Interscalene Brachial Plexus Block with a Continuous Catheter Insertion System and a Disposable Infusion Pump

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Continuous interscalene brachial plexus blockade traditionally requires a hospital stay for local anesthetic infusion, and achieving consistent catheter insertion may be difficult. Incorporating long-acting pain relief from a continuous peripheral nerve block, with a reliable method of catheter insertion, and a self-contained infusion system would be a valuable asset for short-stay care. We compared the efficacy of single injection interscalene brachial plexus blockade to a continuous peripheral nerve block, with an insulated Tuohy system and a disposable infusion pump. Forty adult patients scheduled for open rotator cuff repair were entered in this randomized, double-blinded, placebo-controlled study. Patients received an interscalene brachial plexus blockade and a continuous peripheral nerve catheter as their primary anesthetic and then, were assigned to receive one of two different postoperative infusions: either 0.2% ropivacaine at 10 mL/h via a disposable infusion pump or normal saline at 10 mL/h via a disposable infusion pump (n = 18–20 per group). Visual analog pain scores and postoperative morphine consumption were measured for 24 h. The ropivacaine group showed less pain than the placebo group (P = 0.0001) between 12 and 24 h after the initial injection of local anesthetic. In addition, initial interscalene blockade was successful in all patients and all redosed catheters were functional after 24 h with the continuous catheter insertion system. We conclude that it is possible to achieve a high rate of successful catheter placement and analgesia by using the continuous catheter insertion system and a disposable infusion pump in the ambulatory setting. This method of analgesia may offer improved pain relief after outpatient rotator cuff repair.

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Major shoulder surgery traditionally requires a hospital stay for pain management. Even minor surgery, such as rotator cuff repair, may involve a long incision and substantial soft tissue dissection. As a result, patients frequently require large doses of postoperative IV narcotics. The care required to manage IV analgesic treatment usually makes early hospital discharge difficult and prohibits performance of this surgery on an ambulatory basis. Single injection interscalene brachial plexus block is an effective anesthetic; however, it is limited by the duration of action of the local anesthetic. When these cases are attempted on an ambulatory basis, parenteral narcotics are usually required for postoperative analgesia, and readmission for pain control is common after block resolution (1).

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Continuous peripheral nerve blockade is an alternative technique that can provide prolonged postoperative analgesia. It has been particularly effective in treating pain after shoulder surgery by decreasing postoperative opioid requirements and reducing anesthetic side effects (2). Despite these benefits, the lack of a simple, consistent method of catheter insertion can make this technique unreliable. Because of these difficulties, continuous techniques are often reserved for select cases and can only be performed by individuals with specialized training and hence, is infrequently applied. In addition, this mode of analgesia is only provided on an inpatient basis because of the need for an automated infusion pump and nursing supervision.

A strategy that incorporated long-acting pain relief from continuous peripheral nerve blockade, with a reliable method of catheter insertion, a self-contained infusion system, and no intervention from medical staff would be a valuable asset for short-stay care. We report a prospective, placebo-controlled study that compared the efficacy of single injection interscalene brachial plexus blockade to a continuous peripheral

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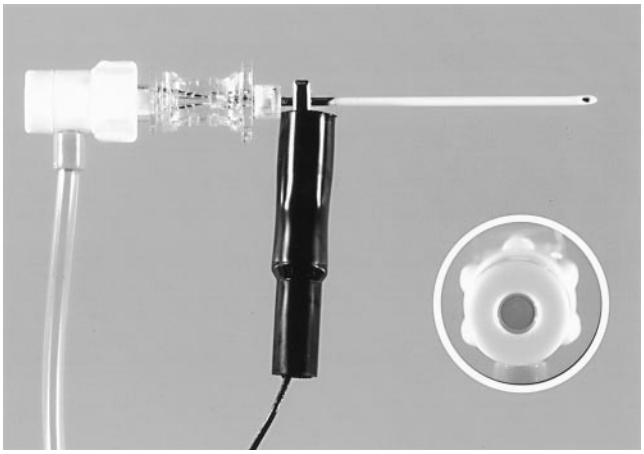

Figure 1. An 18-gauge, insulated Tuohy system (Braun Contiplex®, B. Braun Medical, Bethlehem, PA). Inset shows a luer-lock head with central diaphragm at the proximal end of the needle.

