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# The Effects of Local Anesthetic Concentration and Dose on Continuous Infraclavicular Nerve Blocks: A Multicenter, Randomized, Observer-Masked, Controlled Study

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## Abstract

**BACKGROUND—**It remains unclear whether local anesthetic concentration or total drug dose is the primary determinant of continuous peripheral nerve block effects. The only previous investigation, involving continuous popliteal-sciatic nerve blocks, specifically addressing this issue reported that insensate limbs were far more common with higher volumes of relatively dilute ropivacaine compared with lower volumes of relatively concentrated ropivacaine. However, it remains unknown if this relationship is specific to the sciatic nerve in the popliteal fossa or whether it varies depending on anatomic location. We therefore tested the null hypothesis that providing ropivacaine at different concentrations and rates, but at an equal total basal dose, produces comparable effects when used in a continuous infraclavicular brachial plexus block.

**METHODS—**Preoperatively, an infraclavicular catheter was inserted using the coracoid approach in patients undergoing moderately painful orthopedic surgery distal to the elbow. Patients were randomly assigned to receive a postoperative 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. Both



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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.
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groups, therefore, received 16 mg of ropivacaine each hour with a possible addition of 8 mg every 30 min via a patient-controlled bolus dose. Our primary end point was the incidence of an insensate limb during the 24-h period beginning the morning after surgery. Secondary end points included analgesia and patient satisfaction.

**RESULTS—**Patients given 0.4% ropivacaine ($n$ = 27) experienced an insensate limb, a mean (SD) of 1.8 (1.6) times, compared with 0.6 (0.9) times for subjects receiving 0.2% ropivacaine ($n$ = 23; estimated difference = 1.2 episodes, 95% confidence interval, 0.5–1.9 episodes; $P$ = 0.001). Satisfaction with postoperative analgesia (scale 0–10, 10 = highest) was scored a median (25th–75th percentiles) of 10.0 (8.0–10.0) in Group 0.2% and 7.0 (5.3–8.9) in Group 0.4% ($P$ = 0.018). Analgesia was similar in each group.

**CONCLUSIONS—**For continuous infraclavicular nerve blocks, local anesthetic concentration and volume influence perineural infusion effects in addition to the total mass of local anesthetic administered. Insensate limbs were far more common with smaller volumes of relatively concentrated ropivacaine. This is the opposite of the relationship previously reported for continuous popliteal-sciatic nerve blocks. The interaction between local anesthetic concentration and volume is thus complex and varies among catheter locations.

It remains unclear whether local anesthetic concentration, or simply total drug dose, is the primary determinant of continuous peripheral nerve block effects. This lack of data has resulted in practitioners using multiple different concentration and basal-rate combinations.[1–3] The only previous investigation specifically addressing this issue found that for continuous popliteal-sciatic nerve blocks, insensate limbs were far more common with higher volumes of relatively dilute ropivacaine than with lower volumes of relatively concentrated ropivacaine.[4] It remains unknown whether this relationship is specific to the sciatic nerve in the popliteal fossa or whether it varies among different anatomic locations.

We therefore conducted this multicenter study to test 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 of 16 mg/h, produces comparable effects when used in a continuous infraclavicular brachial plexus block. Our primary end point was the incidence of an insensate limb (e.g., inability to perceive touch on any aspect of the hand) 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 Florida, Gainesville, FL; University of California San Diego, San Diego, CA; University of Louisville, Louisville, KY). All subjects provided written, informed consent. Because this was a multicenter trial, a Data Safety Monitoring Board (University of Florida, Gainesville, FL) reviewed combined data and adverse events.

Patients offered enrollment included adults (18–75 yr) scheduled for moderately painful, ambulatory, unilateral, orthopedic surgery of the upper extremity distal to the elbow who desired a continuous infraclavicular 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); 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; ASA Physical Status IV–VI; and any major incision outside of the brachial plexus sensory distribution (e.g., an iliac crest bone graft).

## Protocol

A stimulating catheter (StimuCath, Arrow International, Reading, PA) was inserted adjacent to the brachial plexus via the coracoid approach[5] using a previously described technique.[1] The catheter was inserted through the needle only after stimulated motor response occurred in any digit(s) with a current between 0.30 and 0.50 mA. Fifty milliliters of mepivacaine 1.5%, with epinephrine, 5 μg/mL, was injected via the catheter with gentle aspiration every 3 mL. The infraclavicular nerve block was evaluated 15 min later and considered successful when patients demonstrated muscle weakness upon index finger flexion and a decreased sensation to cold of the medial aspect of the index finger. Subject demographic and catheter placement data were uploaded via the Internet to a secure,[6] password-protected, encrypted central server (www.PAINfRE.com, General Clinical Research Center, Gainesville, FL).[7]

Patients with a successful catheter placement and nerve block onset per protocol 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.

