

Effects of Local Anesthetic Concentration and Dose on Continuous Interscalene Nerve Blocks: A Dual-Center, Randomized, Observer-Masked, Controlled Study

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Background and Objectives: It is currently unknown if the primary determinant of continuous peripheral nerve block effects is simply total drug dose, or whether local anesthetic concentration and/or volume have an influence. We therefore tested the null hypothesis that providing ropivacaine at different concentrations and rates — but at an equal total basal dose — produces similar effects when used in a continuous interscalene nerve block.

Methods: Preoperatively, an anterolateral interscalene perineural catheter was inserted using the anterolateral approach in patients undergoing moderately painful shoulder surgery. Subjects were randomly assigned to receive a postoperative perineural infusion of either 0.2% ropivacaine (basal 8 mL/h, bolus 4 mL) or 0.4% ropivacaine (basal 4 mL/h, bolus 2 mL) through the second postoperative day. Our primary endpoint was the incidence of an insensate hand/finger during the 24 hours beginning the morning following surgery.

Results: The incidence of an insensate hand/finger did not differ between the treatment groups ($n = 50$) to a statistically significant degree (0.2% ropivacaine, mean [SD] of 0.8 [1.3] times; 0.4% ropivacaine, mean 0.3 [0.6] times; estimated difference = 0.5 episodes, 95% confidence interval, -0.1 to 1.1 episodes; $P = .080$). However, this is statistically inconclusive given the confidence interval. In contrast, pain ($P = .020$) and dissatisfaction ($P = .011$) were greater in patients given 0.4% ropivacaine.

Conclusions: For continuous interscalene nerve blocks, given the statistically inconclusive primary endpoint results and design limitations of the current study, further research on this topic is warranted. In contrast, providing a lower concentration of local anesthetic at a higher basal rate provided superior analgesia. *Reg Anesth Pain Med* 2008; 33:518-525.

Key Words: Anesthesia, Continuous peripheral nerve block, Continuous interscalene nerve block, Patient-controlled regional analgesia, Perineural local anesthetic infusion.

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Accepted for publication May 22, 2008.

Funding for this project provided by NIH grant GM077026 (Principal Investigator: Dr. Ilfeld) from the National Institute of General Medical Sciences (Bethesda, MD); NIH grant RR00082 from the National Center for Research Resources (Bethesda, MD); the Departments of Anesthesiology, University of Florida (Gainesville, FL), University of California San Diego (San Diego, CA), Wake Forest Medical Center (Winston-Salem, NC), Univer-

sity of Louisville (Louisville, KY), University of Ottawa (Ottawa, Ontario, Canada), and the Cleveland Clinic (Cleveland, OH); and Sorenson Medical (West Jordan, UT). Dr. Sessler is supported by the Joseph Drown Foundation (Los Angeles, CA). The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of these entities. A portion of the results of this investigation was submitted in abstract form for the Annual Meeting of the American Society of Anesthesiologists, Orlando, Florida, October 18-22, 2008. Sorenson Medical (West Jordan, UT) provided funding and donated portable infusion pumps for this investigation. This company had no input into any aspect of study conceptualization, design, and implementation; data collection, analysis and interpretation; or manuscript preparation. None of the authors has a personal financial interest in this research.

Reprint requests: Reprints are not available.

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1098-7339/08/3306-0001\$34.00/0

doi:10.1016/j.rapm.2008.05.006

While continuous peripheral nerve blocks provide potent analgesia and other benefits, one well recognized and undesirable side effect is a transiently insensate limb.^{1,2} Because insensate limbs may be prone to accidental injury, it is postulated that such incidences are best minimized.¹⁻⁵ It is currently unknown if the primary determinant of continuous peripheral nerve block effects is simply total drug dose, or whether local anesthetic concentration and/or volume exert an influence. As a result, many different concentration and basal rate combinations have been utilized: for ropivacaine alone, concentrations have included 0.1%,⁶ 0.15%,⁷ 0.2%,⁸ 0.25%,⁹ 0.3%,¹⁰ and 0.4%.¹¹ It was previously reported that for continuous popliteal sciatic nerve blocks, insensate toes/feet were far more common with higher volumes of relatively dilute ropivacaine compared with lower volumes of relatively concentrated ropivacaine.¹² However, it is unclear if this relationship holds for all anatomic locations, or is rather specific to the sciatic nerve in the popliteal fossa.

This issue has additional implications for ambulatory perineural infusion. Providing patients with a ropivacaine (0.2%) continuous interscalene nerve block at 8 mL/h results in potent analgesia following moderate to severely painful shoulder surgery,^{13,14} whereas lower infusion rates are often insufficient.⁸ But, this relatively high basal rate — especially when patient-controlled bolus doses are provided — depletes the local anesthetic reservoir of most disposable portable infusion pumps in less than 60 hours because pump reservoirs are generally restricted to a maximum of 400 mL to 500 mL.^{15,16} Relatively rapid reservoir depletion is problematic because the moderate to severe pain from many shoulder procedures often extends beyond 60 hours.^{13,14} It would thus be beneficial if a slower infusion of more concentrated local anesthetic were equally effective and safe. However, it remains unknown if patient benefits may be retained by increasing the ropivacaine concentration while decreasing the basal rate, and thus retaining the higher delivered dose of local anesthetic.

We therefore conducted a dual center study to test the null hypothesis that providing ropivacaine at different concentrations and rates (0.2% at 8 mL/h *v* 0.4% at 4 mL/h) — but at an equal total basal dose of 16 mg/h — produces similar effects when used in a continuous interscalene brachial plexus block. Our primary endpoint was the incidence of an insensate limb (e.g., inability to perceive touch on any aspect of the hand) during the 24 hour period beginning the morning after surgery. Secondary endpoints included baseline (average) and breakthrough (worst) pain scores, opioid

requirements, sleep disturbances, and patient satisfaction.

Methods

Enrollment

The Institutional Review Board at each participating clinical center approved all study procedures (University of Florida, Gainesville, FL; University of California San Diego, San Diego, CA). All subjects provided written, informed consent; and because this was a multi-center trial, a Data Safety Monitoring Board (University of Florida, 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 shoulder who desired a continuous interscalene nerve block for postoperative analgesia. Exclusion criteria included weight less than 40 kg; a history of opioid dependence or current chronic opioid use (defined as frequent use for more than 1 week prior to surgery); chronic obstructive pulmonary disease; 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 to 6;¹⁷ and any major incision outside of the brachial plexus sensory distribution (e.g., an iliac crest bone graft) or at/distal to the elbow.

Protocol

A stimulating catheter (StimuCath, Arrow International, Reading, PA) was inserted adjacent to the brachial plexus via the anterolateral approach using a previously described technique.^{8,18} The catheter was inserted through the needle only after stimulated motion occurred in the ipsilateral biceps and/or deltoid muscles with a current between 0.30 and 0.70 mA after the catheter was inserted 3 to 5 cm past the needle tip. Forty mL of 1.5% mepivacaine, with epinephrine 5 µg/mL, was injected via the catheter with gentle aspiration every 3 mL. The interscalene nerve block was evaluated 15 minutes later and considered successful when patients demonstrated muscle weakness upon shoulder abduction and a decreased sensation to cold over the distal ipsilateral deltoid muscle. Subject demographic and catheter placement data were uploaded via the Internet to a secure,¹⁹ password-protected, encrypted central server (www.PAINfRE.com;

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