

ANALGESIA AND EFFECTIVENESS OF LEVOBUPIVACAINE COMPARED WITH ROPIVACAINE IN PATIENTS UNDERGOING AN AXILLARY BRACHIAL PLEXUS BLOCK

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A common anesthetic technique for the upper extremity is local brachial plexus anesthesia using levobupivacaine and ropivacaine. To our knowledge, no study has been performed measuring differences in analgesic efficacy and latency when these local anesthetics are used for brachial plexus anesthesia.

We enrolled 54 adults, assessed as ASA class I or II, into this double-blind, prospective investigation to receive 40 mL of 0.5% ropivacaine or levobupivacaine with 1:200,000 epinephrine. Pain was assessed using a 0 to 10 verbal numeric rating scale (VNRS). Motor blockade was determined using a modified Bromage scale. Variables included analgesic duration, latency, and overall patient satisfaction.

The ropivacaine group had significantly higher VNRS

scores at the 8th (P = .001) and 10th (P = .003) postoperative hours. The duration of sensory analgesia was significantly longer in the levobupivacaine group (831 minutes) than in the ropivacaine group (642 minutes; P = .013). Return of motor activity was significantly faster in the ropivacaine group (778 minutes) than in the levobupivacaine group (1,047 minutes; P = .001). No other significant differences were noted between the groups.

When considering levobupivacaine and ropivacaine for brachial plexus anesthesia, levobupivacaine should be considered when postoperative analgesia is a concern but not when an early return of motor activity is required.

Key words: Analgesia, brachial plexus block, levobupivacaine, ropivacaine, transarterial axillary block.

Anesthesia for surgeries to the upper extremity commonly is provided using brachial plexus anesthesia. Bupivacaine, a racemic mixture of the 2 stereoisomers dextrobupivacaine and levobupivacaine, frequently is used as the local anesthetic for brachial plexus anesthesia because it offers the advantage of providing a long duration of action and a favorable ratio of sensory to motor neural block.^{1,2} However, with clinical use, it was noted that using this racemic mixture of bupivacaine resulted in cardiac and central nervous system toxic effects in some patients,^{1,3} which were attributed to the dextrobupivacaine enantiomer.² This prompted researchers to develop new local anesthetic agents with a profile that contained all of the desirable aspects of bupivacaine without the undesirable toxic effects. One of the first local anesthetic agents that emerged as a possible

replacement for bupivacaine was ropivacaine.

Ropivacaine, the S-enantiomer of S-1-propyl-2',6'-piperidoloxylidide is an amino-amide local anesthetic with a chemical structure similar to that of bupivacaine. Numerous comparative studies between ropivacaine and bupivacaine suggested that ropivacaine produced less cardiac and central nervous system toxic effects, less motor block, and a similar duration of action of sensory analgesia.⁴⁻¹² This favorable clinical profile prompted many clinicians to switch from bupivacaine to ropivacaine for all types of neural blockade. However, with clinical use, it was discovered that ropivacaine's latency of sensory analgesia was approximately two thirds that of bupivacaine; therefore, it was not as effective in promoting prolonged postoperative analgesia.^{4,8,13}

Levobupivacaine, the S-enantiomer of bupivacaine is the latest local anesthetic agent introduced into

clinical practice. Studies revealed that the *R*-dextropropivacaine) and the *S*-levobupivacaine) enantiomers of bupivacaine possessed anesthetic activity, but the *S*-enantiomer had significantly less cardiac and neural toxic effects than bupivacaine,¹⁴ while still possessing a similar duration of sensory blockade.^{2,15,16} Levobupivacaine has been shown to be safe and effective for epidural and spinal anesthesia¹⁵ and blockade of the brachial plexus.^{15,17,18} Many clinicians began using levobupivacaine as the agent of choice for neural blockade, but a controversy exists in the literature and in clinical practice concerning which agent (ropivacaine or levobupivacaine) is the ideal for facilitating brachial plexus anesthesia. Some clinical trials report that ropivacaine provides a sensory blockade similar to that of levobupivacaine, while in clinical practice, many practitioners report dissimilar findings.^{15,19} This controversy is compounded by the fact that no direct comparative trials have been performed between these 2 agents in patients receiving brachial plexus anesthesia.¹⁵ Therefore, the purpose of this clinical investigation was to compare the effectiveness, duration, and quality of sensory anesthesia and motor blockade between groups of patients receiving an axillary brachial plexus block with 0.5% ropivacaine or 0.5% levobupivacaine.