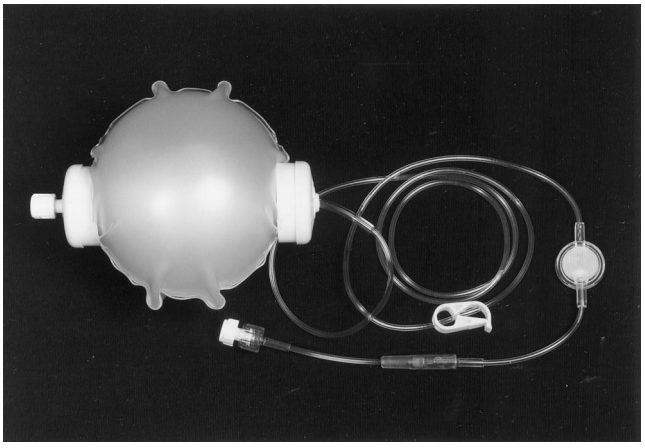

Figure 2. Disposable elastomeric infusion pump (C-bloc Continuous Peripheral Nerve Block System®; I-Flow Corp, Lake Forest, CA) containing 270 mL of study drug that delivers 10 mL/h.

nerve blockade with an introducer system and a disposable infusion pump in patients undergoing open shoulder surgery.

Methods

This study was approved by the IRB and written, informed patient consent was obtained. Forty patients classified as ASA physical status I–III, ages 18 yr or older, participated in this randomized, double-blinded, placebo-controlled study. All patients were scheduled for unilateral, open rotator cuff repair or biceps tendonesis. Patient exclusion criteria included peripheral neuropathy, chronic opioid use, morbid obesity (twice the ideal weight or >130 kg) or contraindications to regional anesthesia.

All patients were scheduled to receive an interscalene brachial plexus block and placement of a peripheral nerve catheter as their primary anesthetic. Attending anesthesiologists experienced with the equipment and technique performed all blocks. Patients were then randomly assigned by prerandomized sealed envelopes to receive one of two different postoperative infusions (n = 18–22 per group). Group 1 received 0.2% ropivacaine at 10 mL/h via a disposable infusion pump and Group 2 received normal saline (placebo) at 10 mL/h via a disposable infusion pump

All patients were brought to the preoperative holding area and monitored by using standard ASA monitors. Patients were sedated with 1–5 mg of IV midazolam and 50–250 μg of fentanyl, titrated to moderate sedation (arousable on command). All interscalene blocks were performed by using the approach of Winnie (3) and the Braun Contiplex® (B. Braun Medical, Bethlehem, PA) insulated Tuohy system (Figure 1) (4). Using this needle and a nerve stimulator, the needle was directed medially with the bevel and orifice directed toward the axilla. After an appropriate motor response was localized (distal to the shoulder) with the lowest achievable current (goal <0.5 mA), 30 mL of 0.5% ropivacaine with epinephrine 1:400,000 was incrementally injected. Maintaining the needle in the same position, a 20-gauge standard epidural catheter was threaded 10 cm past the tip of the needle or as far as possible. After negative aspiration, a 3 mL test dose was given. The time interval between placing the patient supine and the time each catheter was secured was recorded as the time used for insertion.

Immediately after block placement, clinicians were asked to rate the difficulty of catheter insertion on a scale of 1 to 5 (1 = easy to 5 = very difficult). All episodes of local anesthetic toxicity or hemodynamic change requiring anesthesiologist intervention (increased IV fluids or inotropes) were recorded as adverse events. After evidence of a successful motor block (loss of shoulder abduction) the patient was taken to the operating room for surgery. Failure to lose shoulder abduction after 30 min was considered a block failure.

On arrival at the operating room, a disposable elastomeric infusion pump (C-bloc Continuous Peripheral Nerve Block System®; I-Flow Corp, Lake Forest, CA) containing 270 mL of study drug (0.2% ropivacaine or normal saline) was connected to the interscalene catheter and infused at 10 mL/h (Figure 2). During surgery, additional infiltration of local anesthetic was not performed. Intraoperative sedation was provided with IV propofol 10–50 $\mu g \cdot kg \cdot min$, titrated to moderate sedation. Intermittent IV doses of 25 μg of fentanyl and 10 mg of propofol were given for supplemental sedation; 30 mg of IV ketorolac was administered at the conclusion of surgery.

