

The Efficacy of Continuous Bupivacaine Infiltration Following Arthroscopic Rotator Cuff Repair

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Purpose: This prospective, randomized, double-blind study with a placebo group and 2 experimental groups evaluated the efficacy of continuous low-dose bupivacaine infiltration by infusion pump after arthroscopic rotator cuff repair. **Methods:** Sixty patients undergoing arthroscopic rotator cuff repair received a bolus injection in the subacromial space of 35 mL of 0.25% bupivacaine with 1:200,000 epinephrine at surgical closure and were randomized to 1 of 3 groups: 0.25% bupivacaine at 2 mL/hr (n = 20), 0.25% bupivacaine at 5 mL/hr (n = 20), or saline at 5 mL/hr (n = 20) via infusion pump into the subacromial space. Pain was evaluated using the visual analog scale (VAS) and narcotic consumption was measured until 48 hours after surgery and converted to dose equivalents (DE). **Results:** Sixty patients used the infusion pump for a mean of 43.9 hours (range, 15.50 to 50.75 hrs). Mean total narcotic consumption, expressed in DEs, was 2.24 for the 2-mL group, 3.52 for the 5-mL group, and 2.32 for the placebo group. Mean pain score was 2.9 for the 2-mL group, 3.6 for the 5-mL group, and 3.3 for the placebo group. There were no differences in operating room time or infusion pump use time among groups. The 2-mL group had a nonsignificant trend toward less pain and lower narcotic consumption. The 5-mL group evidenced a nonsignificant trend toward more pain and higher narcotic consumption. **Conclusions:** This study neither supports nor refutes the use of infusion pumps. We hypothesized that the placebo group would experience greater pain than the 5-mL group; however, a nonsignificant trend toward the contrary occurred. A trend toward less pain in the 2-mL group was not significant. **Level of Evidence:** Level II, randomized controlled trial of therapeutic treatment that lacks statistical significance and narrow confidence intervals. **Key Words:** Bupivacaine—Continuous local anesthetic—Infusion pump—Postoperative pain—Rotator cuff repair.

Different modalities have been advocated for pain control after outpatient surgery including peripheral blocks, disposable patient-controlled analgesia

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pumps, and simpler continuous infusion pumps in conjunction with intravenous and oral pain medications. The ideal mode of pain relief after outpatient surgery is effective over the first 2 postoperative days, has a low complication risk, is inexpensive, and can be managed by the patient at home.

The disposable infusion pump for continuous local anesthetic has been available for use since the mid-1990s and offers the proposed advantages of decreasing the patient's need for oral narcotics, thereby also decreasing the incidence of nausea, drowsiness, constipation, and other associated side effects. The safety profile of the device when used with bupivacaine 0.25% or 0.5% is good, with only sporadic cases of drug toxicity reported in the literature.

Although infusion pumps are generally consid-

ered safe, recently some discussion has surfaced of cases of chondrolysis after arthroscopic shoulder procedures in which a pain pump was used.^{1,2} In addition, several animal studies have shown chondrolysis and histologic changes after the use of bupivacaine in a joint.³⁻⁵ No randomized studies on this subject exist in the literature, however, and no clear link has been established between chondrolysis and the use of the pump. Specifically, chondrolysis has not been shown to occur with use of the pump in the subacromial space, as it is used in this study.

The infusion pump has been advocated to save money by reducing the patient's time spent in the postanesthesia care unit (PACU), allowing a quicker and easier recovery, saving on therapy costs, and enabling the patient to return to work sooner. In addition, the infusion pump can be managed and removed by the patient without the involvement of a visiting nurse or other costly staff.

