

Patient-controlled Regional Analgesia (PCRA) at Home

Controlled Comparison between Bupivacaine and Ropivacaine Brachial Plexus Analgesia

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Background: The aim of this randomized, double-blinded study was to compare the analgesic efficacy of bupivacaine versus ropivacaine brachial plexus analgesia after ambulatory hand surgery. An additional aim was to study the feasibility and safety of patient-controlled regional analgesia (PCRA) outside the hospital.

Methods: Sixty patients scheduled for ambulatory hand surgery underwent surgery with axillary plexus blockade. After surgery, the plexus catheter was connected to an elastomeric, disposable "home pump," containing 100 ml of either 0.125% bupivacaine or 0.125% ropivacaine. When patients experienced pain, they self-administered 10 ml of the study drug. Analgesic efficacy of PCRA was evaluated by self-assessment of pain intensity by visual analog scale (VAS) and verbal scale. Patients recorded adverse effects, technical problems, use of rescue analgesic tablets, and overall satisfaction. A follow-up telephone call was made the day after surgery.

Results: Visual analog scale scores decreased after each treatment in both groups, but there were no significant differences between the two drugs. One patient in each group took rescue dextropropoxyphene tablets. In both groups, 87% patients expressed their desire to have the same treatment again. On the day of surgery, significantly more patients were satisfied with ropivacaine PCRA. None of the patients had any signs or symptoms of local anesthetic toxicity or catheter infection.

Conclusions: This double-blinded study has demonstrated the feasibility of self-administration of local anesthetic to manage postoperative pain outside the hospital. Ropivacaine and bupivacaine provided effective analgesia, and patient satisfaction with PCRA was high. Patient selection, follow-up telephone call, and 24-h access to anesthesiology services are prerequisites for PCRA at home.

of discharged outpatients suffer from moderate-to-severe pain during the first 24-48 h.¹⁻³ Patients undergoing orthopaedic procedures are at a higher risk than their counterparts undergoing other types of surgery.^{2,3}

After hand surgery, weak opioid agents, nonsteroidal antiinflammatory drugs (NSAIDs), and paracetamol may be insufficient to provide adequate pain relief at home.⁴ Peripheral nerve blocks provide superior analgesia especially during activity and with minimal side effects, but the duration of postoperative pain outlasts the duration of single-dose local anesthetic administration. Recently, a catheter technique has been described that uses disposable and inexpensive elastomeric pumps and allows day patients to self-administer local anesthetic at home after various surgical procedures.⁵ The technique has been used for subacromial, incisional, and perineural administration of local anesthetic in the hospital and outpatient setting.⁶⁻⁹

The aim of this double-blind study was to compare the efficacy of bupivacaine versus ropivacaine catheter brachial plexus analgesia for postoperative pain relief in patients undergoing ambulatory hand surgery. An additional aim was to study the feasibility and safety of patient-controlled regional analgesia (PCRA) outside the hospital.

Methods

After Hospital Ethics Committee approval, written informed consent was obtained from each patient. Sixty patients, American Society of Anesthesiologists (ASA) physical status I or II, scheduled for ambulatory elective hand surgery were included in this double-blind study. Patients with history of neurologic, pulmonary, or moderate-to-severe cardiovascular, hepatic, renal, or psychiatric disease were excluded. Patients were also excluded if they had difficulties in understanding the pump function because of language or other problems. All eligible patients were recruited during the 9-month study period.

The hand surgical procedures are shown in table 1. During the preanesthesia visit, all patients were given an explanation of the visual analog scale (VAS) and verbal pain scoring, use of "home pump" device, and the importance of mailing the completed patient diary. Each patient was also familiarized with the use of PCRA (fig. 1).