At the conclusion of surgery, patients were transferred to the postanesthetic care unit. The patient and

evaluator who conducted the postoperative follow-up were unaware of the identity of the infused solution. When patients met standard postanesthetic care unit discharge criteria, they were transferred to a 23-h recovery care unit. All patients were directed to take oral naproxsyn 500 mg twice a day for four days. Patients were asked to rate their pain by using a visual analog pain scale (VAS) (0 mm = no pain to 100 mm = worst pain imaginable) every 2 h for 24 h after surgery. Data were obtained by a trained nurse, and patients were not awakened during the night. Patients were asked to contact the nurse when they felt shoulder discomfort and desired supplemental analgesics. On request, patients were furnished with a IV morphine patient-controlled analgesia pump. Settings were standardized: 0.05 mg/kg initial loading dose; 0.02 mg/kg dose; 8 min lock-out; 30 mg every 4 h maximum. Total morphine consumption was documented. No additional nursing interventions were provided for pain control.

A sensory/motor examination was performed 24 h after block placement, to document the extent of neural blockade. A blood sample was then collected by venipuncture from an antecubital vein to assess ropivacaine plasma concentrations. The blood from each sample underwent immediate centrifugation at 3000 g, and the plasma was stored at −70°C until analysis. Total bound ropivacaine concentrations were measured by using a gas chromatograph (5890 Series II; Hewlett Packard,) with a nitrogen-phosphorus detector. Samples were prepared after the protocol of Björk et al. (5). All samples were prepared in duplicate and the reported amount calculated from their mean. A correction was made for samples containing <990 μL of plasma. Bupivacaine was chosen as an internal standard with a final concentration of 1000 ng/mL. The calibration curve showed linearity over the 25 to 3000 ng range with a correlation factor ± 0.038 μg for ropivacaine. Accuracy was confirmed by analyzing samples of known concentration.

Each catheter was inspected and then, injected with 20 mL of 0.5% ropivacaine. A change in the sensory/motor examination after 15 min was used as evidence of successful catheter placement. A trained assistant then removed the catheter and asked patients whether they would be willing to remove the catheter at home. Patients were also questioned about their satisfaction, "Would you recommend this type of anesthesia to future patients?" They were also asked to rate their satisfaction with the anesthetic on a scale of 0–10 (0 = dissatisfied to 10 = very satisfied).

Descriptive statistics for outcomes were produced, including mean ± SD. Differences in group demographic characteristics were tested by *t*-test or contingency-table χ^2 test for categorical measures. The nonparametric Wilcoxon ranked sum test was used to compare total morphine use between groups. For the VAS pain scores, a repeated-measures generalized linear models analysis was used to test time and treatment effects taking into account repeated scores on individual patients. Treatment effects were tested first over the entire 24-h period, and then, over the last 12 h only. *Post hoc* tests of treatment difference at separate times by using the nonparametric Wilcoxon ranked sum test were planned, if the overall treatment difference or the time by treatment interaction was significant. In consideration of the two repeated measures analyses, the significance level was set at $\alpha = 0.025$.

Results

Forty patients completed the study protocol, 18 in the placebo group and 22 in the ropivacaine group. There were no differences in age, weight, sex, or ASA physical status between groups (placebo:ropivacaine: weight, 55 ± 17:53 ± 13 kg; height, 171 ± 11:165 ± 24 cm; age, 83 ± 16:78 ± 17 yr; sex, 10:8/12:10 m/f. The time to place the catheter was 10 ± 4 min in the placebo group and 12 ± 4 min in the ropivacaine group ($P = 0.3$). Accepted stimulation current between the two groups (0.6 ± 0.3 vs 0.7 ± 0.2 mA) ($P = 0.4$) was similar. The median ± interquartile range of difficulty of catheter insertion was easy in both groups, 1 ± 1 and 2 ± 2, respectively. There were no failed interscalene blocks, no episodes of acute or chronic local anesthetic toxicity, or hemodynamic instability.

Total postoperative morphine consumption in the placebo group (36 ± 24 mg; median, 37 mg) was greater than in the ropivacaine group (18 ± 29; median, 0) $P = 0.004$. During the first 6 h morphine consumption was small in both groups, 3 ± 6 mg and 0 ± 0 mg, respectively. Of those in the ropivacaine group, 54% of patients required no morphine during the first 24 h. This contrasts to only 5% in the placebo group.

Overall 24-h VAS analysis found a significant treatment-time interaction ($P = 0.0007$), indicating the difference between treatments varied with time after surgery. During the last 12 h overall, the interaction disappeared ($P = 0.6349$) and the ropivacaine group showed significantly less pain than the placebo group ($P = 0.0001$) (Figure 3).