Methods

After approval by the institutional review board, a double-blind, randomized, prospective investigation was performed in groups of patients requesting brachial plexus anesthesia for surgery of the upper extremity at the Naval Medical Center, San Diego, Calif. To be considered for inclusion, subjects had to be assessed as ASA class I or II physical status, be between the ages of 18 and 65 years, and have no history of an allergy or sensitivity to any of the study local anesthetics. In addition, subjects were excluded if they reported neuromuscular, cardiac, renal, liver disease or a history of coagulopathies. After inclusion criteria were met, informed consent was obtained from all subjects, and a computer-generated randomization process allocated the subjects into the levobupivacaine or ropivacaine group. Following the randomization process all subjects were given explicit instructions on how to complete the postoperative data collection instruments and also were instructed to record the time they took their first analgesic as a measurement of the duration of analgesia.

Pain was assessed by using an 11-point (0-10) verbal numeric rating scale (VNRS) in which a score of "0" indicated "no pain" and a score of "10" indicated the "worst pain imaginable." The VNRS measure-

ments were obtained at baseline (before placement of the block), at the time of skin incision, at the completion of the surgical procedure, and at 4, 6, 8, 10, and 24 hours following placement of the block.

Patient satisfaction, as a measure of overall satisfaction with the quality of anesthesia and analgesia provided by the brachial plexus block, was calculated by using a 5-point satisfaction scale that used the following grading criteria: (1) completely dissatisfied, (2) dissatisfied, (3) somewhat satisfied, (4) satisfied, and (5) completely satisfied. All subjects were asked to rate their satisfaction level using this tool during a follow-up telephone call approximately 24 hours after placement of the block.

Duration of motor blockade was determined by asking all subjects to note the time they could first move their fingers on the blocked extremity. *Duration of sensory analgesia* was defined as the time from placement of the brachial plexus block until the time at which the patient required postoperative analgesia. A review of postanesthesia and same-day surgical records was performed to determine analgesic needs while patients were in the hospital. All subjects kept a pain diary in which they indicated the time of day and intensity of pain the first time they required supplemental analgesia for the treatment of discomfort following discharge from the hospital. All subjects were asked to report this pain diary information to one of the investigators during the postoperative follow-up telephone call, approximately 24 hours following surgery. In addition, the total duration of surgery and anesthesia and time in the postanesthesia care and same-day surgical units were noted. Intraoperative data included total analgesics administered and the need for anxiolytic and antiemetic agents.

Before placement of the brachial plexus anesthesia, all subjects were randomized and assigned into 1 of 2 groups. Group 1 was scheduled to receive brachial plexus blockade using 40 mL of 0.5% ropivacaine with 1:200,000 epinephrine, and group 2 was scheduled to receive 40 mL of 0.5% levobupivacaine with 1:200,000 epinephrine. One individual not associated with the investigation prepared all local anesthetic solutions. Subjects and investigators were unaware of the actual composition of the local anesthetic solution used to facilitate the brachial plexus anesthesia until the conclusion of the study. On the day of surgery, all subjects were admitted to the preanesthesia block area of the main operating room, and an intravenous infusion was started using a lactated Ringer's solution in the nonsurgical extremity. Standard monitors included a noninvasive blood pressure monitoring device, electrocardiogram, and a pulse oximeter. All

subjects were premedicated with 0 to 5 mg of midazolam and 0 to 150 µg of fentanyl intravenously.