UNDERMANAGEMENT of pain is common in day surgery patients. Studies have shown that approximately 40-50%

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Table 1. Patient Characteristics and Use of Supplemental Analgesia and Sedation during Surgery

	Ropivacaine (n = 29)	Bupivacaine (n = 31)
Age (yr) (mean ± SD)	45.6 ± 14.5	45.7 ± 16.7
Gender: M/F	16/13	18/13
Duration of surgery (min) (mean ± SD)	67.6 ± 41.3	54.6 ± 25.4
Supplemental drugs during surgery		
Midazolam (mg) (mean ± SD)	2.9 ± 0.32	2.8 ± 0.39
Fentanyl (µg) (mean ± SD)	15.8 ± 5.7	12.9 ± 7.8
Surgical procedure		
Wrist joint arthroscopy	5	3
Finger joint arthrodesis	5	5
Open reduction and internal fixation of fractures	5	6
Tendon repair	5	5
Carpal tunnel decompression	5	6
Tumor excision	2	3
Revision of amputated finger	1	2
Nerve repair	1	1

The patients were premedicated with oral diazepam, 10 mg. An infusion of acetated Ringer's solution was started in a peripheral vein of the nonoperated arm. Using standard ASA monitors, all surgeries were performed with axillary brachial plexus blockade. This block was performed with the patient in the supine position with the arm abducted about 90°, and the hand resting on a pillow close to the patient's head. After skin infiltration with 1% mepivacaine, the axillary brachial plexus was identified by paresthesia technique or by using a nerve stimulator, depending on the preference of

the anesthesiologist. Experienced anesthesiologists performed all the blocks. For the nerve stimulation technique, an insulated stimulating needle (Contiplex®, B. Braun, Melsungen, Germany) was connected to the active lead of the peripheral nerve stimulator (PNS; Stimplex, B. Braun, Melsungen, Germany). Once the needle was placed subcutaneously, the PNS was activated using a frequency and intensity of 2 Hz and 1 mA, respectively. When evoked motor activity of the median, ulnar, or radial nerve was localized at less than 0.5 mA, 20 ml of 1.5% mepivacaine was injected into the plexus sheath. The Contiplex® catheter was inserted, and another 20 ml of 1.5% mepivacaine was administered *via* the catheter.

With the paresthesia technique, all patients received 20 ml of 1.5% mepivacaine through the introducer cannula for the plexus blockade. The Contiplex® catheter was introduced 2 or 3 cm beyond the tip of the introducer cannula, and another 20 ml was injected through the catheter. The catheters were fixed to the skin with transparent adhesive dressing (Tegaderm, 3M Corporation, St. Paul, MN) and tape. The sensory and motor blocks were tested 20–30 min after the last injection. Musculocutaneous block was not performed. If the sensory block at the site of incision was inadequate, local anesthesia (2% mepivacaine) was infiltrated by the surgeon. Pain during surgery was managed with 25–50 µg intravenous fentanyl, and anxiety or restlessness was managed by titrated doses of 1.25 mg of intravenous midazolam and 20–30 mg of intravenous propofol, if necessary. Surgery was performed with axillary brachial plexus block; if the block was unsuccessful, general anesthesia was given. After surgery, all patients were nursed at the postanesthesia care unit (PACU). Pain was assessed by VAS every hour. Pain above 30 mm on the 100-mm VAS was managed by PCRA. Patients were kept in the PACU (longer than usual) until the effects of brachial plexus block had dissipated and the patient experienced pain. Before discharge from PACU, patients self-administered 1 or 2 doses of PCRA. This administration was done to confirm the position of the catheter and the efficacy of PCRA and also to ensure that the patient understood the home pump device.

Patients were included in the study only if it was clear they comprehended instructions. Instructions were given by the anesthesiologist before the block and repeated by the PACU nurse at discharge. Verbal advice was reinforced by written instructions, including a diagram showing how the PCRA system works (fig. 1). The risk of local anesthetic toxicity as a result of noncompliance with instructions was emphasized to the patient and escort. The information also included the following: importance of closing the clamp after maximum 6 min (confirmed by a clicking sound), timing the bolus with a kitchen timer, avoidance of excessive shoulder movement to prevent catheter tip displacement, and good

