor block onset in both major terminal nerve distributions within the 15 minutes after the local anesthetic injection (for both pre- and postoperative local anesthetic administration). In case of failure, the patient was removed from further study.

A ropivacaine 0.2% perineural infusion was initiated (basal rate 6 mL/h; patient-controlled bolus of 4 mL; 30-minute lockout) and continued at least through the data collection telephone call the morning after surgery (described under End Points section below). Unacceptable pain remaining 20 minutes after a patient-controlled bolus dose was treated with oral oxycodone (5–10 mg) and/or IV morphine (2–4 mg).

End Points

Subjects were contacted via telephone at 10:00 the morning after surgery to collect information regarding study outcome measures for both inpatients and outpatients (exception: inpatient opioid consumption was collected from medical records). The primary end point was prospectively designated as the average pain in the 3 hours before the data collection telephone call as measured on the NRS.[15] High-quality published evidence suggests that rating pain within 24 hours corresponds well to averaged momentary assessments but that patients begin to inflate recalled pain relative to averaged momentary assessments beyond several days.[15] Secondary end points included the maximum pain within the previous 3 hours as measured using the NRS as well as the opioid consumption (measured in morphine IV equivalents) since recovery room discharge, fluid leakage at the catheter insertion site, and the degree of numbness in the foot/toes (reported on a Likert 0–10 scale: 0 = normal sensation; 10 = insensate).

Statistical Analysis

To calculate a sample size, we focused on our primary hypothesis that during a continuous popliteal sciatic nerve block, postoperative analgesia will be improved with the perineural catheter tip at the level of the sciatic nerve bifurcation compared with when the catheter tip is 5 cm cephalad/proximal to the bifurcation. The primary end point was the average pain in the 3 hours before a data collection telephone phone call the morning after surgery, measured with the NRS. A previously published clinical trial using an insertion technique, equipment, and postoperative infusion similar to the current protocol revealed the mean average pain score of 3.8 on the NRS and an SD of 2.6 the day after foot/ankle surgery.[16] On the basis of these data, we expected an SD of 2.5 for the NRS mean of average pain on postoperative day 1,[16] and given a 2-sided type I error protection of 0.05 and power of 0.80, we prospectively calculated that approximately 65 subjects in each treatment arm were required to detect a difference between treatment group mean of 1.25 (the IRB approved a total of 150 enrollees to account for dropouts).

Normality of distribution was determined using the Shapiro-Wilk normality test (Prism 6; GraphPad, San Diego, CA). For normally distributed data, comparisons for parametric and nonparametric data were tested using the t test or Mann-Whitney test and presented as mean (SD) or median (interquartile range), respectively. Nominal data were analyzed by using the Pearson χ^2 test. P value <0.05 was considered significant. Significant findings in secondary outcomes should be viewed as suggestive, requiring confirmation in a future trial before considering them as definitive.[17]

RESULTS

Of the 136 subjects enrolled (Fig. 1), 1 was found to have an exclusion criterion before randomization (neuropathy involving the surgical extremity), and in 5 others, the location 5 to 8 cm above the bifurcation was judged inferior to the bifurcation site because of poor imaging of the sciatic nerve. The remaining 130 subjects were randomly assigned to 1 of the 2 treatment groups (Tables 1 and 2), and all but 1 (proximal to bifurcation without sensory/motor changes after bolus) had a catheter inserted successfully per protocol. Within the operating room, 1 subject (at bifurcation) had his surgery cancelled because of electrocardiogram changes unrelated to the perineural catheter insertion (subject was to receive mepivacaine bolus after surgery). The remaining 128 subjects completed the study (64 in each treatment group).

Primary End Point

The average NRS of subjects with a catheter inserted at the sciatic nerve bifurcation was a median (10th, 25th to 75th, and 90th quartiles) of 3.0 (0.0, 2.4–5.0, and 7.0) vs 2.0 (0.0, 1.0–4.0, and 5.0) for subjects with a catheter inserted proximal to the bifurcation ($P = 0.008$; Fig. 2).

Secondary End Points

Similarly, the proximal group reported lower "maximum" pain scores (Fig. 2). The proximal group also required a lower total opioid rescue dose although this difference did not reach statistical significance ($P = 0.097$; Fig. 3). There were no clinically relevant or statistically significant differences between the treatment groups for any other secondary end point (Table 3).