The operative arm was positioned to expose the axilla. The axilla then was prepped using aseptic technique with povidone iodine (Betadine) solution, and the axillary artery was identified by palpation. The skin was anesthetized with 1 mL of 1% lidocaine solution. A 1/2-inch, 26-gauge needle was inserted through the area of anesthetized skin into and through the axillary artery until it was noted that no blood could be aspirated through the needle. This negative aspiration of blood indicated that the needle was positioned beyond the posterior wall of the artery and in the area of the brachial plexus. One milliliter of the test solution then was injected to test for possible intravascular placement of the needle. All subjects were observed for possible intravascular placement for approximately 1 minute following the injection of the test solution, and then the remaining 40 mL of the anesthetic was administered in 5-mL increments following aspiration. The needle was removed, and firm digital pressure was held at the site for 5 minutes to assist in proximal spread of the anesthetic.

Sensory and motor block were evaluated preoperatively to determine a baseline and every 5 minutes for 30 minutes or until onset of blockade was noted. Loss of sensation was assessed with the Semmes-Weinstein Monofilament Device (Northcoast Medical, Morganhill, Calif). This device permits application of a 6.65-monofilament thread to the skin at a fixed pressure of 279.4 g of force. A modified Bromage scale for the upper extremity was used to assess motor function. This scale consists of the following 4 scores: 0, able to raise the extended arm to 90° for a full 2 seconds; 1, able to flex the elbow and move the fingers but unable to raise the extended arm; 2, unable to flex the elbow but able to move the fingers; and 3, unable to move the arm, elbow, or fingers.

All subjects were transported to the operative suite and positioned on the surgical table. Monitors used included electrocardiogram, pulse-oximetry, and a noninvasive blood pressure monitoring device. The operative extremity was prepped and draped.

Before surgical incision, the adequacy of the block was assessed using an Allis clamp test, which is an evaluation of sensation by asking subjects to report whether they can feel discomfort when pressure is applied with the Allis clamp at the distal portion of the operative extremity or in the area of the surgical site. If the subject reported no sensation and reported no discomfort on surgical incision, the block was determined satisfactory. If the subject reported discomfort during the Allis test, at surgical incision, or

during the operation, the block was determined as unsatisfactory or a "failed block," and a general anesthetic was initiated.