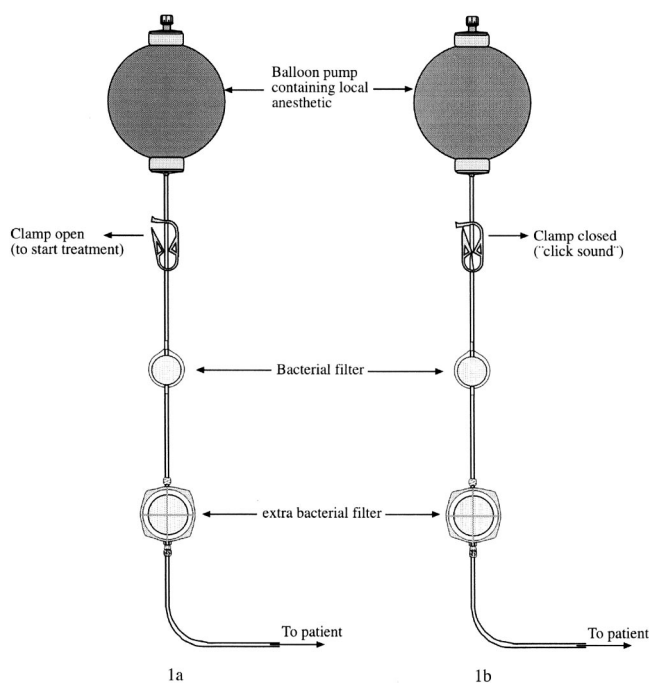


Fig. 1. When the patient experiences pain, the clamp is opened (A) to start the infusion. After the prescribed time, the patient closes the clamp (“click sound”) to stop treatment (B).

hygiene in armpit without removing Tegaderm dressing. Patients were given instructions about removal of the catheter at the end of treatment. Patients and escorts were also instructed to clamp the pump tubing and immediately contact the anesthesiologist on call if they experienced numbness of lips or tongue, a metallic taste, tinnitus, or anxiety and tremor. Patients were provided with the name, telephone and pager numbers of the physician to be contacted in case of local anesthetic toxicity symptoms or other problems; they were also provided with the telephone number to contact the anesthesiologist on call.

After surgery, the catheter in the plexus sheath was connected to a sterile, elastomeric, disposable balloon home pump (I-Flow Corporation, Lake Forest, CA) containing 100 ml of the study drug. The pump is designed to deliver the total volume in 1 h; however, by closing and opening the clamp on demand, it can function as a patient-controlled anesthesia (PCA) device (fig. 1). Depending on the computer-generated randomization list, the patients received either 0.125% bupivacaine or 0.125% ropivacaine for postoperative analgesia. The technique of PCRA has been described elsewhere.⁵ Briefly, the patient self-administers a bolus of 10 ml (12.5 mg) of the local anesthetic drug by opening a clamp for 6 min (fig. 1). The patients were instructed to avoid self-administering the study drug more than once an hour. The patients were informed that they had 10 doses (100 ml) of study medicine and that they should not wait too long but rather start the drug administration as soon as they experienced pain in the surgical area. Patients were given dextropropoxyphene tablets on discharge and instructed to take a 100-mg tablet if PCRA was ineffective. Each patient received a patient diary, which included separate pages for each of the possible 10 home treatments. Every time patients used the home pump, they indicated their VAS before and about 20 min after treatment in the diary. The patients also graded their analgesia on a 5-grade scale (no pain relief, pain relief less than 50%, pain relief by 50%, pain relief more than 50%, total pain relief). This assessment was made for the day of surgery and the day after surgery. On each page, there was also space for comments regarding analgesia, use of rescue medication, side effects, technical problems, and suggestions for improvement. The patients graded their satisfaction with the technique on the day of and day after surgery (very satisfied, satisfied, dissatisfied, very dissatisfied). A follow-up telephone call was made the day after surgery by a research nurse who was blinded to the study protocol. At this time, she inquired about analgesia, pump function, and side effects; she also reminded the patient to return the patient diary after the plexus catheter was removed and the home-pump discarded.

Statistical Analysis

For power analysis, Statistica Windows Release 4.0 (Statsoft Inc., Tulsa, OK) was used. Approximately 24 patients on each arm of the study would be needed with an α error of 0.05 and a β error of 0.1, assuming a normal distribution and a two-tailed test. Group size was selected by using proportions sample size estimates to detect a 25% decrease in VAS scores and an assumed SD of 25 mm. The Kruskal-Wallis test was used for comparison of group differences. Patient data were analyzed with analysis of variance and the chi-square test (with Yates correction where appropriate). In cases of normal distribution, numerical variables were expressed as mean \pm SD. A Bonferroni adjustment was made for multiple comparisons. The presence of side effects was evaluated by using Fisher exact test. Statistical significance was assumed at $P < 0.05$.