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 the designated 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 so 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 infraclavicular catheter to prolong the initial surgical block in the case of an unexpected delay in the surgical start (perineural catheters were placed in preoperative waiting 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 breakthrough 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 informed that an insensate extremity is expected after surgery. However, if any part of their surgical extremity was completely insensate after 09:00 the morning after surgery, patients were to stop 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 hand/fingers. 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.[8] 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 secure PAINfRE.com Web site. The case report forms' data were subsequently entered into a separate database which was, 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 the null hypothesis that altering the concentration of ropivacaine while providing an equal total dose does not change the incidence of an insensate limb in the 24-h period beginning at 09:00 on POD 1. Based on previously published data,[1] 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 that is virtually identical to the two-sided Z-test when sample sizes are approximately equal.[9] All other outcome variables (secondary, ordinal) were analyzed by the two-sided Wilcoxon's test that 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.[10] $P < 0.05$ was considered significant. Significant findings in secondary outcomes should be viewed as suggestive, requiring confirmation in a future trial before considering them as definitive.

## RESULTS

Sixty patients enrolled and 51 had a perineural catheter successfully placed per protocol. Of the remaining subjects, one exhibited no sensory or motor block 15 min after being given a local anesthetic bolus via the catheter and was not randomized per protocol. The 50 remaining subjects were randomized to one of the two treatment groups. The demographic, morphometric, and surgical characteristics were similar in each group (Table 2 and Table 3). Applying statistics to preintervention variables for subjects randomized to treatment groups is inappropriate and no statistical comparisons were applied to these data.

### Primary End Point

Patients given 0.4% ropivacaine ($n = 27$) experienced an insensate limb a mean (SD) of 1.8 (1.6) times, compared with 0.6 (0.9) times for subjects receiving 0.2% ropivacaine ($n = 23$; estimated difference = 1.2 episodes, 95% confidence interval, 0.5–1.9 episodes; $P = 0.001$). Among patients assigned to 0.4% ropivacaine, 67% experienced at least one instance of an insensate extremity; in contrast, only 35% of the patients receiving 0.2% 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). In contrast, the median opioid requirements in Group 0.4% was 100% more than in Group 0.2% on POD 1 and 50% more on POD 2 (Table 4). In addition, sleep disturbances were more common the evening of POD 0 in Group 0.4% (Table 4), and satisfaction with postoperative analgesia (scale 0–10, 10 = highest) was scored a median (25th–75th percentiles) of 10.0 (8.0–10.0) in Group 0.2% and 7.0 (5.3–8.9) in Group 0.4% ($P = 0.018$). Because each comparison dilutes all other $P$ values, we restricted our analysis to four comparisons among secondary end points: the average pain scores over 3 days and satisfaction scores ($P$ values provided when statistical analysis was applied).[10] There were no infusion pump malfunctions.

### Protocol Violations and Adverse Events

One subject from Group 0.2% experienced clear fluid leaking from her catheter site in the evening of POD 0 and removed her catheter. One subject from Group 0.4% continued her infusion until the morning of POD 3. One subject from each treatment group received a 20 mL perineural catheter injection of 1% lidocaine and/or IV opioids on POD 1 for unacceptable surgical pain. Per our intention-to-treat plan, all of these patients were retained in their respective treatment groups.[11]

## DISCUSSION

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%,[12] 0.15%,[13] 0.2%,[14] 0.25,[3] 0.3%,[15] and 0.4%.[2] The issue has particular importance for ambulatory infusion, where the local anesthetic reservoir volume and patient monitoring are limited.[16] Reducing the volume of local anesthetic delivered has the advantage of prolonging infusion duration.[1] Unfortunately, simply decreasing the basal infusion rate, and therefore total drug dose, may result in a concomitant decrease in analgesia and other infusion benefits.[14] Therefore, using a relatively high concentration of local anesthetic at a slow infusion rate is an attractive possibility.[2]

However, a transiently insensate limb is a well-recognized effect of continuous peripheral nerve blocks.[1,17–20] It is thought that an insensate extremity is best minimized during continuous peripheral nerve blocks because insensate limbs may be prone to accidental injury.[16,19–22] This concern of injury has resulted in recommendations to protect the surgical extremity in a sling and/or brace (upper extremity surgery) for the duration of infusion.[16,21,23] Patients in our study who were given 0.4% ropivacaine at 4 mL/h experienced an insensate limb three times more often than patients given the same basal dose (16 mg/h), but as 0.2% ropivacaine at 8 mL/h. This is the opposite of the relationship previously reported for continuous popliteal-sciatic nerve blocks.[4] The interaction between local anesthetic concentration and volume is thus complex and varies among catheter locations.