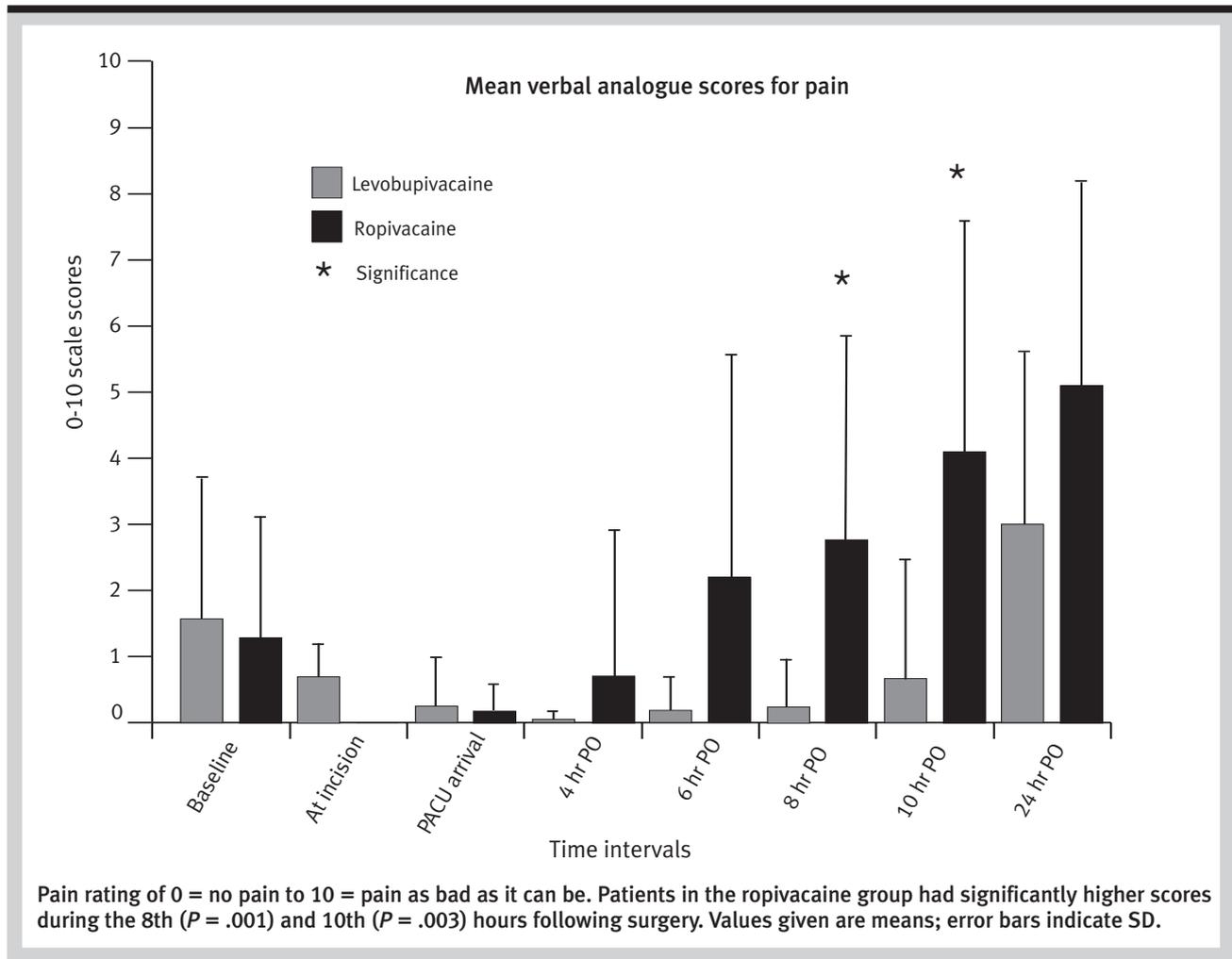
Inferential and descriptive statistics were used for data analysis. Descriptive statistics were used for demographic variables. A χ^2 test was used to note difference in successful and unsuccessful blocks between groups. Satisfaction scores were analyzed by using a Mann-Whitney *U* test. A Student *t* test was used to analyze VNRS scores, surgical and anesthesia duration, duration of sensory and motor blockades, and postoperative analgesic requirements between groups. A *P* value of less than .05 was considered significant. Before the investigation, a power analysis determined a sample size of 27 subjects per group would be sufficient when the estimated difference in postoperative sensory analgesia was 143 minutes when a power of 0.80 and an α of .05 were used. After factoring in an attrition rate of 10% (3 subjects per group), the final sample size required was 60 subjects, or 30 subjects per group.

Results

A total of 60 subjects were enrolled and randomized into 1 of the 2 treatment groups. In the final analysis, a total of 6 subjects were disenrolled for the following reasons: the need to obtain a bone graft from the iliac crest, 3 patients; failed block, 2 patients; and mild cardiac dysrhythmia, 1 patient before placement of the block, leaving a final sample of 54 subjects for analysis. All subjects who were disenrolled were given a general anesthetic. Subjects who required a bone graft received a successful blockade of the brachial plexus but were not included in final analysis because of anticipated difficulty differentiating the pain from the primary and secondary surgical sites. The need for obtaining bone from the iliac crest for grafting was not revealed to investigators until after the block was placed. Of the subjects dropped from the study, 5 had been assigned to group 1 and 1 had been assigned to group 2. Both patients with failed blocks had been assigned to group 1.