Results

No differences in the distribution of the hand surgical procedures were observed between the two groups. Demographic data are summarized in table 1. All surgeries could be performed with brachial plexus block, and none of the patients required general anesthesia. However, two patients in each group required 100–200 mg propofol. To complete the surgery with plexus block, 44 patients required midazolam and 17 patients needed intravenous fentanyl. The mean doses of these drugs are shown in table 1. There were no significant differences between the two groups with regard to the number of patients who required these drugs or the drug doses. All 60 patients (100%) returned their patient diaries; however, the response rate to individual questions varied. None of the patients had problems self-administering the local anesthetic bolus when they needed pain relief or indicating their pain intensity by VAS in the diary. The number of comments regarding side effects and technical problems decreased over time: 24 patients had comments about the first treatment, 10 patients for the fifth treatment, and only 2 for the tenth treatment. None of the patients required the pump after 2 days, and catheters were withdrawn on day 3.

Analgesia

All 60 patients recorded their pain scores before and after each treatment. Before treatment, the highest pain scores in the ropivacaine group ranged from 56 mm to 68 mm and in the bupivacaine group from 39 mm to 67 mm. After treatment, the VAS scores decreased and in the ropivacaine group ranged from 17 mm to 33 mm and in the bupivacaine group from 23 mm to 43 mm (fig. 2). Figure 2 shows that VAS scores decreased after each treatment in both groups. Because patients used their PCRA at different times, it was not possible to make

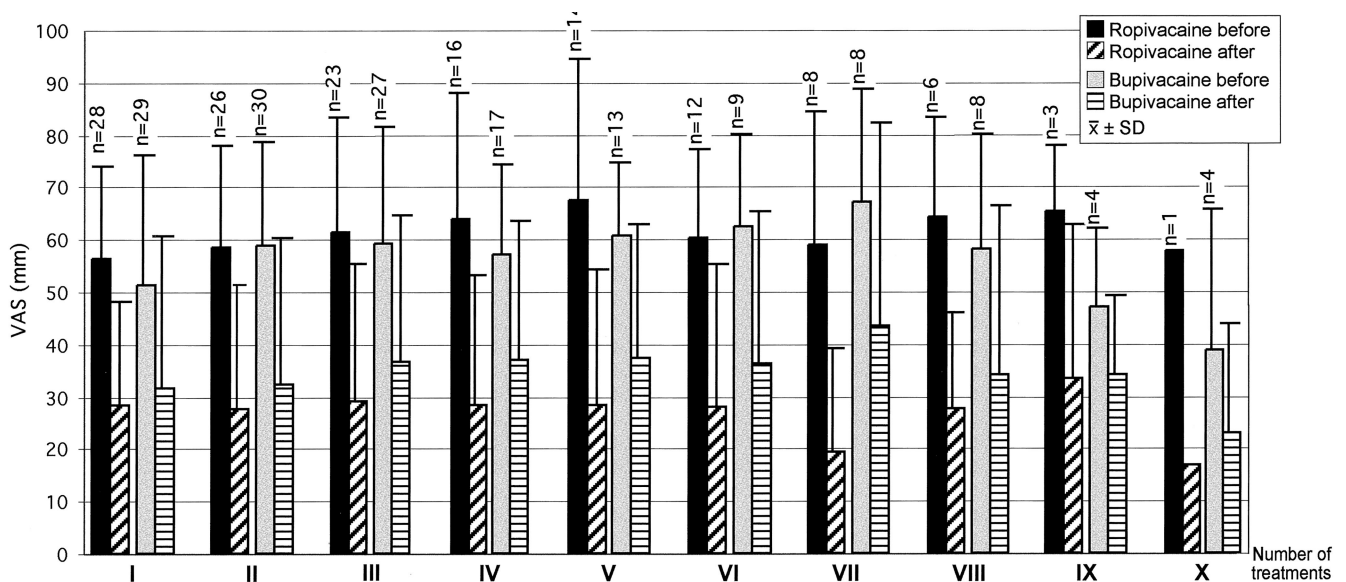


Fig. 2. The figure shows visual analog scale scores ($\bar{x} \pm SD$) before and after each treatment with ropivacaine or bupivacaine. Reduction of VAS scores was seen after every treatment with both drugs. Numbers on top of the bars represent the number of patients who used PCRA and show decreasing use of PCRA over time.