Protocol Violation

The original study protocol specified assessing both sleep disturbances and satisfaction with analgesia, as reflected on the ClinicalTrials.gov registry. However, these outcome measures were inadvertently excluded from the case report forms, and therefore, the data were not collected as originally intended.

DISCUSSION

This dual-center, randomized, subject-masked, controlled, parallel-arm clinical trial demonstrates that, for *continuous* popliteal sciatic nerve blocks, a catheter inserted 5 cm proximal to the sciatic nerve bifurcation—compared with at the bifurcation—provides superior postoperative analgesia in
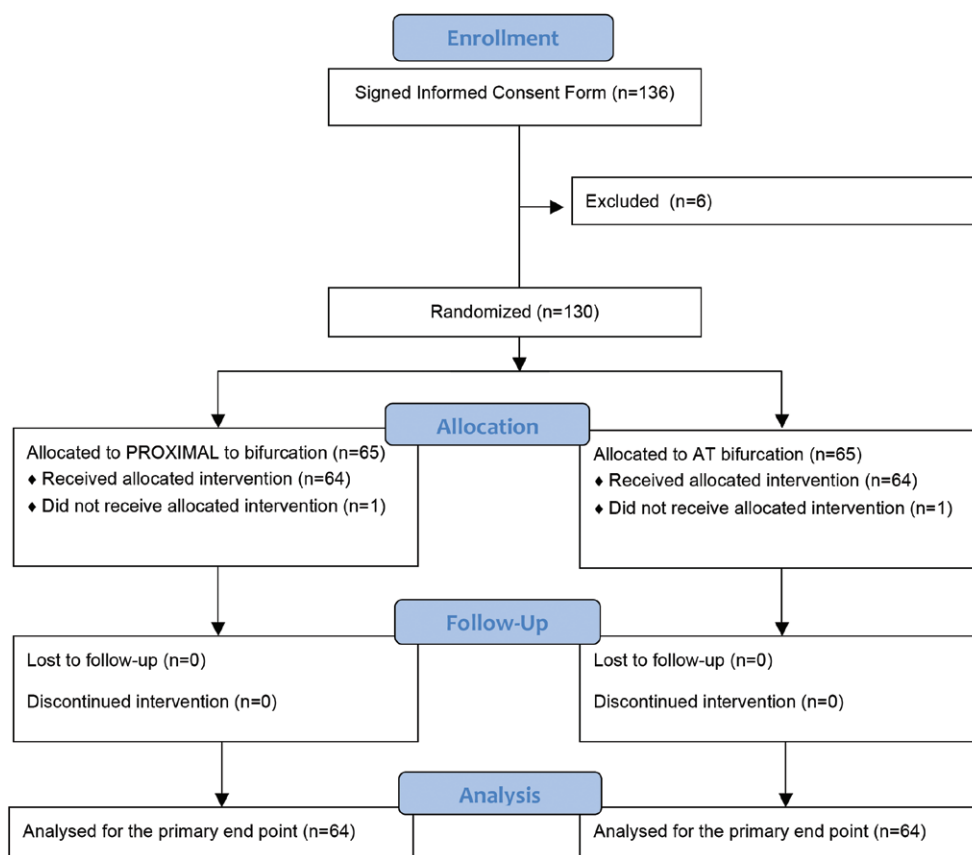
Figure 1. CONsolidated Standards Of Reporting Trials (CONSORT) flow diagram.

Table 1. Subject Characteristics

	At bifurcation (n = 65)	Proximal to bifurcation (n = 65)
Age (y)	47 (16)	47 (17)
Sex (female), n (%)	35 (55)	34 (53)
Height (cm)	171 (10)	171 (10)
Weight (kg)	81 (17)	81 (15)
Body mass index (kg/m^2)	27.6 (4.8)	27.3 (4.3)

Values are reported as mean (SD) or number (%) of subjects.

