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Continuous Popliteal Sciatic Nerve Block for Postoperative Pain Control at Home

A Randomized, Double-Blinded, Placebo-Controlled Study

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Background: **This randomized, double-blinded, placebo-controlled study investigated the efficacy of patient-controlled regional analgesia using a sciatic perineural catheter in the popliteal fossa and a portable infusion pump for outpatients having moderately painful, lower extremity orthopedic surgery.**

Methods: **Preoperatively, patients (n = 30) received a sciatic nerve block and perineural catheter in the popliteal fossa. Postoperatively, patients were discharged with both oral opioids and a portable infusion pump delivering study solution (0.2% ropivacaine or 0.9% saline) *via* the catheter for 3 days. Investigators and patients were blinded to random group assignment. Daily end-points included pain scores, opioid use and side effects, sleep quality, and symptoms of catheter- or local anesthetic-related complications.**

Results: **Ropivacaine (n = 15) infusion significantly reduced pain compared with saline (n = 15) infusion ($P < 0.001$). For example, the average pain at rest (scale: 0–10) on postoperative day 1 (median, 25^{th}-75^{th} percentile) was 4.0 (3.5–5.5) for the saline group, *versus* 0.0 (0.0–0.0) for the ropivacaine group ($P < 0.001$). Oral opioid use and related side effects were significantly decreased in the ropivacaine group. For example, on postoperative day 1, median tablet consumption was 8.0 (5.0–10.0) and 0.0 (0.0–0.0) for the saline and ropivacaine groups, respectively ($P < 0.001$). Sleep disturbance scores were more than 10-fold greater for saline administration than for ropivacaine infusion ($P < 0.001$). Overall satisfaction was significantly greater in the ropivacaine group. Other than two inadvertent catheter dislodgements, no catheter- or local anesthetic-related complications occurred.**

Conclusions: **After moderately painful orthopedic surgery of the lower extremity, ropivacaine infusion using a portable mechanical pump and a popliteal sciatic perineural catheter at home decreased pain, opioid use and related side effects, sleep disturbances, and improved overall satisfaction.**

MORE than 40% of ambulatory patients undergoing orthopedic procedures experience moderate to severe postoperative pain at home.[1] Single-injection sciatic nerve blockade in the popliteal fossa provides up to 24 h of analgesia following lower extremity procedures,[2] after which ambulatory patients must usually rely on oral opioids to control their pain. Opioids, however, are associated with undesirable side effects, such as nausea and vomiting, sedation, pruritus, and constipation. Multiple studies have demonstrated that a single-injection popliteal sciatic nerve block reduces overall postoperative pain and opioid requirements.[2,3] One previous investigation involving hospitalized patients suggests that local anesthetic infused *via* a popliteal sciatic perineural catheter extends these benefits for up to 48 h.[4] At-home popliteal sciatic perineural infusion has been reported as a case report in two patients.[5] However, the efficacy of this technique has not been investigated in a randomized, double-blinded, placebo-controlled manner.

A pump which allows for patient-controlled local anesthetic bolus dosing, also called patient-controlled regional analgesia (PCRA), provides equivalent or superior analgesia with lower local anesthetic consumption compared with continuous infusions alone. This has been demonstrated with a variety of perineural techniques.[6–8] PCRA is important for ambulatory patients, as the infusion may be tailored to provide a minimum basal rate, yet allows bolus dosing for break-through pain and before physical therapy. Recently, a portable, PCRA-capable pump with simple controls has been described for brachial plexus[9,10] and femoral perineural local anesthetic infusion.[11] We hypothesized that these pumps could be used successfully to treat ambulatory patients with a popliteal sciatic perineural catheter as well.

The primary objective of this randomized, double-blinded, placebo-controlled study was to determine if local anesthetic infused *via* a popliteal sciatic perineural catheter decreases postoperative baseline and breakthrough pain for patients having moderately painful orthopedic surgery of the lower extremity below the knee. Secondary outcomes investigated included oral opioid requirements, opioid-related side effects, sleep disturbances, and patient satisfaction.

Materials and Methods

Enrollment

The Institutional Review Board approved the study protocol. We prospectively enrolled patients scheduled for moderately painful ambulatory unilateral orthopedic surgery of the lower extremity distal to the knee, with surgical incision(s) expected to be outside of the saphe-

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nous nerve distribution. Inclusion criteria included: (1) American Society of Anesthesiologists physical status I or II, (2) aged 18 yr or older, (3) ability to provide informed consent, and (4) understanding of the possible local anesthetic-related complications, the study protocol, and care of the catheter and infusion pump system. In addition, patients were required to have a caretaker who would remain with them through the first postoperative night and be available and capable of removing the catheter in the evening of postoperative day (POD) 2. Exclusion criteria included any contraindication to popliteal nerve block, history of opioid dependence or allergy to study medications, current chronic analgesic therapy, coagulopathy, known hepatic or renal insufficiency, peripheral neuropathy, and patient refusal. Enrollment began March 6, 2001, and concluded January 8, 2002.

