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The Effects of Varying Local Anesthetic Concentration and Volume on Continuous Popliteal Sciatic Nerve Blocks:

A Dual-Center, Randomized, Controlled Study

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Abstract

BACKGROUND—It remains unknown whether local anesthetic concentration, or simply total drug dose, is the primary determinant of continuous peripheral nerve block effects. We therefore tested the null hypothesis that providing different concentrations and rates of ropivacaine, but at equal total doses, produces comparable effects when used in a continuous sciatic nerve block in the popliteal fossa.

METHODS—Preoperatively, a perineural catheter was inserted adjacent to the sciatic nerve using a posterior popliteal approach in patients undergoing moderately painful orthopedic surgery at or distal to the ankle. Postoperatively, patients were randomly assigned to receive a perineural ropivacaine infusion of either 0.2% (basal 8 mL/h, bolus 4 mL) or 0.4% (basal 4 mL/h, bolus 2 mL) through the second postoperative day. Therefore, both groups received 16 mg of ropivacaine each hour with a possible addition of 8 mg every 30 min via a patient-controlled bolus dose. The primary end point was the incidence of an insensate limb, considered undesirable, during the 24-h period beginning the morning after surgery. Secondary end points included analgesia and patient satisfaction.

RESULTS—Patients given 0.2% ropivacaine ($n = 25$) experienced an insensate limb with a mean ($_{SD}$) of 1.8 (1.8) times, compared with 0.6 (1.1) times for subjects receiving 0.4% ropivacaine ($n =$

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25; estimated difference = 1.2 episodes, 95% confidence interval, 0.3–2.0 episodes; $P = 0.009$). In contrast, analgesia and satisfaction were similar in each group.

CONCLUSIONS—For continuous popliteal-sciatic nerve blocks, local anesthetic concentration and volume influence block characteristics. Insensate limbs were far more common with larger volumes of relatively dilute ropivacaine. During continuous sciatic nerve block in the popliteal fossa, a relatively concentrated solution in smaller volume thus appears preferable.

Continuous peripheral nerve blockade involves the percutaneous insertion of a catheter directly adjacent to a peripheral nerve. The catheter is then infused with local anesthetic, resulting in potent, site-specific analgesia that lasts well beyond the normal duration of a single-injection nerve block.^{1,2}

However, a transiently insensate limb is a well-recognized effect of perineural local anesthetic infusion.^{1–5} It is postulated that an insensate extremity is best minimized during continuous peripheral nerve blocks because insensate limbs may be prone to accidental injury.^{4–8} This concern of injury has resulted in recommendations to protect the surgical extremity in a sling and/or brace and use crutches or walkers (lower extremity surgery) for the duration of infusion.^{2,3,7,9} Some have suggested delaying hospital discharge until sensation returns.⁵

Local anesthetic pharmacodynamics varies considerably among introduction techniques. For example, during subarachnoid block, the total dose is the primary determinant of clinical effects, even when the concentration and volume of local anesthetic are varied over a large range.¹⁰ In contrast, the effects are mixed for epidural local anesthetic infusions; total dose is the primary determinant of analgesia quality and dermatomal spread, whereas concentration is the primary determinant of motor block and sympathectomy/hypotension.¹¹ At a constant total dose, local anesthetic volume is the primary determinant of efficacy for single-injection axillary blocks.¹² However, the relative importance of local anesthetic concentration and/or volume versus dose remains unexamined for continuous peripheral nerve blocks.

We therefore tested the null hypothesis that providing ropivacaine at different concentrations and rates (0.2% at 8 mL/h vs 0.4% at 4 mL/h), but at an equal total basal dose (16 mg/h), produces comparable effects when used in a continuous sciatic nerve block. Our primary end point was the incidence of an insensate limb (e.g., inability to perceive touch on any aspect of the foot) during the 24-h period beginning the morning after surgery.

METHODS

Enrollment

The Institutional Review Board at each participating clinical center approved all study procedures (University of FL, Gainesville, FL; University of CA San Diego, San Diego, CA). All subjects provided written, informed consent; because this was a multicenter trial, a Data Safety Monitoring Board (University of FL, Gainesville, FL) reviewed combined data and adverse events.