We can only speculate on why the relationship between ropivacaine concentration and effect are opposite for continuous popliteal-sciatic and infraclavicular nerve blocks. 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 a continuous popliteal nerve block via a catheter placed using the intertendonous approach, the sciatic nerve is relatively compact at the level of infusion and a small volume of local anesthetic may more easily contact the entire target nerve.[24] In contrast, for a continuous infraclavicular brachial plexus block, local anesthetic must spread to three different cords which are often on

different sides of the axillary artery.[25] Therefore, for an infraclavicular perineural infusion, a higher basal rate (and thus volume) may provide improved spread of local anesthetic, decreasing the dose of anesthetic at any one cord (and thus an insensate limb), but improving the chance that all cords receive at least a minimum dose of anesthetic (and thus improved analgesia).

### Catheter Placement Success Rate

The failure to place 9 of the 60 (15%) catheters per protocol deserves comment. Failures usually occurred when the stimulating current could not be reduced below 0.5 mA while retaining a motor response as specified by the study protocol. Using an identical catheter-insertion technique and protocol, a previous study reported the same issue for 5 of 35 attempts (14%). Among these failures in both studies, approximately 80% of catheters were ultimately placed, only at a minimum needle current of more than 0.5 mA, and approximately 50% of these resulted in a successful surgical block. Therefore, the overall catheter-insertion success rates for both studies were comparable at approximately 90%.

### Study Limitations

A limitation of our study is that 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. Although the postoperative questionnaire included validated measures, such as the Numeric Rating Scale for pain assessment,[8] the instruments used to assess sleep quality and analgesia satisfaction have not been previously validated. There are two additional significant limitations of this study. First, 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. Because these were ambulatory patients, there was no way to evaluate or control for the thoroughness of patient self-examinations and, therefore, the accuracy of this measurement remains unknown. Second, 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 0.4% ropivacaine self-administered more bolus doses, resulting in a higher total dose of delivered ropivacaine. This methodological weakness decreases confidence in the rejection of our null hypothesis.

It is noteworthy that, even given the weaknesses of this study, our results are of clinical use: if practitioners desire to minimize the incidence of numbness during continuous infraclavicular nerve blocks, this study provides valid information to help achieve this goal. In other words, regardless of the total amount of local anesthetic delivered to each treatment group, providing a 0.2% ropivacaine infusion at a basal rate of 8 mL/h resulted in a lower incidence of patient-identified insensate limbs relative to a 0.4% ropivacaine infusion at a basal rate of 4 mL/h.