Catheter Insertion

After obtaining written informed consent, an intravenous cannula was placed. Patients were placed in the prone position with both legs extended and their ankles at the inferior edge of the gurney (toes "hanging" off the end of the gurney). Standard noninvasive monitors were applied, and oxygen (8–10 l/min) was administered *via* a facemask. Intravenous midazolam and fentanyl were titrated for patient comfort in divided doses, while ensuring that patients remained responsive to verbal cues throughout the procedure. All popliteal blocks and catheters were placed by one of the authors (B.I.). The area that would be subsequently covered by the catheter dressing was prepared with chlorhexidine gluconate and isopropyl alcohol (ChloraPrep One-Step, Medi-Flex Hospital Producs, Inc., Overland Park, KS), and then shaved with a surgical safety razor, if necessary. After sterile preparation (with additional chlorhexidine gluconate) and draping, a skin wheal of local anesthetic was raised 1 cm directly caudad to the apex of the popliteal fossa (bounded by the semimembranosus muscle medially, and biceps femoris muscle laterally), but at least 7 cm cephalad to the popliteal fossa skin crease.[12,13] With the bevel directed cephalad, a 102-mm, 18-gauge, insulated stimulating needle (Contiplex, B. Braun Medical, Bethlehem, PA) was inserted through the skin wheal 45–60° to the skin–gurney plane with a cephalad and anterior orientation within the parasagittal plane. This was connected to a nerve stimulator (Stimuplex-DIG, B. Braun Medical, Bethlehem, PA) that was initially set at 1.2 mA and 2 Hz. Continuous aspiration was applied to the syringe. If the sciatic nerve was not identified after 5–8 cm of insertion, depending on patient habitus, the needle was withdrawn to the skin and redirected through the same entry point either medially or laterally until plantar flexion was elicited with a current between 0.30 and 0.40 mA.[14]

For the surgical block, 50 ml of anesthetic solution was injected in divided doses, with gentle aspiration every 3 ml. The injectate contained mepivacaine, 1.5%; sodium bicarbonate, 5 mEq; epinephrine, 125 μg; and preservative-free clonidine, 100 μg. A 20-gauge, multi-port, polyamide catheter (B. Braun Medical, Bethlehem, PA) was then passed through the needle so that 5 cm of the catheter was located past the tip of the needle. The needle was then removed over the catheter.

After negative aspiration, the catheter was injected with 1 ml of sterile saline, 0.9%, to ensure its patency. The catheter was then secured with sterile liquid adhesive (Mastisol, Ferndale Laboratory, Ferndale, MI) and sterile tape (Steri-Strips, 3 M Corporation, St. Paul, MN). An occlusive dressing (Tegaderm, 3 M Corporation, St. Paul, MN) was placed over the site to retain sterility, and the catheter further secured cephalad up the lateral aspect of the thigh with 1" tape (Durapore, 3 M Corporation, St. Paul, MN) to the level of the inguinal skin crease. Patients were withdrawn from the study if a sensory block failed to develop at 15 min or if the catheter was placed in a vessel. Block failure was defined as a lack of any sensory changes to touch from baseline in the plantar aspect of the foot. Specific nerve distributions and degree of sensory blockade were not formally evaluated. The popliteal sciatic nerve block was intended to provide surgical anesthesia for all patients.

If a tourniquet was expected to be placed on the leg below the knee, a saphenous nerve block was placed as previously described by Bouaziz *et al.* with the patient in a supine position.[15] Following sterile preparation, a 5 cm, 22-gauge, insulated stimulating needle (Stimuplex, B. Braun Medical, Bethlehem, PA) attached to a nerve stimulator (same as for the popliteal sciatic nerve block) was used to deposit 10 ml of anesthetic in divided doses after vastus medialis motion was elicited with a current of less than 0.50 mA. The injectate contained mepivacaine, 1.5%, sodium bicarbonate, 1 mEq, and epinephrine, 25 μg. This nerve block was not formally evaluated in regard to the current investigation.

Intraoperative sedation was provided with intravenous propofol (0–50 $\mu g \cdot kg^{-1} \cdot min^{-1}$, titrated for patient comfort). Alternatively, higher doses of intravenous propofol and nitrous oxide inhaled *via* a laryngeal mask airway were used at the attending anesthesiologists' discretion. Whether block inadequacy or simply patient–physician preference resulted in a general anesthetic was not evaluated. No anesthetic or analgesic medication besides propofol and nitrous oxide were administered following nerve block placement(s).