A significant difference between groups was noted in VNRS scores only at the 8th and 10th hours of measurement (Figure 1). At the eighth hour, a mean \pm SD VNRS score of 0.48 ± 1.15 was noted in group 2 compared with 2.76 ± 3.14 in group 1 ($P = .001$). At the 10th hour, a mean \pm SD VNRS score of 1.07 ± 2.00 was noted in group 2 compared with 3.32 ± 3.21 in group 1 ($P = .003$). The VNRS scores approached significance at the sixth hour of measurement in which a mean \pm SD score of 0.31 ± 0.89 was noted in group 2 compared with 0.60 ± 1.85 in group 1 ($P = .095$). No significant differences in VNRS scores were noted

Figure 1. Eleven-point numeric rating scale



PO = Postoperative

PACU = Postanesthesia care unit

between groups for any other time intervals. Satisfaction scores also were similar between groups at all time intervals (Figure 2).

When time to need for the first postoperative analgesia was analyzed, a significant difference was noted between groups (Figure 3). Subjects in group 2 requested analgesia at a mean \pm SD of 832 ± 285 minutes following placement of the block compared with 642 ± 247 minutes in group 1 ($P = .013$). Return of motor function also was noted to be significantly different between groups (Figure 4). A mean \pm SD time to motor activity was $1,047 \pm 275$ minutes in group 2 compared with 779 ± 280 minutes in group 1 ($P = .001$).

Age, sex, weight, time to place the block, time from initiation of block to start of surgery, and need for supplemental propofol support intraoperatively also were measured, and no significant differences were noted between groups (Table 1). Each subject was asked whether he or she would have a brachial plexus block

used for future surgical procedures of the upper extremity, and only 1 subject (group 1) reported a block would not be requested for future surgical procedures.

No significant differences were noted between groups for a positive Allis test at the initiation of the surgical procedure. Nine subjects in group 2 and 8 subjects in group 1 required additional supplementation for a positive Allis test result. Measurement of time to a negative response using the Semmes-Weinstein sensory measurement device was not significant between groups; group 2 required a mean \pm SD of 19.06 ± 8.34 minutes to achieve a negative response, whereas group 1 required 13.5 ± 7.84 minutes ($P = .105$). The time to reach a Bromage score of 2 was not significantly different between groups; group 2 required a mean \pm SD of 19.67 ± 8.34 minutes compared with 27.5 ± 31.4 minutes in group 1 ($P = .739$). No significant differences were noted between groups in relation to the amount of preoperative and intraop-

Figure 2. Comparison of patient satisfaction scores

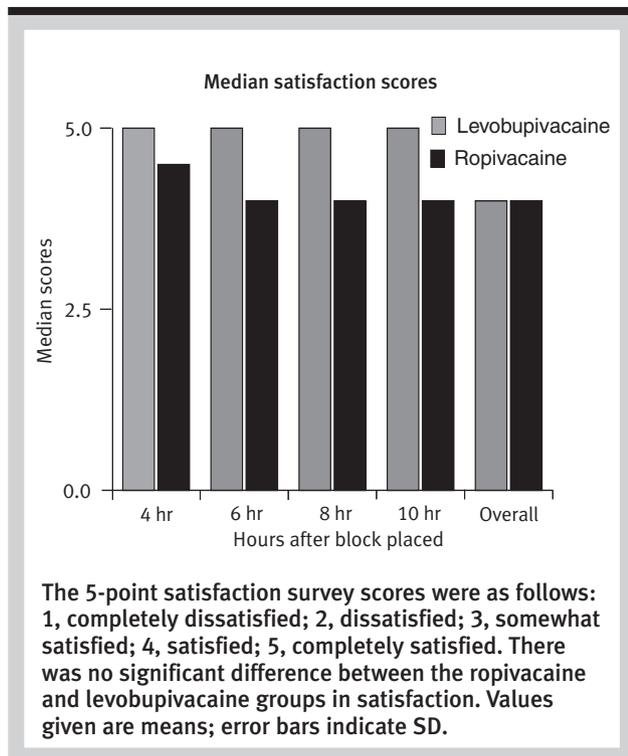
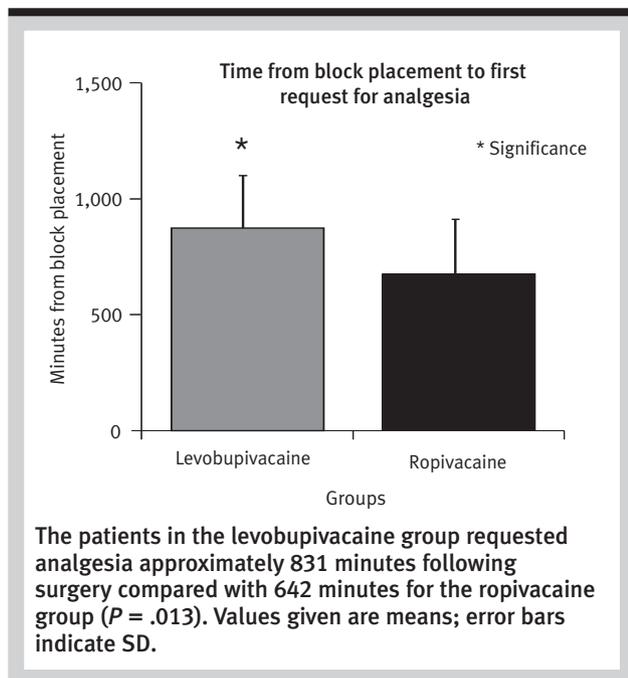