Two catheters in the ropivacaine group were noted to be dislodged at the 24-h evaluation and were not redosed. One patient requested the catheter not be redosed because of the feeling of dyspnea. One catheter was blood tinged, however, without symptoms of local anesthetic toxicity, and was not redosed. These four patients were included in all data analysis, including serum ropivacaine measurement. A fifth patient complained of neck pain after 6 h of infusion and requested the catheter be removed. Subsequent VAS

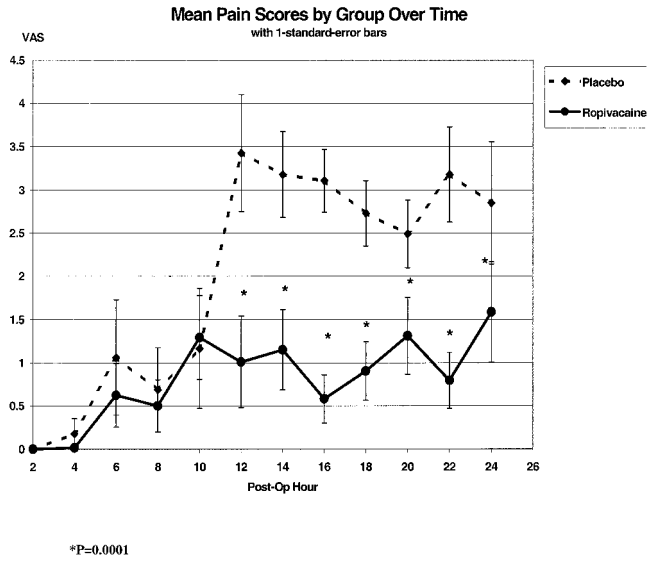

Figure 3. Mean visual analog pain scores (VAS) by group over time ± SD (0 = no pain/10 = worst pain imaginable), reported by patients every 2 h postoperatively for the first 24 h after receiving interscalene brachial plexus block and a continuous infusion of placebo or 0.2% ropivacaine at 10 mL/h. *P* values are for intergroup comparisons at each measurement interval. Bars = one standard error. **P* = 0.0001.

scores and ropivacaine assays were not completed on this patient. Of note, the patients with dyspnea, a blood-tinged catheter, and the complaint of neck pain all used 0 mg of morphine in 24 h. The mean total serum ropivacaine level was 1.04 ± 0.5 μg/mL in those receiving the ropivacaine infusion and 0.34 ± 0.3 μg/mL in those receiving the saline infusion ($P < 0.0001$) (Figure 4). No patients in the placebo group had dislodged catheters. There were 35 patients with an intact catheter for bolus at 24 h. All 35 (100%) had a positive change in sensory/motor examination after catheter bolus.

Five study participants (12.5%) were unwilling to remove the continuous catheter at home (two people in the placebo group and three people in the ropivacaine group). The mean satisfaction with anesthesia scores was 10 ± 1 in both groups. In general, patients in both groups were satisfied with their analgesia (9 ± 2 and 10 ± 1, respectively).

Discussion

The results of this study demonstrate it is possible to extend the duration of a peripheral nerve block by using a continuous peripheral nerve block and a self-contained disposable infusion pump. In addition, the insertion system was effective in achieving successful single injection neural blockade (100%) and continuous catheter placement. The fact that mean morphine consumption was reduced from 36 mg to 18 mg, and no morphine was required in 54% of patients could allow most patients to be discharged with a satisfactory degree of pain control.

This method of pain relief provided patients with a 50% reduction ($P = 0.001$) in morphine consumption over 24 hours. Both groups consumed small amounts of morphine (placebo = 0 mg vs CPNB = 3 mg) during the initial 6 hours after single injection block. This demonstrates the effectiveness of a single injection block during the initial postoperative 6 hours. The demand for 36 mg of morphine (in the subsequent 18-hour period after block resolution) emphasizes the magnitude of pain after rotator cuff repair and shows why achieving adequate pain relief with narcotics would be difficult on an ambulatory basis. Given the reduction in morphine consumption in those patients treated with the disposable infusion pump, a trial substituting oral analgesia for the IV morphine appears appropriate.

Comparing the catheter insertion system and the disposable infusion pump to conventional morphine treatment, as opposed to an alternative catheter system, is one potential weakness of the study, particularly when trying to extrapolate this treatment for outpatients. However, this method of analgesia was chosen in this initial trial for two reasons. First, to provide a standard reference to accurately quantify the degree of pain relief achieved in these patients. Second, severe pain was anticipated in patients receiving placebo after block resolution. Given that these patients were in a supervised environment, we felt compelled to provide more than oral analgesics.