Although orthopaedists have made extensive use of the infusion pump over the past 15 years, little scientific evidence exists to support the use of the pump. Few randomized, controlled evaluations of infusion pumps have been reported in the literature, and they show varying results. The results of a prospective, randomized, blinded study of patients undergoing subacromial decompression have been reported.⁶ The treatment group, receiving 0.25% bupivacaine at 2 mL/hour via infusion pump consumed less narcotics and reported less pain than the placebo group. Similar findings were reported in a study of patients receiving a mixture of bupivacaine and morphine via infusion pump after subacromial decompression.⁷ However, no significant difference in pain, narcotic consumption, or recovery of motion was reported in a comparable study.⁸

Most of the studies in the literature evaluate a combination of different procedures (subacromial decompressions, labral repairs, etc.), which complicates the interpretation of their results. No studies have specifically examined the use of infusion pumps in the setting of arthroscopic rotator cuff repair. The purpose of this prospective study was to compare the efficacy of 2 doses of continuous low-dose bupivacaine with placebo infiltration by infusion pump after arthroscopic rotator cuff repair with subacromial decompression. Our hypothesis was that the 2 mL/hour infiltration would control pain better than placebo and that the 5 mL/hour infiltration would control pain better than either the 2 mL/hour infiltration or the placebo infiltration.

METHODS

After approval by our human subjects committee, 60 patients were enrolled sequentially over the course of 18 months in this prospective, blinded, randomized, placebo-controlled study. Each patient signed an informed consent before surgery with the understanding that he or she would be taken out of the study if the arthroscopy findings did not show a rotator cuff tear. Patients were asked to participate if they were found to have a tear of the rotator cuff on magnetic resonance imaging, arthrogram, or arthroscopy, were scheduled for arthroscopic rotator cuff repair with subacromial decompression, and were over 18 years of age. Exclusionary criteria were known allergy or hypersensitivity to local anesthetic medications or epinephrine, history of infection at the surgical site within 1 year, history of substance abuse, history of a chronic pain syndrome or neuropathy, history of mental compromise, use of antidepressants, need for concomitant procedure such as an acromioclavicular joint resection, labral repair, biceps tendinosis, or regional block perioperatively, history of a previous rotator cuff repair, and need for open rotator cuff repair.

Up to 2 weeks before surgery, at the preoperative visit, patients were instructed in the management of the infusion pump (PainBuster; dj Orthopaedics, Vista, CA) and the pain visual analog scale (VAS) was reviewed.⁹ Arthroscopic rotator cuff repair with subacromial decompression was carried out with standard technique, using the semilateral position. Fifty-eight of the surgeries were done by the senior author and 2 were done by his coworkers. At the conclusion of surgery, the catheter for the infusion pump was placed from the anterior shoulder into the subacromial space under direct visualization (Fig 1). After closure, patients received a bolus injection of 35 mL of 0.25% bupivacaine with 1:200,000 epinephrine into the subacromial space. Patients were then started on either 0.25% bupivacaine at 2 mL/hour, 0.25% bupivacaine at 5 mL/hour, or normal saline at 5 mL/hour via the infusion pump. Randomization to 1 of the 3 groups was done by computer on the day of surgery.

Standard postoperative and rehabilitative protocols were followed. Pendulum and passive range of motion exercises were begun on postoperative day 2, at the time of the first therapy visit and pain pump removal. Active assisted exercises began on week 6 and active exercises were started at week 8. Strengthening began at 12 weeks. Routine pain orders during the time of the study included hydrocodone for pain after discharge. No muscle relaxants or anti-inflammatory

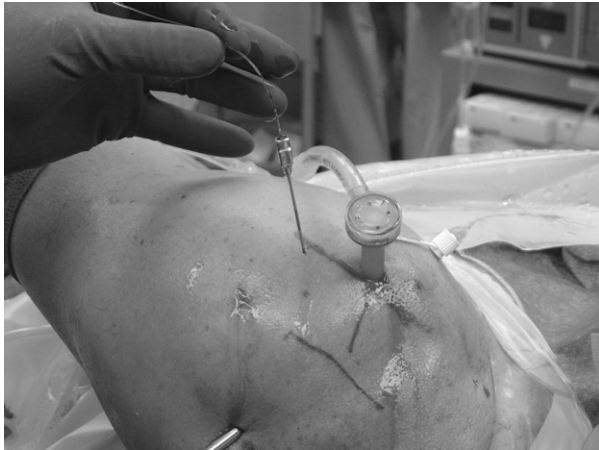


FIGURE 1. Insertion of infiltration catheter of PainBuster Infusion Pump catheter, through a spinal needle into subacromial space. The infusion pump provides continuous infusion of local anesthetic directly into the surgical site.