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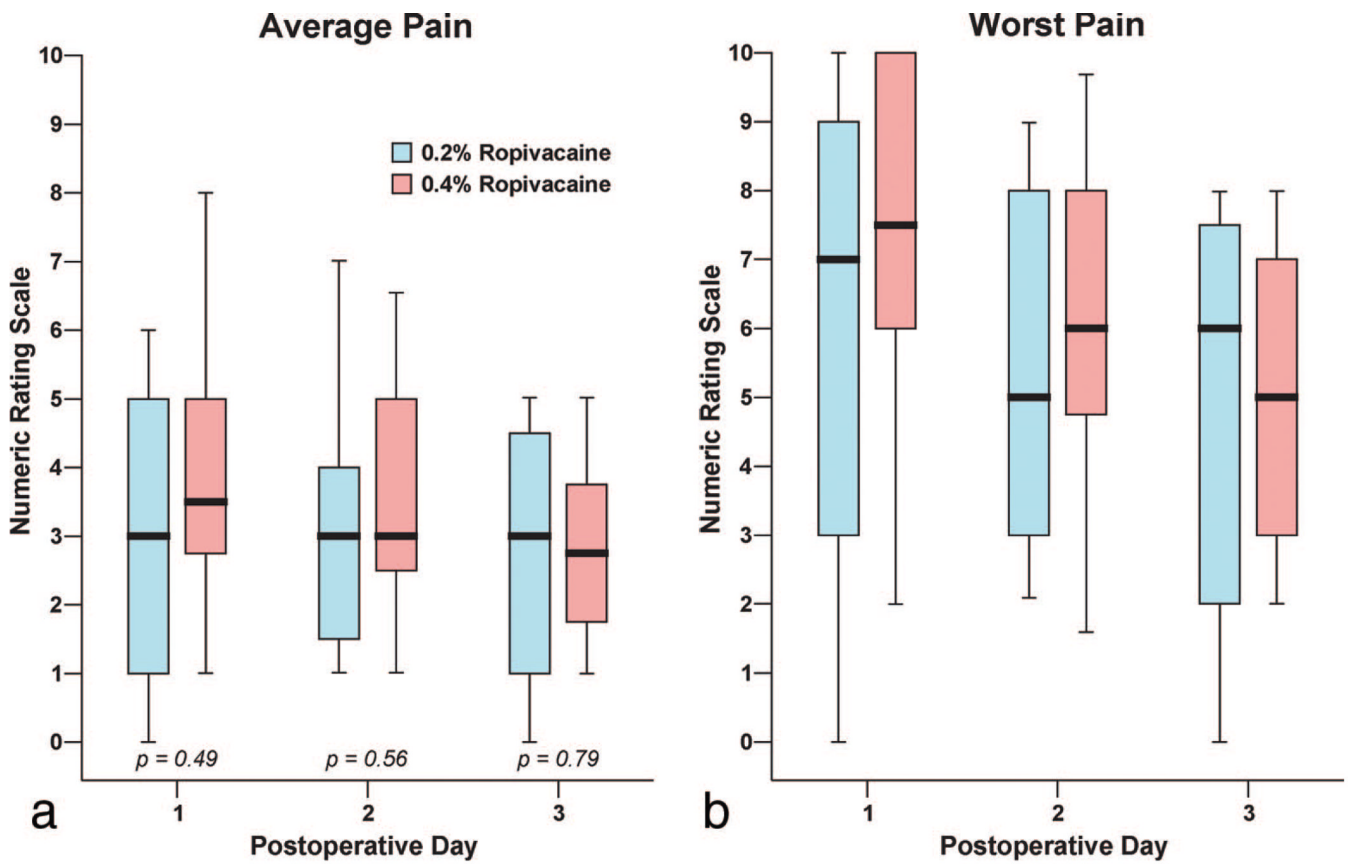


**Figure 1.**

Effects of infraclavicular perineural ropivacaine concentration on *postoperative pain* after moderately-painful surgery distal to the elbow. Pain severity indicated using a Numeric Rating Scale (NRS) 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* = 23)** | **Group 0.4% (*n* = 27)** |
|---|---|---|
| Age (yr) | 51 (28–57) | 44 (27–57) |
| Sex (female/male) | 10/13 | 11/16 |
| Height (cm) | 168 (162–178) | 168 (163–178) |
| Weight (kg) | 75 (64–89) | 73 (65–95) |
| Minimum current via needle (mA) | 0.49 (0.40–50) | 0.48 (0.44–0.50) |
| Minimum current via catheter (mA) | 0.45 (0.39–51) | 0.42 (0.30–0.51) |
| Subjects receiving an additional 20 mL mepivacaine bolus (#) | 14 | 15 |
| Intraoperative midazolam (mg) | 3 (2–4) | 3 (2–4) |
| Intraoperative fentanyl (μg) | 188 (50–200) | 125 (100–200) |
| Intraoperative morphine (mg) | 0 (0–0) | 0 (0–0) |
| Surgery duration (min) | 75 (60–115) | 75 (55–95) |
| Subjects from site A/B/C (#) | 13/8/2 | 15/10/2 |

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* = 23)** | **Group 0.4% (*n* = 27)** |
|---|---|---|
| Metacarpal arthroplasty | 6 | 5 |
| Radial or ulnar ORIF/ fusion/resection | 12 | 15 |
| Thumb suspensionplasty/ fusion | 4 | 6 |
| Scaphoid ORIF or styloidectomy | 1 | 1 |

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.

ORIF = open reduction internal fixation.

**Table 4**

Secondary Endpoints

| | **Group 0.2% (*n* = 23)** | **Group 0.4% (*n* = 27)** |
|---|---|---|
| Home oral opioid consumption (mg)* | | |
| Postoperative day 1 | 10 (0–20) | 20 (10–30) |
| Postoperative day 2 | 10 (5–20) | 15 (5–30) |
| Postoperative day 3 | 15 (5–30) | 15 (5–25) |
| Awakenings because of pain (#) | | |
| Postoperative day/night 0 | 0 (0–2) | 2 (0–4) |
| Postoperative day/night 1 | 0 (0–1) | 0 (0–3) |
| Postoperative day/night 2 | 0 (0–2) | 0 (0–1) |

Values are reported as median (25th–75th percentiles).

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

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.