Randomization

After successful block and catheter placement, patients were assigned to receive one of two possible postoperative catheter infusions: ropivacaine, 0.2%, or sterile saline, 0.9%. An investigational pharmacist using a

computer-generated randomization table performed group assignment. Assignment was not known to the patients or any clinical personnel. Group designation was not revealed to the investigators until after all clinical data were collected and the study completed.

Postoperatively, when patients met our facility's standard ambulatory home-discharge criteria, the catheter was tested for intravascular positioning with gentle aspiration. Following a negative aspiration, a 10 ml bolus of study fluid, into which 30 μg of fresh epinephrine had been added, was injected incrementally *via* the catheter. Subsequently, a portable, programmable, battery-powered, mechanical infusion pump (Microject PCA Pump, Sorenson Medical, West Jordan, UT) was attached to the catheter with a reservoir containing 550 ml of study solution. A continuous infusion of 8 ml/h was begun with a 2 ml patient-controlled bolus available every 20 min.

Patient Education

The patient and caretaker were given standard postoperative outpatient instructions, including a prohibition of weight bearing on the surgical limb, as well as the importance of elevating the extremity and ambulating with crutches. In addition, verbal and written instructions on the use of the pump and catheter were given. Specific attention was given to signs and symptoms of local anesthetic toxicity, catheter site infection, and catheter migration. Multiple telephone and pager numbers for physicians available at all times were given to each patient. Patients were instructed not to drive motorized vehicles and to keep the operative limb well protected during the infusion period. The following supplies were given to patients: a medication log, a prescription for an oral opioid (oxycodone, 5 mg), three additional occlusive dressings, a pair of nonsterile gloves, and a hospital-addressed and stamped padded envelope for return of the pump. The opioid prescription was identical to that used for patients undergoing similar operations at our facility, but who did not participate in this study.

In the event of "break-through" pain, patients were instructed to first use the bolus function of the infusion pump. If the pain had not resolved after 20 min, patients were instructed to use oral opioids and to record this use in their medication log. Prior to discharge from the ambulatory surgical center, all patients were given oral methadone (5 mg) since approximately half of the enrolled population (patients receiving placebo) would experience resolution of surgical anesthesia without the benefit of a ropivacaine perineural infusion for analgesia.

Patient Follow-up

Patients could contact a physician at any time during the study period by telephone. Patients were telephoned beginning the night of surgery, and each evening thereafter until the night following catheter removal. Information obtained included pain scores at rest and with limb motion, oral opioid use, opioid-related side effects, and sleep quality (see Appendix 1 for questionnaire). For the primary outcome variable, "average pain at rest," patients were asked to rate their surgical pain for the previous 24 h using a scale of 0–10, 0 being no pain at all and 10 being the worst pain they could imagine. The exact question asked was, "While you are sitting down with your foot elevated, what was the *average* pain you have felt?"

Gross sensory and motor functions were reviewed. Patients were also questioned about symptoms of local anesthetic toxicity and the appearance of the catheter site. In the evening of postoperative day (POD) 0, patients were instructed to contact the physician if they awoke the next morning without any feeling in their toes. If this occurred, the patient reprogrammed the basal infusion rate of the pump from 8 to 6 ml/h using instructions provided by the physician that morning. In the evening of POD 1, all patients were asked if they recalled self-administering an average of one or more bolus injections every 2 h that day. If so, the patient increased the basal infusion rate of the pump by 2 ml/h (pump maximum: 9.9 ml/h) using instructions provided by the physician over the telephone.

In the evening of POD 2, patients' caretakers were instructed on removal of the catheter using the pair of nonsterile gloves, with the physician in telephone contact throughout. The presence of a blue catheter tip confirmed complete removal. Residual study fluid was disposed of in a sink or toilet. Patients were asked if they would repeat this method of postoperative pain control in the future, and their satisfaction with their postoperative pain control on a scale of 0–10 (0 = very dissatisfied to 10 = very satisfied). In the evening of POD 3, patients were instructed to return their medication log and infusion pump to the surgical center in the preaddressed stamped envelope the next morning.

Statistical Analysis

Sample size calculations were centered on our primary hypothesis that local anesthetic infusion *via* a popliteal sciatic perineural catheter decreases postoperative pain. To this end, we chose the outcome variable "average pain at rest" on POD 1 to estimate a probable sample size. We considered a 50% reduction in pain scores to be clinically relevant (mean pain score decrease from 4 to 2 on the scale of 0–10). Based on a SD of each group of 2 and assuming a two-sided type I error protection of 0.05 and a power of 0.80, approximately 15 patients in each group were required to reveal a 50% reduction in mean pain scores. Parametric data are reported as mean ± SD. Nonparametric data are reported as median with 25^{th}–75^{th} and 10^{th}–90^{th} percentiles as indicated in table and figure legends. Normality of distribution was determined