medications were routinely prescribed. Patients reported their pain verbally in the PACU and used the pain VAS to report their pain at 1, 2, 4, 8, 12, 24, and 48 hours after surgery. Narcotic consumption was recorded in the PACU. Following discharge from the hospital, patients reported their pain and recorded narcotic consumption at the scheduled time intervals. Narcotic consumption was measured and converted into dose equivalents (DE; 10 mg intravenous morphine sulfate = 1 DE).¹⁰ Combined and averaged values over the 48-hour period were examined.

The infusion pump remained in place for 48 hours or until the pump malfunctioned. Follow-up telephone calls were made to the patients by the research coordinator approximately 48 hours after surgery. Patients were asked to rate the effectiveness of their pain management and to comment on future use of the infusor pump. Patients returned to the clinic for a wound check and collection of data after 7 days. Surgeons, research staff, and patients were blinded to treatment group throughout the study.

Our initial power analysis indicated that we needed 46 patients per group (138 patients total) to provide 80% power. Because of financial constraints, an interim analysis was done at 60 patients to see if any trends could be identified. After examining the information, we agreed to terminate the enrollment at 60 patients with a power of 60%. Baseline patient characteristics of age, sex, and body mass index were analyzed to ensure there were no differences among groups. Independent *t* tests were used for continuous variables; χ^2 tests were used for categorical variables.

Univariate analyses were performed to assess differences among groups for pain and narcotic consumption at each measurement time. Pain scores were averaged at each measurement time and analyzed using independent *t* tests; tests for trends were performed if appropriate. Independent *t* tests were used to compare narcotic consumption in DEs among groups. Differences in satisfaction between groups were analyzed using a χ^2 test. Statistical tests of baseline data were 2-tailed; tests of the dependent variables were 1-tailed. *P* = .05 was used for all analyses.

RESULTS

Thirty-four men and 26 women with a mean age of 60 years (range, 27 to 84) used the infusion pump for a mean of 44 hours (range, 15 to 51). Five patients removed their catheters before 48 hours. Three of these pumps were clogged (all in the 2-mL group), 1 pump in the placebo group was leaking, and 1 patient in the placebo group asked to have the pump removed. No differences in length of operating room time or infusion pump time were found among the 3 groups (Table 1). No difference was noted in the size of the tear or the number of sutures needed for repair (Table 2). Borderline differences were identified in age (*P* = .08) and sex (*P* = .05) among groups (Table 1) and thus an analysis was performed to determine differences in narcotic consumption between men and women, which could have been a confounder in the association of narcotic consumption and treatment group. Although women (3.26 DE) had higher narcotic consumption than men (2.26 DE), this difference was not statistically significant (*P* = .13). Additionally, when stratified by sex, no statistically significant

TABLE 1. Baseline Characteristics and Surgical Data

Variable	Group (n)				<i>P</i> Value
	Total (N = 60)	Placebo (20)	2-mL (20)	5-mL (20)	
Sex					.05
Male	57%	70%	65%	35%	—
Female	43%	30%	35%	65%	—
Mean age* (yr)	60	61	55	64	.08
Mean length of surgery (min)	99	109	95	94	.21
Mean length of infusor pump use (hr)	43.9	43.0	43.8	44.9	.82

*Age at time of surgery.

TABLE 2. Size of Tears and Total Number of Sutures Used by Group

Size of Tear	Placebo Group	2-mL Group	5-mL Group	P Value
Small (≤ 1.5 cm)	55%	45%	50%	
Medium (1.6 to 2.9 cm)	20%	25%	40%	
Large (≥ 3.0 cm)	25%	30%	10%	.4
Number of sutures (mean)	4.5 \pm 2.7	4.3 \pm 1.9	4.8 \pm 2.5	.8

Size of tear analyzed with ANOVA. Number of sutures statistics analyzed by χ^2 .

differences in DE usage were found among the 3 groups ($P = .1730$).