Table 2. Primary Surgical Procedures

	At bifurcation (n = 65)	Proximal to bifurcation (n = 65)[a]
Achilles tendon repair	8 (12)	7 (11)
Ankle arthroplasty or ORIF	14 (22)	12 (18)
Arthrodesis or fusion	7 (11)	8 (12)
Arthrotomy, synovectomy, and/or debridement	6 (9)	6 (9)
Foot osteotomy or ORIF	14 (22)	16 (25)
Hallux valgus repair	10 (15)	12 (18)
Ligament or tendon repair	6 (9)	4 (6)

Values are reported as number of subjects (%).
ORIF = open reduction, internal fixation.
[a]Percentages do not add to 100% because of a rounding error.

subjects having moderately painful foot and ankle surgery. This is in marked contrast with *single-injection* popliteal sciatic nerve blocks for which benefits are afforded to local anesthetic injection below the bifurcation. The etiology of these differing results for single-injection versus continuous peripheral nerve blocks remains unknown, and we can only speculate on possible explanations.

One possible explanation involves the paraneural compartment.[18] The sciatic nerve is surrounded by a paraneural sheath, which continues distal to the sciatic bifurcation.[19] Superficial to this sheath is the subepimyseal perineural space, and deep to the sheath is a thin layer of fat and the perineurium of the sciatic and terminal nerves, which is often difficult to differentiate with ultrasound from the subepimyseal space superficial to the paraneurium (at least until the space itself is distended with fluid).[14] Local anesthetic injected superficial to the paraneurium within the subepimyseal space—as done in the current study—has to pass through both the paraneurium and epineurium to reach the nerve fibers. In contrast, local anesthetic injected deep to the paraneurium must diffuse across only the epineurium, and at an equivalent volume, the paraneural sheath will essentially retain the local anesthetic close to the nerve in this relatively small subparaneural space, resulting in a spread over a longer length of nerve.[20]

Three clinical trials that found benefits to an injection just distal to the bifurcation were published before knowledge of the importance of the paraneural sheath was widespread within the regional anesthesia community,[14,18] as evidenced by the fact that none of the 3
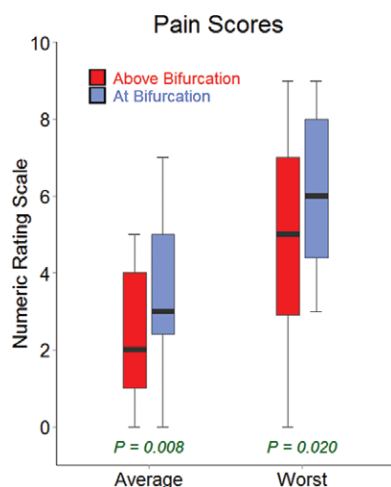
Figure 2. Perineural catheter location—either at or 5–8 cm proximal to the sciatic nerve bifurcation—effects on *average* and *maximum* postoperative pain after moderately painful foot/ankle surgery with a ropivacaine 0.2% perineural infusion. Pain severity indicated using a numeric rating scale of 0 to 10, with 0 equal to no pain and 10 being the worst imaginable pain. Data include the 3-hour period before a data collection telephone call the morning after surgery. Data are expressed as median (horizontal bars) with 25th–75th (box) and 10th–90th (whiskers).

Figure 3. Perineural catheter location—either at or 5–8 cm proximal to the sciatic nerve bifurcation—effects on opioid consumption after moderately painful foot/ankle surgery with a ropivacaine 0.2% perineural infusion. Data include the period from recovery room discharge until the data collection telephone call the morning after surgery. Data are expressed as median (horizontal bars) with 25th–75th (box) and 10th–90th (whiskers).
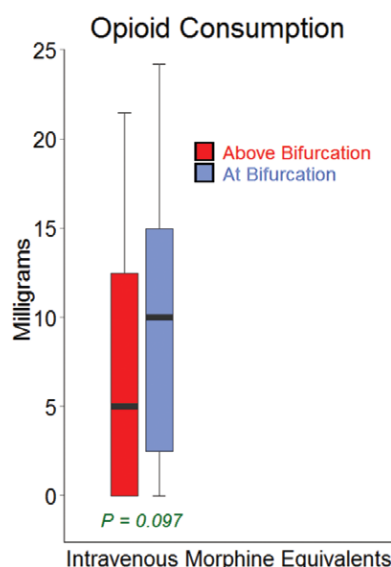
mentioned differentiating between injections superficial and deep to the paraneural sheath within their Methods sections.[4–6] It is possible that injections proximal to the sciatic bifurcation in these studies had a lower incidence of subparaneural injection than the injections below the bifurcation, resulting in the differing results between the 2 locations. In this hypothetical scenario, the location of injection above or below the bifurcation might be less relevant than the positioning of the needle tip relative to the paraneural sheath.[21–23] Indeed, a subsequent investigation purposefully injecting local anesthetic deep to the paraneural sheath for blocks both at or distal to the bifurcation reported equivalent outcomes for the 2 locations.[24] In the current study, the initial injection (whether saline or local anesthetic) via the Tuohy needle for both locations relative to the bifurcation was purposefully subepimyseal (superficial to the paraneurium).