Table 1. Population Data for the Two Study Groups

	Ropivacaine (n = 15)	Placebo (n = 15)	*P* Value
Age (yr)	56.1 ± 12.4	51.5 ± 13.4	0.337
Sex (F/M)	10/5	11/4	1.000
Height (cm)	168.9 ± 11.9	166.6 ± 9.3	0.560
Weight (kg)	78.7 ± 17.9	75.4 ± 21.0	0.648
Intravenous fentanyl (μg)*	143.3 ± 56.3	133.3 ± 48.8	0.607
Intravenous midazolam (mg)*	2.8 ± 1.1	2.9 ± 1.0	0.866
Tourniquet duration (min)	65.6 ± 30.2	69.7 ± 29.9	0.714
Surgery duration (min)	84.5 ± 48.9	86.9 ± 42.3	0.887

Values are mean ± SD.

* Sedation only for preoperative block placement.

using the Kolmogorov-Smirnov test with Lilliefors correction (Sigma Stat 2.03, SPSS, Inc., Chicago, IL). For normally distributed data, single comparisons were tested using the *t* test, whereas multiple comparisons were made using repeated measures ANOVA with Tukey *post hoc* pairwise testing, when appropriate. For nonparametric data, the Mann–Whitney Rank Sum test or repeated measures ANOVA for ranks was used. Nominal data were analyzed using either chi-square or the Fisher exact test, as appropriate. $P < 0.05$ was considered significant. For purposes of data analysis, patients were always considered a member of their original randomized group, regardless of inadvertent catheter dislodgement.

Results

Thirty patients were approached for study inclusion. All chose to be enrolled. All patients had a posterior popliteal sciatic nerve block and a perineural catheter placed successfully. These patients were randomized to receive either ropivacaine (n = 15) or placebo (n = 15) infusion. There were no statistically significant differences between these groups in demographics, intravenous sedation for block placement, tourniquet and surgical duration, or surgical procedures (tables 1 and 2). All patients were pain-free with a dense sensory block (determined grossly) at discharge from the surgical facility.

During the infusion, patients receiving ropivacaine experienced significantly less postoperative pain compared with patients receiving normal saline both on average while resting (fig. 1A) and worst overall (fig. 1B). Patients receiving ropivacaine required significantly fewer opioid tablets to achieve this degree of comfort (fig. 2). Of the 15 patients receiving ropivacaine, 12 (80%) required no opioids during their infusion. In contrast to this, only 1 of the 15 (7%) patients receiving placebo delayed their first oral opioid use until discontinuation of their infusion ($P < 0.001$). Correspondingly, patients receiving ropivacaine experienced almost no opioid-related side effects or sleep disturbances compared with the placebo group (fig. 3, table 3).

Three patients, all from the ropivacaine group, lacked any feeling in their toes the morning after surgery. As per study protocol, their basal infusion rate was decreased from 8 to 6 ml/h. Within 4 h, these complete sensory

Table 2. Surgical Procedures for Each Study Group

Surgical Procedure	Ropivacaine (n = 15)	Placebo (n = 15)
Achilles tendon repair	0	1
Ankle ORIF	1	1
Clawtoes correction	4	4
Hallux rigidus correction	1	2
Hallux valgus correction	1	2
Hammertoes correction	3	2
Calcaneal excision/resection	3	2
Subtalar fusion	1	1
Tibial reconstruction	1	0

ORIF = open reduction, internal fixation.