Patients offered enrollment included adults (18–75 years) scheduled for moderately painful, ambulatory, unilateral, orthopedic surgery of the lower extremity at or distal to the ankle who desired a continuous sciatic nerve block for postoperative analgesia. Exclusion criteria included weight <40 kg, a history of opioid dependence or current chronic opioid use (defined as frequent use for more than 1 wk before surgery), known contraindication to any study medication, known hepatic or renal insufficiency/disease, insulin-dependent diabetes mellitus, known neuropathy of any etiology in the surgical extremity, pregnancy, incarceration, difficulty understanding the study protocol or caring for the infusion pump/catheter system, American Society of Anesthesiologists physical status 4–6, and any major incision outside of the sciatic

nerve distribution of the lower leg (e.g., a planned incision into the saphenous nerve distribution).

Protocol

A stimulating catheter (StimuCath, Arrow International, Reading, PA) was inserted adjacent to the sciatic nerve via the posterior popliteal intertendinous approach¹³ using a previously described technique.^{3,14} Fifty milliliters of mepivacaine 1.5%, with epinephrine, 5 µg/mL, was injected via the catheter with gentle aspiration every 3 mL. The popliteal sciatic nerve block was evaluated 15 min later and considered successful when patients demonstrated muscle weakness upon plantar flexion and a decreased sensation to cold of the skin on the plantar aspect of their foot. Subject demographic and catheter placement data were uploaded via the Internet to a secure,¹⁵ password-protected, encrypted central server (www.PAINfRE.com, General Clinical Research Center, Gainesville, FL).¹⁶

Patients with a successful catheter placement per protocol and nerve block onset were retained in the study. Patients were randomized to one of two groups, ropivacaine 0.2% or 0.4%, stratified by institution using computer-generated tables and provided to study centers via the PAINfRE.com Web site. Placement of a femoral or saphenous single-injection nerve block with 20 mL of mepivacaine 1.5%, with epinephrine 5 µg/mL, was left to the discretion of the attending anesthesiologist.

After surgery, the ropivacaine infusion was initiated using a portable, programmable, disposable, electronic infusion pump (ambIT PCA, Sorenson Medical, West Jordan, UT). The pumps were programmed by investigators and the infusion basal rate and patient-controlled bolus dose volume depended upon treatment group (Table 1). Although patients were not specifically informed of their ropivacaine concentration, the infusion pump and local anesthetic reservoir accessible to subjects revealed enough information that subjects should not be considered masked to treatment group. At the discretion of investigators, a 20-mL bolus of mepivacaine 1.5% (with epinephrine, 5 µg/mL) could be injected via the popliteal catheter to prolong the initial surgical block in the case of an unexpected delay in the surgical start (perineural catheters were placed in preoperative holding areas, or “block rooms,” before entering the operating room).

Patient Education

Patients were discharged home with their infusion pump and perineural catheter *in situ*. Patients were instructed on care of the perineural catheter, the infusion pump, and signs and symptoms of local anesthetic toxicity; they were also given contact details for a continuously available local physician. For break-through pain, patients were instructed to depress the bolus button on their infusion pump, wait 15 min, and then take 5–10 mg of the oral opioid oxycodone if necessary.

Patients were also informed that an insensate extremity is expected after surgery because of the dense surgical block (reinforced with the ropivacaine infusion). However, if any part of their surgical extremity was completely insensate after 09:00 AM the morning after surgery, patients were to pause their infusion until they regained feeling in their extremity, and then restart the infusion. “Completely insensate” was defined as being unable to determine with eyes closed that another individual was touching various parts of the foot/toes. Patients were instructed to perform this examination during telephone calls in both the morning and afternoon of postoperative day (POD) 1–3. They were also encouraged to perform the examination throughout the infusion period, beginning the morning of POD 1.

Patients were contacted by health care providers beginning the night of surgery, and each afternoon thereafter through POD 3. Patients were questioned about symptoms of local anesthetic toxicity, catheter migration, and infection, gross sensory and motor function, and the appearance of the catheter site. In the afternoon of POD 2, patients' caretakers removed the catheters with a physician in telephone contact. The presence of a metallic catheter tip confirmed complete removal.