However, these suppositions would only explain why catheters of the current study inserted at the bifurcation did not result in superior analgesia compared with those located 5 cm proximal to the bifurcation, in contrast to similar single-injection block studies. Importantly, they do not explain our finding of superior analgesia found with proximal catheter insertion. One possible explanation for our results is a difference in internal structure—or internal architecture (the connective tissue component)—of the sciatic nerve above and at the bifurcation,[18] resulting in differing degrees of local anesthetic penetration. Similarly, the subepimyseal space above the bifurcation may provide a more hospitable pocket to hold and/or spread low volumes of catheter infusate adjacent to the nerve. Extending this concept, it is possible that the physical properties of the sciatic nerve at the bifurcation require a greater volume, concentration, or mass of local anesthetic for equivalent efficacy. There are undoubtedly many additional possible explanations for the differing results found between single-injection and continuous peripheral nerve blocks, and this area of investigation requires further examination.

Study Limitations
Although the subjects of this investigation were masked to treatment group assignment, investigators were aware of the randomization results. In addition, the results apply only to the specific local anesthetic type, concentration, volume, and rate of the current study. As noted previously, all injections via the Tuohy needle and perineural catheters were located *superficial* to the paraneural sheath, within the subepimyseal space, and introduction of local anesthetic either through a needle or catheter into the space *deep* to the paraneurium would probably influence the outcomes.

Furthermore, we evaluated only one 3-hour period the morning after surgery, and although the difference between groups was statistically significant, a 1-point decrease (33%) on the NRS from a median of 3 to 2 remains of questionable clinical significance.[25]

Although both treatment groups received identical portable electronic infusion pumps and programmable settings (basal rate, bolus dose, and lockout period), the actual number of doses self-administered by each subject is unavailable. Consequently, the possibility remains that subjects assigned to the proximal group self-administered more bolus doses, resulting in a higher delivered mass of ropivacaine. Finally, we do not have data assessing both sleep disturbances and satisfaction with analgesia as these variables were inadvertently excluded from the case report forms.

Table 3. Postrandomization End Points

	At bifurcation (n = 64)[a]	Proximal to bifurcation (n = 64)[a]	P
Local anesthetic injected *preoperatively*, n (%)	58 (91)	56 (88)	0.59
Catheter placement time (min)	4 (3–5)	5 (4–6)	0.07
Time last bolus until 10:00 postoperative day 1 (h)	24 (21–26)	24 (22–26)	0.25
Saphenous nerve block administered, n (%)	37 (58)	33 (52)	0.54
Outpatient, n (%)	56 (88)	55 (86)	0.80
Numbness in foot/toes (0–10 scale)[b]	5.0 (0.0–7.0)	5.0 (3.0–8.0)	0.42
Leakage at the catheter site, n (%)[b]	10 (16)	11 (17)	0.75

Values are reported as number (%) of subjects or median (interquartile).
[a]One subject randomized to each treatment group was excluded from the analysis (1 failed catheter insertion and 1 cancelled surgery).
[b]By the data collection telephone call at 10:00 the morning after surgery.

In conclusion, for continuous popliteal sciatic nerve blocks, a catheter inserted 5 cm proximal to the sciatic nerve bifurcation provides superior postoperative analgesia in subjects having moderately painful foot or ankle surgery compared with catheters located at the bifurcation. ▦

DISCLOSURES
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Attestation: Amanda M. Monahan approved the final manuscript.
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Contribution: This author helped conduct the study and write the manuscript. In addition, she has seen the original study data.
Attestation: Cindy H. Wen approved the final manuscript.
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Contribution: This author designed the original study, secured appropriate funding, has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
Attestation: Brian M. Ilfeld approved the final manuscript.
This manuscript was handled by: Terese T. Horlocker, MD.

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