The disposable infusion pump was a reliable method of local anesthetic delivery. Advantages for use in the outpatient setting are the pump is simple, has no mechanical parts, and requires no intervention by patient or staff. Limitations of the system are the inability to tailor infusion rates or deliver a bolus of local anesthetic. Furthermore, because there is no high-pressure alarm or an ability to flush the catheter, identifying and correcting an occlusion could be difficult in the ambulatory setting.

This is the first study examining 0.2% ropivacaine at 10 mL/h for interscalene infusion. The rate was chosen to maximize local anesthetic delivery and minimize breakthrough pain. This concentration and rate has been successfully used at our institution for infusions lasting longer than four days with minimal need for supplemental dosing or occurrence of adverse side effects. Lierz et al. (6) reported on the success of 4–6 mL/h 0.2% ropivacaine infused for six days without adverse events. In addition, Tuominen et al. (7) have demonstrated that by using 0.25% bupivacaine infusions (approximately 18.5 mg/h) for 48 hours, a potentially more toxic local anesthetic, was effective and resulted in nontoxic serum blood levels. Singelyn et al. (8) recently reported the efficacy of continuous interscalene analgesia with bupivacaine, sufentanil, and clonidine and concluded that a

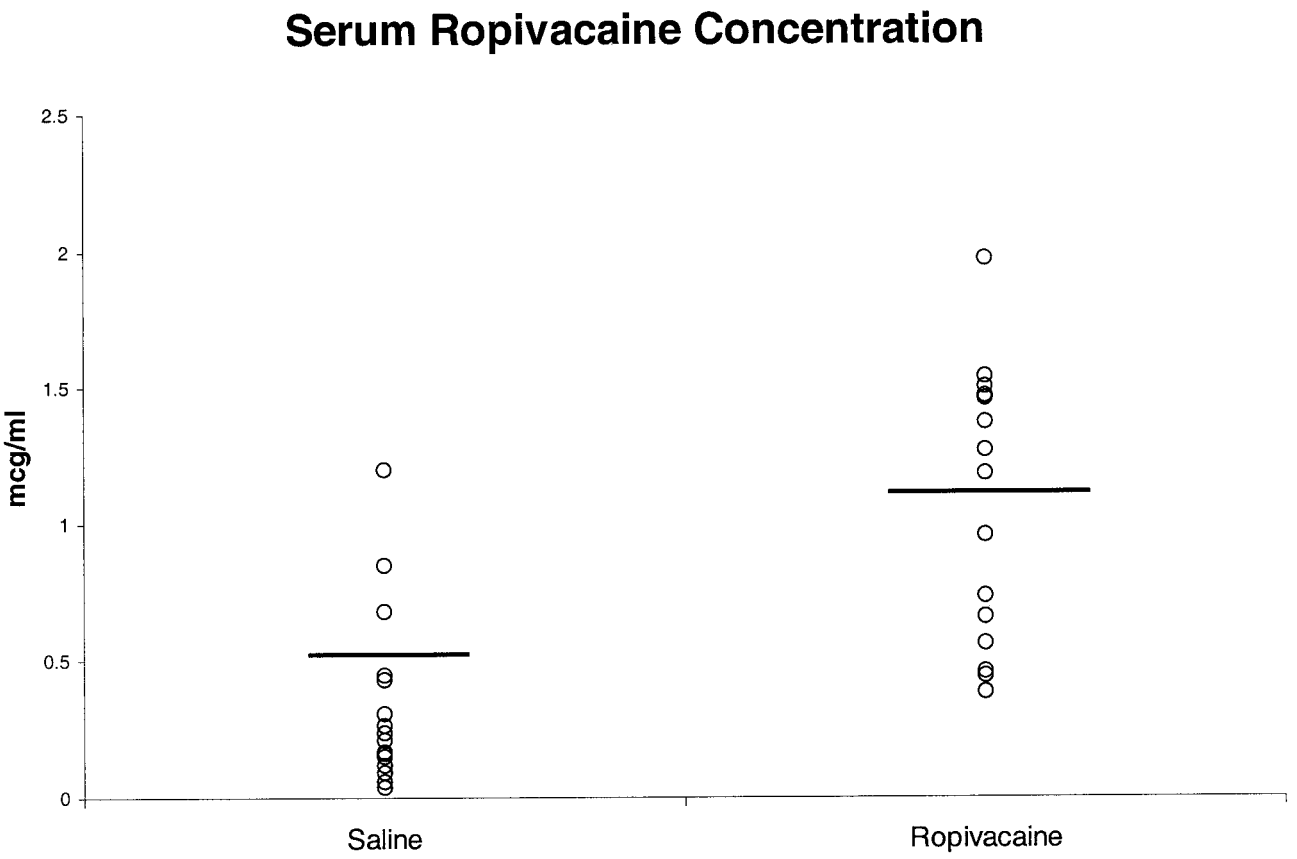

Figure 4. Total serum ropivacaine levels at 24 h in patients receiving continuous interscalene brachial plexus blockade of 0.2% ropivacaine or saline at 10 mL/h via a disposable infusion pump. Horizontal bars indicate mean values.

baseline infusion and intermittent bolus was ideal. Yet, the data from this study demonstrate that for a 24-hour infusion, intermittent bolus was not essential. Studies comparing the two methods of administration are unavailable.

In this study, after 24 hours of accumulation, mean total serum ropivacaine concentration was 1.04 ± 0.5 μg/mL. This value is only marginally larger than the concentration (0.34 ± 0.3 μg/mL) obtained 24 hours after a single injection block. It compares favorably to that measured by Erichsen et al. (9) in a study examining the pharmacokinetics of epidural ropivacaine. They found a mean total ropivacaine plasma concentration of 0.88 mg/L after 24 hours of a 20 mg/h infusion, corresponding to a mean total dose of 511 mg. They concluded that the pharmacokinetics of ropivacaine were independent of dose; however, total clearance decreased with time over 24 hours. The consistent increase in total plasma concentration was in contrast to a decrease in unbound concentrations typically associated with central nervous system symptoms. This decrease was attributed to the increase in α-1-glycoprotein, which occurs after infusion of local anesthetics similar to that used in this study.