Measurements

Subjects were contacted by telephone in the mornings of POD 1–3 by a clinical research nurse at the University of Florida General Clinical Research Center. Nurses were masked to treatment group. Pain severity and oral oxycodone use for the previous 12 h (POD 1) or 24 h (PODs 2 and 3) were recorded. Pain severity was evaluated using a numeric rating scale of 0–10, with 0 equal to no pain and 10 being the worst imaginable pain.¹⁷ The number of awakenings resulting from pain the previous night was also recorded, as were the number of times the infusion pump was paused because of an insensate extremity. Patient satisfaction with postoperative analgesia was recorded on POD 2 using a 0–10 scale, 0 equal to “very unsatisfied” and 10 equal to “very satisfied.” All data were recorded on case report forms and then uploaded to the PAINfRE.com Web site. The case report forms data were subsequently entered into a separate database which were, upon study completion, compared with the Web site data to identify and correct any data entry errors. Of note, the number of patient-administered bolus doses and total infusion volume were not available to investigators.

Statistical Analysis

The study was powered for one primary end point related to the primary null hypothesis that differing the concentration but providing an equal total dose of ropivacaine has no impact on the incident number of numbness events. The primary end point was incidence of an insensate extremity in the 24-h period beginning at 09:00 AM on POD 1. Based on previously published data,^{2,3} the planning distribution for the number of events for the two groups (0.2% vs 0.4%) was: 0 (60% vs 24%), 1 (30% vs 48%), 2 (10% vs 22%), and 3 (0% vs 6%). Based on a two-sample, two-sided *t*-test, to obtain 80% power at $P = 0.05$, a sample size of 25 patients per group was required. The calculation used large sample methods, but simulation results agreed well for both Type I error (0.05) and power (79.0%).

Because the number of events is a quantitative end point, we used the two-sample two-sided *t*-test which is virtually identical to the two-sided *Z*-test when sample sizes are approximately equal.¹⁸ All other outcome variables (secondary, ordinal) were analyzed by the two-sided Wilcoxon's ranked sum test, which provides distribution-free *P* values and is highly robust against outliers. A two-sided $P < 0.05$ was considered statistically significant for the primary end point. Because each comparison dilutes all other *P* values, we restricted our analysis to four comparisons among secondary end points.¹⁹ $P < 0.05$ was again considered significant. Significant findings in secondary outcomes should be viewed as suggestive, requiring confirmation in a future trial before considering them as definitive.

RESULTS

Fifty-two patients enrolled and all but one had a perineural catheter successfully positioned per protocol. Two subjects exhibited no sensory or motor block 15 min after being given a local anesthetic bolus via the catheter. One of these two subjects had a catheter placed using ultrasound assistance with a subsequent dense sensory and motor block (see Protocol Violations below). The other of the two was not randomized per protocol. The 50 remaining subjects (96% of those enrolled) were randomized to one of the two treatment groups. The demographic, morphometric, and surgical characteristics were similar between groups (Tables

2 and 3). However, applying statistics to preintervention variables for subjects randomized to treatment groups is inappropriate. For this reason, no statistical comparisons were applied to the data of these two tables.

Primary End Point

Patients given 0.2% ropivacaine ($n = 25$) experienced an insensate limb a mean ($_{SD}$) of 1.8 (1.8) times, compared with 0.6 (1.1) times for subjects receiving 0.4% ropivacaine ($n = 25$; estimated difference = 1.2 episodes, 95% confidence interval, 0.3–2.0 episodes; $P = 0.009$). Among patients assigned to 0.2% ropivacaine, 64% experienced at least one instance of an insensate extremity; in contrast, only 36% of the patients receiving 0.4% ropivacaine had an insensate extremity even once.

Secondary End Points

There were minimal differences between the two treatment groups for average (Fig. 1a) and worst daily pain scores (Fig. 1b), and both groups required similar doses of supplemental oral opioids (Table 4). However, patients assigned to 0.2% ropivacaine were awakened at night by pain slightly more often (Table 4). Satisfaction with postoperative analgesia was scored a median (25th–75th percentiles) of 10.0 (8.0–10.0) in Group 0.2% and 10.0 (9.8–10.0) in Group 0.4% ($P = 0.13$). There were no infusion pump malfunctions.

Protocol Violations and Adverse Events

One subject had a perineural catheter placed per protocol, but exhibited no sensory or motor block 15 min after the initial local anesthetic bolus. The catheter was removed and replaced using ultrasound guidance and not solely nerve stimulation. Local anesthetic (20 mL) was administered and a sensory and motor block evolved within 15 min. The patient was randomized although the catheter had not been placed per protocol.