statistical comparisons between the two drugs. One patient in the ropivacaine group and two in the bupivacaine group did not have pain and therefore did not use the pump. The time intervals for treatment varied considerably and ranged from 3 to 12 h. Reflecting the natural course of postoperative pain and decrease of pain over time, the percentage of patients recording their pain decreased over time: 95% for the first treatment, 55% for fourth treatment, 21% for eighth treatment, and 7% for the tenth treatment.

On the day of surgery, 19 of 28 patients (67.9%) in the ropivacaine group and 15 of 30 patients (50%) in the bupivacaine group had 50% or more reduction in VAS; the day after surgery, the number of patients was 12 of 16 (75%) and 10 of 20 (50%) in the ropivacaine and bupivacaine groups, respectively. These differences were not statistically significant. There were no differences between the groups in the frequency of use of PCRA. Two patients in each group had poor analgesia; of these, only one patient in each group took rescue dextropropoxyphene tablets.

Patient Satisfaction

There was a significant difference between the groups in regard to satisfaction with PCRA on the day of surgery: 81% patients were satisfied or very satisfied with ropivacaine PCRA versus only 52% with bupivacaine PCRA ($P < 0.05$). On the day after surgery, the percentage of satisfied or very satisfied was similar, with 79% and 83% for ropivacaine and bupivacaine, respectively. The main reasons for dissatisfaction were persistent numbness of fingers and inability to extend fingers; some patients also complained of inadequate analgesia and motor weakness of arm and fingers. In both groups, 87% patients ex-

pressed their desire to have the same treatment again. None of the patients had problems with removing their plexus catheters.

Side Effects and Technical Problems

Table 2 shows the side effects and technical problems in the two groups. The most common complaint was numbness of fingers, which occurred much more frequently after bupivacaine administration (29% vs. 6.9%; table 2). In general, the severity of numbness decreased over time; however, three patients considered numbness of fingers so unpleasant that they dropped out of the study. Two of these patients had received bupivacaine and one ropivacaine. The incidence of other side effects and technical problems was generally low (table 2). No catheter infection was noted.

Discussion

The results of the present controlled study show that the technique of self-administration of local anesthetic to

Table 2. Side Effects and Technical Problems

	Ropivacaine (n = 29)	Bupivacaine (n = 31)
Numbness of fingers	2 (6.9%)*	9 (29%)†
Motor block (poor arm control)	0	2 (6.5%)
Dizziness	1 (3.4%)	0
Nausea	0	1 (3.2%)
Technical problems		
Catheter out	1 (3.4%)	1 (3.2%)
Wet feeling in armpit	1 (3.4%)	0

* One patient dropped out after the sixth treatment because of excessive numbness; † Two patients dropped out because of numbness, one after the fourth and the other after the fifth treatment.

manage postoperative pain is feasible and effective outside the hospital. We have described the use of PCRA for postoperative pain management after various surgical procedures.⁵ This study is the first controlled trial to evaluate the efficacy of perineural PCRA after ambulatory surgery. Our results show that both local anesthetic drugs provide effective analgesia; however, we were unable to detect any significant differences in VAS between the two drugs. It is not possible to make statistical comparisons of pain scores between the two drugs because we have no indications as to the time after surgery when patients used their PCRA at home. Further, the number of patients using PCRA after the fifth treatment is rather small. The time intervals between the treatments for both drugs were similar and ranged from 3 to 12 h. Satisfaction scores were high: 83% patients were satisfied with PCRA, and 87% would prefer PCRA again. Significantly more patients were satisfied with ropivacaine PCRA; however, this finding was reported only for the day of surgery. In general, the VAS scores after treatment were relatively high; we speculate that the patients accepted some pain to avoid the unpleasant feeling of persistent motor block and numbness. Three patients were dissatisfied with PCRA because of persistent numbness of fingers and inadequate analgesia; two of them received bupivacaine and one received ropivacaine. These results appear to be the result of better sensory motor differential blockade by ropivacaine.¹⁰ Similar results were reported by Borgeat *et al.*¹¹ when they compared bupivacaine and ropivacaine for analgesia with interscalene block after shoulder surgery. The incidence of other side effects such as nausea and dizziness was extremely low. There were few technical problems; two catheters got dislodged on the day after surgery, and one patient complained of a wet feeling in the armpit. Common suggestions by patients were shaving the armpit and better catheter fixation to reduce the risk of catheter displacement.