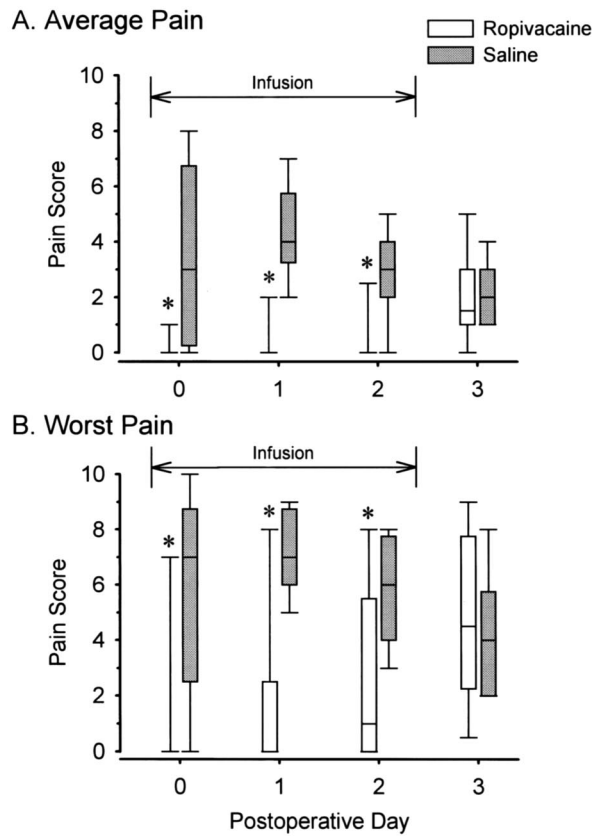

Fig. 1. Effects of popliteal sciatic perineural infusion of either ropivacaine or placebo on average pain at rest (*A*) and worst pain overall (*B*) following moderately painful lower extremity surgery (scale: 0–10). Note: the infusion was discontinued after postoperative day two as indicated by the horizontal line. Data are expressed as median (horizontal bar) with 25th–75th (box) and 10th–90th (whiskers) percentiles for patients randomly assigned to receive either 0.2% ropivacaine (n = 15) or 0.9% saline placebo (n = 15). For tightly clustered data (*e.g.*, Panel A, postoperative day 0, ropivacaine group), the median approximated the 10th, 25th, and 75th percentile values. In this case, the median is zero and no box is evident, although the 90th percentile is noted. $P < 0.05$: *, compared to saline for a given postoperative day.

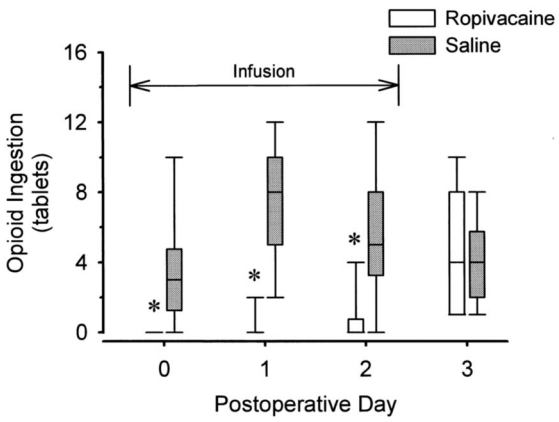

Fig. 2. Effects of popliteal sciatic perineural infusion of either ropivacaine or placebo on opioid use following moderately painful lower extremity surgery. Each tablet consisted of oxycodone, 5 mg. Patients recorded opioid use in a daily log. Note: the infusion was discontinued after postoperative day two as indicated by the horizontal line. Data are expressed as median (horizontal bar) with 25th–75th (box) and 10th–90th (whiskers) percentiles for patients randomly assigned to receive either 0.2% ropivacaine (n = 15) or 0.9% saline placebo (n = 15). For tightly clustered data (*e.g.*, postoperative day 0, ropivacaine group), the median approximated the 10th, 25th, and 75th percentile values. In this case, the median is zero and no box is evident, although the 90th percentile is noted. $P < 0.05$: *, compared to placebo for a given postoperative day.

blocks resolved. Two patients, both from the ropivacaine group, used their bolus function an average of 1 time every 2 h. As per study protocol, their basal infusion rate was increased from 8 to 9.9 ml/h on POD 1 (pump maximum). The average satisfaction with postoperative analgesia on a scale of 0 (dissatisfied) to 10 (very satisfied) was scored 9.7 ± 0.9 by those who received ropivacaine and 5.5 ± 3.0 by those who received placebo ($P < 0.001$). Whereas all patients who received ropivacaine would repeat this analgesic method, only 7 patients (46%) receiving placebo would repeat this technique ($P = 0.002$).

One patient from each group had their catheter inadvertently dislodged in the evening of POD 1 following the patient-contact telephone call. For purposes of data analysis, these patients were considered a member of their original randomized group, retaining the "intention-to-treat" protocol. Other than these two cases, there were no apparent local anesthetic- or catheter-related complications during infusion. Patients used and reprogrammed the portable, mechanical infusion pumps without difficulty. Likewise, patients' caretakers were able to safely remove all of the perineural catheters at home.

Table 3. Number of Awakenings per Night

Postoperative Night	Ropivacaine (n = 15)	Placebo (n = 15)	*P* Value
0 (with infusion)	0.2 ± 0.6	2.3 ± 1.8	< 0.001
1 (with infusion)	0.1 ± 0.3	1.6 ± 0.5	0.002
2 (without infusion)	1.2 ± 1.6	0.7 ± 1.2	0.328

Values are mean ± SD. Responses greater than or equal to 4 were recorded as "4."

The only complaint consistently noted by patients (roughly 50%) was leakage of clear fluid from under the occlusive dressing. In addition, one infusion pump had to be replaced on the morning of POD 2 when it failed to function without apparent cause. This patient, who was receiving a saline infusion, returned to the surgical center roughly 1 h after the pump failure was discovered to have the pump replaced. Pump examination by the manufacturer confirmed a pump malfunction. The unit was removed from service. Approximately 30% of patients had at least one nonscheduled contact with the "on call" physician during the course of their infusion. All infusion pumps were returned to the surgical center *via* the postal service.