One subject from Group 0.2% without comorbidities had an unremarkable perioperative course, but reported a moderate sensory and motor deficit in the sciatic nerve distribution after infusion discontinuation on POD 2. A neurology consultant believed the patient had a sciatic nerve deficit just caudal to the gluteus maximus muscle of unknown etiology (greatly cephalad to the perineural catheter insertion and surgical site). The deficit fully resolved within 2 mo.

DISCUSSION

This investigation provides evidence that, for continuous popliteal-sciatic nerve blocks, local anesthetic concentration and volume influence perineural infusion effects in addition to the total mass of local anesthetic administered. In a 24-h period, patients given 0.2% ropivacaine at 8 mL/h experienced an insensate limb three times more often than patients given the same basal dose (16 mg/h), but as 0.4% ropivacaine at 4 mL/h.

The relative importance of local anesthetic concentration versus dose has clinical consequence given the wide range of local anesthetic concentrations investigators have used during perineural infusion: for ropivacaine alone, concentrations have included 0.1%,²⁰ 0.15%,²¹ 0.2%,²² 0.3%,²³ and 0.4%.²⁴ The issue has particular importance for ambulatory infusion where the local anesthetic reservoir volume and patient monitoring are limited.⁶ In this case, reducing the volume of local anesthetic delivered has the advantage of prolonging infusion duration.²⁵ Unfortunately, simply decreasing the basal infusion rate, and therefore total drug dose, may result in a concomitant decrease in analgesia and other infusion benefits.²² Therefore, using a relatively high concentration of local anesthetic at a low infusion rate is an attractive possibility and has been reported.²⁴

Insensate Extremity

The reported incidence of an insensate extremity for continuous sciatic nerve block when infusing ropivacaine 0.2% at 8 mL/h is 20%–25%.^{2,3} But among our patients who were given this ropivacaine concentration and basal rate, nearly three times this many (64%) reported an insensate extremity at least once during the 24-h study period. There is limited evidence that a stimulating catheter may decrease the catheter-to-nerve distance,²⁶ theoretically increasing the incidence of an insensate extremity, and partially explaining the lower incidence in one of the previous studies that used nonstimulating catheters.² However, the second study was completed with a nearly identical catheter/infusion protocol, as well as identical patient instructions and definition of an insensate extremity.³ We speculate that particular attention to this end point in the present study increased the reported incidence. Our results suggest that the insensate limbs during ambulatory continuous peripheral nerve blocks may be far more common than generally appreciated. Because there are no definitive studies showing that insensate extremities have more morbidity, the clinical relevance of our findings remains unknown.

Dose—Response

This is not the first dose—response investigation involving perineural infusion.^{5,22,27–30} However, previous studies varied either local anesthetic concentration or rate/volume while holding the other constant, resulting in differing drug doses.^{5,22,28–30} When both variables were allowed to vary, an equal mass among groups was not required.²⁷ Our study is thus unique in that it varied both concentration and infusion rate in a static ratio so that the total dose from the basal infusion was comparable in each treatment group.

We can only speculate on why 0.2% ropivacaine at 8 mL/h resulted in a higher incidence of an insensate extremity compared with a concentration of 0.4% at 4 mL/h. Anatomic relationships of the perineural space and target nerve/plexus may play a significant role in determining the relative effects of volume and concentration for perineural infusions. For example, the relatively confined perineural space, such as found for the brachial plexus between the anterior and middle interscalene muscles, might influence the relative concentration/volume effects differently than the perineural space of the femoral nerve at the level of the inguinal ligament at which local anesthetic may more easily spread medially and laterally beneath the fascia iliaca.³¹ Based on this possibility, we propose that the difference between groups in the present study may have been due primarily to the greater basal infusion rate rather than the lower concentration.

Study Limitations

Subjects and investigators were not masked to treatment group, although it is improbable that patients had a bias toward one concentration and data collection was performed by clinical research nurses masked to treatment group assignments. In addition, the primary end point used in this study was somewhat subjective in that patients and their caretakers evaluated extremity sensation and reported the results without a clinical examination by an investigator. Furthermore, although each patient-controlled bolus dose delivered the same ropivacaine dose for both treatment groups (8 mg available every 30 min), the actual delivered doses for each group are unavailable. Therefore, it is possible that patients assigned to 0.2% ropivacaine self-administered more bolus doses resulting in a higher total dose of delivered ropivacaine.