Figure 3. Comparison of duration of analgesia

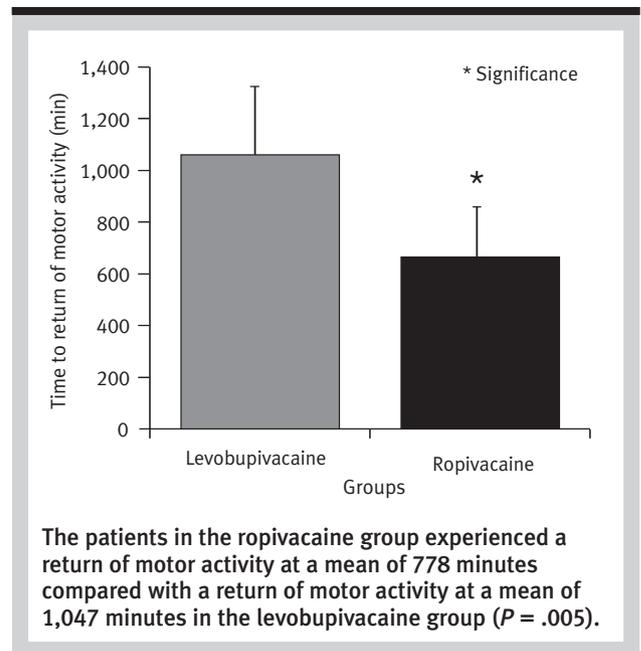


erative opioid or anxiolytic requirements or the occurrence of block-related side effects.

Discussion

In this investigation, the duration of analgesia provided by levobupivacaine was considerably longer

Figure 4. Comparison of return of motor activity



than that provided by ropivacaine. A recent investigation by Cox and colleagues,¹⁸ examining the differences between levobupivacaine and bupivacaine for axillary brachial plexus blockade, found similar results. The duration of analgesia of levobupivacaine in our investigation was 831 minutes, compared with 1,039 minutes found by Cox et al.¹⁸ One possible hypothesis for the similar findings is that in both investigations, the volume of levobupivacaine used to perform the block was the same.

The duration of analgesia provided by ropivacaine in our investigation was considerably longer than the duration found by McGlade et al.⁸ The duration of analgesia in our investigation was 642 minutes, compared with 430 minutes in the study by McGlade et al.⁸; both investigations used similar volumes of ropivacaine. Therefore, one hypothesis for the difference in duration of analgesia in our investigation may be a difference in technique. Specifically, our investigation used a transarterial approach to the brachial plexus using a 26-gauge, 1/2-inch needle, with a deposit of all local anesthetic posterior to the artery, while McGlade et al.⁸ used the axillary approach and a standardized technique with a peripheral nerve stimulator.