Despite this degree of success, the use of continuous local anesthetic infusions at home is still an investigational area of pain control. The concern for local anesthetic toxicity occurring outside of the hospital could pose potential risk, if not recognized and treated. To minimize patient risk, the local anesthetic, ropivacaine, and the 0.2% concentration were chosen because of its improved safety profile when infused in volunteers (10). The pump is tamper resistant and unable to deliver a larger dose. Furthermore, caregivers were experienced with the signs or symptoms of local anesthetic toxicity.

Although unlikely, serious complications, such as seizures and cardiac arrest are theoretically possible. Tuominen et al. (11) reported an unintentional arterial catheterization and subsequent bupivacaine toxicity with a continuous interscalene brachial plexus block. In that case, the resulting central nervous system toxicity occurred in association with initial dosing. Migration of a continuous interscalene catheter after correct placement has not been reported. In this study, one catheter had blood-tinged fluid on aspiration after 24 hours. It is unclear whether this was from IM placement, blood in the brachial plexus sheath, or

inadvertent vascular cannulation. However, this reinforces the need to confirm correct catheter placement, if outpatient discharge is planned. At our institution, catheter position is confirmed by documenting a block after dosing through the catheter. An alternative is to radiographically image the catheter; however, determining the location of the catheter tip may be difficult with this technique.

One reason the widespread use of continuous peripheral nerve blockade has been limited is lack of a simple consistent method of catheter insertion. Recently, Singelyn et al. (8) reported use of continuous interscalene anesthesia and noted that 84% (21 of 25) of catheters were very difficult to insert. This contrasts with the ease and success of catheter insertion in this study. This success is encouraging, however the anesthesiologists performing the technique were experienced with the equipment, and the majority used it over the past five years during development. This familiarity may have influenced the perceived difficulty with insertion and the success rate. However, given the success in this series of patients, a prospective trial examining new-user learning curves is needed to further evaluate the equipment.

Other studies (12,13) have demonstrated the efficacy of continuous interscalene brachial plexus blockade for shoulder surgery. However, previous studies have all focused on inpatients with a limited degree of successful catheter insertion. The data in this study demonstrate it is possible to achieve good results by using the insertion system and a disposable infusion pump. This method of analgesia may offer improved pain relief in outpatient rotator cuff repair. However, before expanding this model for use outside of a supervised setting, adequate provisions for patient follow-up and safety monitoring need to be established. From the results of this study, we conclude that larger prospective trials are needed to examine this technique of pain relief in outpatients.

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