Discussion

This randomized, double-blinded, placebo-controlled study demonstrates that potent analgesia is achievable using a perineural infusion of ropivacaine *via* a popliteal sciatic perineural catheter following moderately painful lower extremity surgery. The local anesthetic infusion provided analgesia so complete that 80% of patients receiving ropivacaine did not require a single oral opioid tablet during their infusion, and reported *average* resting pain as less than 1 on a scale of 0–10. This compares with 7% of patients receiving placebo delaying first oral opioid use until after infusion discontinuation, and *average* resting pain scores of 3 to 4. The *worst* resting pain scores reflect break-through pain, and the difference between treatment groups is even more pronounced (fig. 1B). Consequently, patients receiving ropivacaine experienced a significant decrease in sleep disturbances, oral opioid use, and opioid-related side effects (figs. 2 and 3). These benefits were attained for ambulatory patients with the use of a portable, programmable, PCRA-capable infusion pump. The degree of analgesia and the relative simplicity of the catheter–pump system led to a very high rate of satisfaction for all subjects receiving ropivacaine.

Block and Catheter Technique

The popliteal approach to the sciatic nerve is simple to perform and has a high success rate.[4] The initial single-injection nerve block provides complete anesthesia distal to the knee, with the exception of the saphenous nerve distribution (medial cutaneous innervation of the leg). Postoperative perineural local anesthetic infusion provides analgesia in the same tibial and common peroneal nerve distribution. However, the sciatic nerve is intercepted distal to the hamstring muscles of the posterior thigh, allowing patients to retain knee flexion during perineural infusion.

The *posterior* approach to the sciatic nerve was used as the authors were most familiar with this technique.

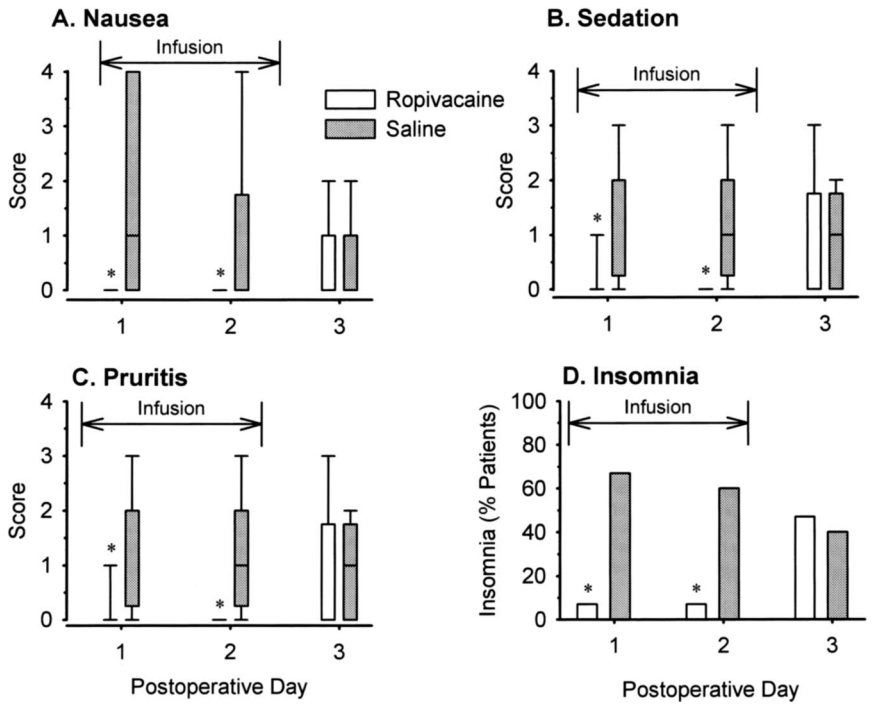

Fig. 3. Effects of popliteal sciatic perineural infusion of either ropivacaine or placebo on opioid-related side effects and sleep quality following moderately painful lower extremity surgery. Endpoints included nausea (*A*), sedation (*B*), pruritis (*C*), and insomnia (*D*). Note: the infusion was discontinued after postoperative day two as indicated by the horizontal line. (*A–C*): Data are expressed as median (horizontal bar) with 25th–75th (box) and 10th–90th (whiskers) percentiles for patients randomly assigned to receive either 0.2% ropivacaine (n = 15) or 0.9% saline placebo (n = 15). For tightly clustered data (*e.g.*, Panel B, postoperative day 1, ropivacaine group), the median approximated the 10th, 25th, and 75th percentile values. In this case, the median is zero and no box is evident, although the 90th percentile is noted. (*D*): Data expressed as fraction of patients reporting insomnia. $P < 0.05$: *, compared to placebo for a given postoperative day. See Appendix 1 for side-effects intensity scale. The legend applies to all panels.