In our investigation, there was a difference between the duration of motor blockade and the duration of analgesia. The duration of motor blockade of 1,047 minutes for levobupivacaine was slightly longer than the duration of analgesia of 831 minutes. This result is nearly identical to the results of Cox et al.,¹⁸ who found the duration of motor blockade for levobupiva-

Table. Demographic and clinical variables*

	Levobupivacaine (N = 29)	Ropivacaine (N = 25)	Significance
Age (y)	29.7 ± 10.9	27.0 ± 7.5	.376
Weight (kg)	85.0 ± 15.5	79.5 ± 11.9	.453
Time required to place block (min)	5.8 ± 4.5	7.8 ± 9.4	.661
Time from initiation of block to surgical start (min)	65.4 ± 24.2	71.9 ± 47.0	.011
Sex			.465
Male	24	19	
Female	5	6	

* Data are given as mean ± SD, except for sex, which is given as number of subjects.
NS = Not significant

caine was 1,050 minutes.¹⁸ In our investigation, the duration of motor blockade for ropivacaine was 778 minutes, slightly longer than the 642-minute duration of analgesia. This is in contrast with the study by McGlade et al,⁸ in which nearly identical times were found for sensory and motor blockade for ropivacaine.⁸ Again, a difference in technique is one hypothesis for the different findings.

In our investigation, we noted an apparent waning of the analgesic effectiveness of ropivacaine at the fourth hour after surgery based on the VNRS score at that hour. While not statistically significant, this trend continued until significance was finally achieved at the eighth hour following placement of the block. It is unknown how long a significant difference between the groups existed because VNRS scores were not obtained beyond the 10th hour in the present investigation; therefore, no definitive time point could be isolated to identify an exact time of sensory analgesia. In this study, we used time until the first request for postoperative analgesia to determine the duration of sensory analgesia. In future investigations, we recommend that VNRS measurements be performed for at least 24 hours to determine a more definitive length of sensory analgesia.

It is interesting to note that both groups reported high satisfaction scores and a desire to have brachial plexus anesthesia for future surgical procedures of the upper extremity. All subjects reported that they were satisfied with their overall level of analgesia and that the brachial plexus anesthesia and the supplemental analgesics adequately controlled postoperative pain.

While the time until supplemental analgesia for the treatment of breakthrough pain was measured between groups, we did not measure the total amount of supplemental analgesics taken postoperatively by the groups.

It was hypothesized that the total postoperative analgesic requirements would have been lower in group 2 because of the prolonged time until they required supplemental analgesia was required, but we could not say definitely that the need for postoperative analgesia was lower in group 2 because we did not measure this variable. In future investigations, we recommend that the total postoperative analgesic requirements be measured between groups to determine whether a significant difference in analgesic requirements exists.

One observation we noted was an association between the duration of motor blockade and the onset of pain. We hypothesized that as long as motor blockade existed, the extremities could not be mobilized and pain would not be perceived. This hypothesis would explain why subjects in group 2 had lower postoperative analgesic requirements.

Finally, by using the Semmes-Weinstein monofilament device, we noted an approximate 6-minute difference in the time to achieve sensory blockade, and the difference was not statistically significant. However, it seemed clinically that some patients reported a negative response to the monofilament device measurement but not a complete loss of sensation to the blocked extremity. Perhaps the Semmes-Weinstein monofilament device is not the best device to use to determine sensory loss, and the device itself may have accounted for the relatively high incidence of blocks that needed supplementation in the surgical field by the surgeon. Nevertheless, results of this study demonstrated that the brachial plexus block produced by 0.5% levobupivacaine resulted in an increased duration of time until supplemental analgesia was required and an increase in the duration of motor block compared with the analgesia and motor block produced by the same volume and concentration of ropivacaine.

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ACKNOWLEDGMENT

The Chief, Bureau of Medicine and Surgery, Navy Department, Washington, DC, Clinical Investigation Program, sponsored this report #S-01-083, as required by NSHSBETHINST 6000.41A.

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