Clinicians must be cognizant of the fact that our results hold only for the concentration/rate combination examined in this study. The present study provides evidence that concentration cannot be ignored in lieu of anesthetic mass, but perhaps there is a superior concentration/rate combination to those used in this investigation; only additional dose—response studies can

provide practitioners with the optimal ropivacaine concentration and infusion rate combination.
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Figure 1.

Effects of popliteal sciatic perineural ropivacaine concentration on postoperative pain after moderately painful surgery at or distal to the ankle. Pain severity indicated using a numeric rating scale of 0–10, with 0 equal to no pain and 10 being the worst imaginable pain. Data are expressed as median (horizontal bar) with 25th–75th (box) and 10th–90th (whiskers) percentiles for patients randomly assigned to Group 0.2% (0.2% ropivacaine, 8 mL/h basal, 4 mL bolus) or Group 0.4% (0.4% ropivacaine, 4 mL/h basal, 2 mL bolus). Because each comparison dilutes all other *P* values, we restricted our analysis to four comparisons among secondary end points. *P* values are provided where statistical comparisons were applied.

Table 1
Perineural Ropivacaine Infusion Profile by Treatment Group

Ropivacaine concentration	Basal rate (mL/h)	Basal dose (mg/h)	Bolus volume (mL)	Bolus dose (mg)	Lockout duration (min)	Maximum dose (mg/h)
0.2% (2 mg/mL)	8	16	4	8	30	24
0.4% (4 mg/mL)	4	16	2	8	30	24

Table 2

Population Data and Surgical Information

	Group 0.2% (n = 25)	Group 0.4% (n = 25)
Age (yr)	51 (35–60)	55 (38–66)
Sex (female/male)	19/6	19/6
Height (cm)	163 (157–170)	170 (163–175)
Weight (kg)	73 (61–82)	73 (68–92)
Minimum current via needle (mA)	0.48 (0.44–0.48)	0.46 (0.34–0.48)
Minimum current via catheter (mA)	0.40 (0.30–0.52)	0.46 (0.64–0.58)
Subjects receiving an additional 20-mL mepivacaine bolus (#)	14	15
Intraoperative midazolam (mg)	4 (2–4)	4 (2–4)
Intraoperative fentanyl (µg)	150 (100–200)	100 (100–200)
Intraoperative morphine (mg)	0 (0–0)	0 (0–0)
Surgery duration (min)	60 (40–105)	50 (35–70)
Subjects from site A/B (#)	8/17	8/17

Values are reported as median (25th–75th percentiles) or number of subjects, as indicated. Applying statistics to preintervention variables for subjects randomized to treatment groups is inappropriate. For this reason, no statistical comparisons were applied to the data of this table.

Table 3
Primary Surgical Procedures

	Group 0.2% (n = 25)	Group 0.4% (n = 25)
Achilles tendon repair	1	1
Calcaneal osteotomy	6	5
Claw-/Hammer-toes correction	1	2
Hallux valgus correction	3	3
Metatarsal osteotomy	5	8
Subtalar arthrodesis	3	1
Other	6	5

Applying statistics to preintervention variables for subjects randomized to treatment groups is inappropriate. For this reason, no statistical comparisons were applied to the data of this table.

Table 4

Secondary End Points

	Group 0.2% (n = 25)	Group 0.4% (n = 25)
Home oral opioid consumption (mg) ^a		
Postoperative day 1	0 (0–10)	0 (0–10)
Postoperative day 2	5 (0–17.5)	0 (0–20)
Postoperative day 3	20 (12.5–30)	10 (2.5–20)
Awakenings because of pain (#)		
Postoperative day/ night 0	1.7 (0–2.4)	0 (0–1)
Postoperative day/ night 1	0.3 (0–2)	0 (0–1)
Postoperative day/ night 2	1.7 (0–4)	0 (0–1)

Values are reported as median (25th—75th percentiles). Because each comparison dilutes all other *P* values, we restricted our analysis to four comparisons among secondary end points. For this reason, no statistical comparisons were applied to the data of this table.

^aOral opioid provided as 5 mg oxycodone tablets. Values include home opioid consumption in the 24 h previous to the daily data collection phone calls.