However, a lateral approach,[16] while usually requiring additional passes with the stimulating needle to locate the sciatic nerve,[17] offers several advantages over the posterior approach. Patients may remain supine for block and catheter placement, as opposed to the prone position with a subsequent roll supine for a saphenous nerve block. The catheter dressing appears to be more secure in the lateral, *versus* posterior, position. And the catheter entry site and occlusive dressing may be monitored by the patient more easily in the lateral, *versus* posterior, position. While there is data to suggest that the two approaches provide equivalent surgical anesthesia following single-injection nerve blockade,[17] whether or not the two are equivalent for postoperative analgesia during perineural local anesthetic infusion requires further investigation.

We chose to accept a motor response only in the tibial, and not the common peroneal, nerve distribution to standardize all patients for this investigation. There is evidence to suggest, "the intensity of the current at which sciatic nerve stimulation is achieved is a more important factor in determining the quality of [a single-injection] nerve block than the type of motor response obtained."[14] However, whether or not this holds true for postoperative analgesia during perineural local anesthetic infusion requires further investigation.

Study Limitations

As this study was designed to evaluate postoperative perineural infusion, the initial surgical block was not evaluated systematically. A prospective trial with blockade results from all nerve distributions is required to properly evaluate the technique and equipment used for this investigation. A potential fault of this study design is that patients receiving a saline infusion may have had their initial regional block duration shortened from a "wash out" effect, as has been described for epidural anesthesia.[18] However, the time from block placement until initial oral opioid use for patients in the placebo group was, in our experience, comparable to patients receiving single-injection popliteal sciatic nerve blocks for similar procedures. Finally, the benefits of multimodal analgesia using acetaminophen and nonsteroidal anti-inflammatory medication have been previously demonstrated.[19] The omission of these medications most likely reduced analgesia efficacy in both study groups, but had a greater effect on patients receiving a saline infusion. However, we believe these are subtle biases that do not negate the striking advantages of perineural ropivacaine infusion found in this study.

The Safety of Ambulatory Infusion

Although at-home perineural local anesthetic infusion offers significant improvements in pain control following many ambulatory procedures, there are several potential inherent risks, including catheter site infection, nerve injury, and catheter migration with local anesthetic toxicity.

In this study, there were no medical complications attributable to the initial regional block, catheter placement, or local anesthetic infusion. However, the small number of patients does not permit us to draw definite conclusions about its relative safety. To maximize safety with this technique, patients are given extensive written and verbal instruction regarding the signs and symptoms of possible catheter- and local anesthetic-related compli-

cations. Patients have the ability to contact a physician at all times, and are contacted by telephone at least once a day, and specifically asked about these symptoms. Because not all patients desire, or are capable of accepting, the extra responsibility that comes with the catheter and pump system, appropriate patient selection is crucial for safe ambulatory local anesthetic infusion.

The programmable nature of the pump used in this study provides infusion flexibility. We have found that allowing patients to vary their basal rate (with instructions provided by a health-care provider *via* the telephone) allows analgesia optimization. This was especially important for the 20% of patients who received ropivacaine in this study and lacked sensation in their toes on the morning of POD 1. An insensate extremity may be injured without patient awareness, and we therefore believe should be avoided if possible. The programmable nature of the pump used in this study allows for a decrease (or increase) in the basal infusion rate. However, allowing patient access to the pump controls also provides the potential for accidental misprogramming or abuse. The pump used in this study has a maximum basal rate of 9.9 ml/h and bolus dose of 2 ml, and a minimum bolus lockout period of 6 min. Therefore, if a patient reprogrammed the pump with these settings, and repeatedly triggered the bolus function, a maximum volume of 29.9 ml/h could be infused. It would require intentional abuse of the pump system for this complication to occur. Alternatively, a lockable cover is available if the health-care provider does not desire the option of pump reprogramming.

Many questions remain regarding ambulatory perineural local anesthetic infusion, including the optimal catheter insertion technique and system, infusion pump, basal infusion rate, bolus dose and lockout period, local anesthetic and concentration, infusion additives, and cost-effectiveness. In keeping with evidence-based medical practice, we believe that the optimal techniques, equipment, and patient oversight should be determined by prospective controlled trials, and not merely by institutional preference.