Perineural and incisional catheter techniques are being used increasingly to manage postoperative pain in hospital and day surgery patients.⁶⁻⁹ Local anesthetics can be delivered through such catheters as continuous infusions, ground infusions with possibility of on-demand bolus doses, or on-demand bolus doses by PCRA. We prefer the PCRA bolus approach for the following reasons. It is well accepted that there is a great interindividual variation in analgesic requirements for postoperative pain. Because the duration of a single-dose local anesthetic varies considerably, PCRA by intermittent on-demand bolus doses may be preferable to continuous infusion because it permits the patient to correct for individual variations in intensity and duration of postoperative pain and also the duration of analgesia after a single administration, which varied from 3 to 12 h in our study. Our previous study⁵ (and the current one) showed that the range of bolus administrations at home

can vary from 0 to 10 (maximum allowed). With continuous infusion catheter techniques, many patients receive overdoses because of the erroneous belief that every patient has severe, unremitting pain all the time. In the current study, three patients did not use the pump because they did not have any pain. Comparisons between intermittent bolus and continuous infusion techniques for epidural or perineural analgesia have shown that intermittent bolus techniques, especially by PCRA, provide as good or better analgesia with significant dose reduction and consequently fewer side effects and better patient satisfaction.¹²⁻¹⁶ PCRA permits the patients to maintain adequate analgesia regardless of changes in pain intensity over time. Further, it has been demonstrated that axillary plexus postoperative analgesia by intermittent bolus administration results in lower plasma bupivacaine levels compared with continuous infusion, despite similar infusion rates.¹⁷ However, it should be noted that in a study of interscalene brachial plexus analgesia, Singelyn *et al.*¹⁸ have demonstrated that a basal infusion combined with small patient-controlled boluses was associated with similar analgesia and significant decrease of drug consumption when compared with continuous infusion. A possible disadvantage of the PCRA technique may be either a too strong motor block after the bolus and a too weak sensory before the next bolus. Further studies are necessary to address these issues.

The issue of local anesthetic potency difference between bupivacaine and ropivacaine is controversial. Some studies have shown that epidurally administered ropivacaine is up to 40% less potent than epidural bupivacaine.¹⁹ However, at high concentrations for axillary plexus block for surgery, the two drugs appear to be equipotent.²⁰⁻²² Our results suggest that the two drugs are also equipotent for axillary plexus postoperative analgesia.

In addition to questions about feasibility, there may be concerns about safety and infection risk with the use of such catheter techniques at home. The main concern with this technique is the risk of accidental delivery of the entire contents of the balloon pump if the patient fails to close the clamp. Although it did not happen in the current study, this accident has occurred in 2 of more than 700 patients we have studied. In one patient, 50 ml of 0.5% ropivacaine (250 mg) was delivered into a catheter placed subacromially for pain management after shoulder surgery; in another patient, 140 ml of 0.125% bupivacaine (175 mg) was delivered into two catheters (70 ml in each breast) placed subcutaneously for pain relief after breast augmentation surgery. None of these patients experienced any symptoms of toxic effects of local anesthetics. However, because of close proximity to blood vessels, the blood levels of local anesthetics are higher when administered in a brachial plexus sheath than when given subacromially or subcutaneously. In