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References

1. Rawal N, Hylander J, Nydahl PA, Olofsson I, Gupta A: Survey of postoperative analgesia following ambulatory surgery. Acta Anaesthesiol Scand 1997; 41:1017–22

2. Rongstad K, Mann RA, Prieskorn D, Nichelson S, Horton G: Popliteal sciatic nerve block for postoperative analgesia. Foot Ankle Int 1996; 17:378–82

3. Rorie DK, Byer DE, Nelson DO, Sittipong R, Johnson KA: Assessment of block of the sciatic nerve in the popliteal fossa. Anesth Analg 1980; 59:371–6

4. Singelyn FJ, Aye F, Gouverneur JM: Continuous popliteal sciatic nerve block: An original technique to provide postoperative analgesia after foot surgery. Anesth Analg 1997; 84:383–6

5. Klein SM, Greengrass RA, Gleason DH, Nunley JA, Steele SM: Major ambulatory surgery with continuous regional anesthesia and a disposable infusion pump. ANESTHESIOLOGY 1999; 91:563–5

6. Singelyn FJ, Gouverneur JM: Extended "three-in-one" block after total knee arthroplasty: Continuous versus patient-controlled techniques. Anesth Analg 2000; 91:176–80

7. Singelyn FJ, Vanderelst PE, Gouverneur JM: Extended femoral nerve sheath block after total hip arthroplasty: Continuous versus patient-controlled techniques. Anesth Analg 2001; 92:455–9

8. Singelyn FJ, Seguy S, Gouverneur JM: Interscalene brachial plexus analgesia after open shoulder surgery: Continuous versus patient-controlled infusion. Anesth Analg 1999; 89:1216–20

9. Ilfeld BM, Enneking FK: A portable mechanical pump providing over four days of patient-controlled analgesia by perineural infusion at home. Reg Anesth Pain Med 2002; 27:100–4

10. Ilfeld BM, Morey TE, Enneking FK: Continuous infraclavicular brachial plexus block for postoperative pain control at home: A randomized, double-blinded, placebo-controlled study. ANESTHESIOLOGY 2002; 96:1297–1304

11. Chelly JE., Gebhard R., Coupe K, Greger J, Khan A: Local anesthetic delivered via a femoral catheter by patient-controlled analgesia pump for pain relief after an anterior cruciate ligament outpatient procedure. Am J Anesthesiol 2001; 28:192–4

12. Vloka JD, Hadzic A, April E, Thys DM: The division of the sciatic nerve in the popliteal fossa: Anatomical implications for popliteal nerve blockade. Anesth Analg 2001; 92:215–7

13. Vloka JD, Hadzic A, Lesser JB, Kitain E, Geatz H, April EW, Thys DM: A common epineural sheath for the nerves in the popliteal fossa and its possible implications for sciatic nerve block. Anesth. Analg 1997; 84:387–90

14. Vloka JD, Hadzic A: The intensity of the current at which sciatic nerve stimulation is achieved is a more important factor in determining the quality of nerve block than the type of motor response obtained [letter]. ANESTHESIOLOGY 1998; 88:1408–11

15. Bouaziz H, Benhamou D, Narchi P: A new approach for saphenous nerve block [letter]. Reg Anesth 1996; 21:490

16. Vloka JD, Hadzic A, Kitain E, Lesser JB, Kuroda M, April EW, Thys DM: Anatomic considerations for sciatic nerve block in the popliteal fossa through the lateral approach. Reg Anesth 1996; 21:414–8

17. Hadzic A, Vloka JD: A comparison of the posterior versus lateral approaches to the block of the sciatic nerve in the popliteal fossa. ANESTHESIOLOGY 1998; 88:1480–6

18. Sitzman BT, Difazio CA, Playfair PA, Stevens RA, Hanes CF, Herman TB, Yates HK, Leisure GS: Reversal of lidocaine with epinephrine epidural anesthesia using epidural saline washout. Reg Anesth Pain Med 2001; 26:246–51

19. Kehlet H, Dahl JB: The value of "multimodal" or "balanced analgesia" in postoperative pain treatment. Anesth Analg 1993; 77:1048–56

Appendix

Nightly Questionnaire. *Asked POD 1–3. Response scores are in *italics* (negative responses = *0*).

Pain Scores

Please answer the following questions regarding your surgical pain since the last time we spoke using a scale of 0–10, 0 being no pain at all and 10 being the worst pain you can imagine.

1. What was the *worst* pain you have felt?
2. While you were sitting down with your foot elevated, what was the *average* pain you have felt?

*Opioid-Related Side Effects**

Have you experienced nausea *(1–3)* or vomiting *(4)* since the last time we spoke? *If "yes" only to nausea, then:* How would you describe your nausea: minimal *(1)*, moderate *(2)*, or severe *(3)*?

Have you felt unusually sleepy since the last time we spoke? *If "yes", then:* Would you say you were drowsy *(1)*, dosing intermittently *(2)*, mostly *asleep (3)*, or awake only when aroused *(4)*?

Have you experienced unusual itching on any part of your body since the last time we spoke?" *If "yes", then:* "How would you describe your itching: only under your surgical dressings *(1)*, or on other parts of your body [minimal *(2)*, moderate *(3)*, or severe *(4)*]?

*Sleep Quality**

Did you have difficulty sleeping last night because of pain *(yes = 1)*?

Did you awaken last night because of pain?" *If "yes," then:* "How many times did you awaken last night because of pain *(if=>4 awakenings, score = 4)*?