the worst-case scenario, up to 80 ml of 0.125% bupivacaine or ropivacaine could be delivered. However, this volume is not delivered immediately but over a period of nearly 1 h (1.67 ml/min or 2.1 mg/min). Although relatively high, these doses are below safe large doses reported in the literature. In a volunteer study, the mean intravenous doses tolerated were 124 ± 38 mg for ropivacaine and 99 ± 30 mg for bupivacaine.²³ The safety of brachial plexus block using continuous infusions and intermittent boluses of local anesthetics is well documented. Catheters have been left in the axillary plexus sheath for up to 16 days without any untoward effects.^{24,25} Bupivacaine infusions through brachial plexus catheters at the rate of 25 mg/h and 18 mg/h for 65 h and 48 h, respectively, have not been associated with toxic serum levels.^{26,27} Similarly, ropivacaine in doses up to 300 mg (40 ml, 0.75%)²⁸ and 2.75–4.5 mg/kg have been used to induce brachial plexus block without central nervous system or cardiovascular toxicity.^{20,29,30}

Infusions of 0.2% ropivacaine into a brachial plexus sheath at a rate of 10 ml/h for 24 h,⁹ or 6.8 ml/h for 1 week (total cumulative dose, 904 mg),³¹ were not associated with any signs or symptoms of toxicity.

Theoretically, the risk of toxicity is greater if the catheter migrates into a blood vessel. Although there are rare reports of intravascular migration of epidural catheters, this occurrence has not been reported for peripheral block catheters.⁸ The use of less toxic ropivacaine and the recent availability of safer elastomeric pumps and lightweight, battery-driven pumps with lockout function can be expected to greatly reduce the risk of local anesthetic toxicity. To reduce the risk of toxic complications, the following measures were taken in this study: (1) clear verbal and written instructions to patient and escort about PCRA technique, (2) use of timer encouraged to assure correct dosing, (3) information provided regarding symptoms caused by local anesthetic overdose, and (4) telephone (and pager) number of anesthesiologist responsible for study and on-call anesthesiologist provided. It has been shown that compliance with postoperative instructions can be improved by ensuring comprehension of instructions and patient education regarding risks of noncompliance³². Nevertheless, the possibility of local anesthetic toxicity should be noted because the consequences of this risk are serious when the patient is outside the hospital. It is emphasized that the small number of patients in this study does not allow us to draw conclusions regarding safety with this drug delivery system. Further, the drug delivery may be imprecise,⁸ and there are no safeguards to prevent overdose by this device.

Another concern of sending patients home with indwelling catheters is the risk of infection. We have used this technique in more than 600 ambulatory surgery patients, and catheter infection or toxicity symptoms were not reported at the follow-up call or when the

patient diaries were returned. The possible reasons for lack of infection could be catheters placed under sterile conditions and connected to a closed pump system for delivery of local anesthesia, subcutaneous tunneling of catheters, documented bacteriostatic effect of local anesthetic drugs, and good patient compliance of hygiene instructions. Infection has not been reported from other studies with this technique, in which perineural catheters were used to manage postoperative and chronic pain in outpatients.^{8,9} In inpatients, catheters have been left in the axillary plexus sheath for long periods without any reports of infection.^{24,25} A report of intermittent bolus administration of bupivacaine into the axillary sheath for 41 days showed the catheter to be culture-negative on removal.³³ In this study, it was presumed that the patient report any symptoms or signs of infection during the follow-up call or in the patient diary. The risk of infection needs to be studied systematically by culture of catheter, local site inspection, presence of leukocytosis, and fever.

Local anesthetics are well recognized for their efficacy as peri- and postoperative analgesics; several recent placebo-controlled studies have demonstrated better efficacy of local anesthetics when administered through perineural,⁹ incisional,⁷ or intraperitoneal catheters.³⁴ Nevertheless, a limitation of this study was the noninclusion of a placebo control group. Further, a controlled group without regional techniques and with standard analgesics only would be necessary to confirm the superiority of PCRA.

In conclusion, this controlled trial has demonstrated that analgesia by local anesthetic drugs is feasible outside the hospital. We were unable to detect any significant differences in VAS between ropivacaine and bupivacaine. The overall satisfaction with the technique, regardless of the selected drug, was high. Patient selection, clear instructions about technique, follow-up telephone call, and 24-h access to anesthesiology services are prerequisites for PCRA at home. Further careful evaluation of a larger group of patients is required to determine the overall safety of this technique.

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