A similar analysis was performed to determine whether age was acting as a confounder in the association of DE and treatment group. Those patients over 60 years of age were found to have higher DE usage than those under 60 years, with borderline statistical significance ($P = .08$). However, in the final analysis of covariance, with adjustments made for sex and age group (<60 yrs v ≥ 60 yrs), no statistically significant ($P = .17$) differences in narcotic consumption were found among the 3 groups. Mean total narcotic consumption is displayed in Fig 2.

No differences were found in pain scores among treatment groups (Fig 3). Sex and age were both analyzed as possible confounders, still revealing no statistically significant differences in pain scores among groups. No complications occurred in any of the 3 groups. Examining both outcome parameters, narcotic consumption, and pain VAS scores, nonsignificant trends toward more pain in the 5-mL group and less pain in the 2-mL group were present. The

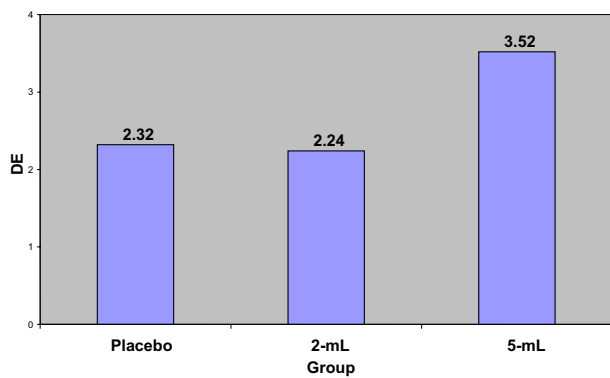


FIGURE 2. Mean total narcotic consumption expressed in dose equivalents. No significant differences ($P = .17$) were found among groups.

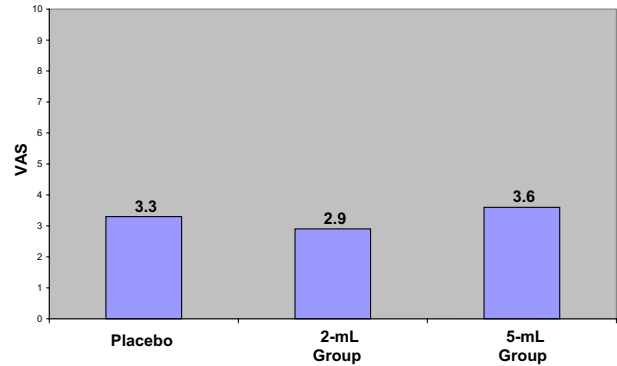


FIGURE 3. Mean pain visual analog scale scores. No significant differences ($P = .45$) were found among groups.

narcotic consumption ($P = .005$) and pain VAS ($P = .005$) were significantly different at the 12-hour mark between the placebo group and the 2-mL group, and pain VAS neared significance ($P = .055$) between the 2-mL group and 5 mL-group (Fig 4). Pain VAS was also significantly differently at the 24-hour mark between the placebo group and the 2-mL group. No other relationships were noted.

In the placebo group, 55% ($n = 11$) reported good/excellent pain control and 55% ($n = 11$) recommended the infusor pump for future use. In the 2-mL group, 75% ($n = 15$) reported good/excellent pain control and 75% ($n = 15$) recommended the infusor pump for future use. In the 5-mL group, 65% ($n = 13$) reported good/excellent pain control and 70% ($n = 14$) recommended the infusor pump for future use.

DISCUSSION

To date, studies on infusion pump use in shoulder surgery have focused on subacromial decompression, open rotator cuff repair, or a mixture of different arthroscopic procedures. Few prospective, randomized studies focusing on subacromial decompression showed improved pain control. An investigation of 62 patients undergoing arthroscopic subacromial decompression with treatment groups receiving either saline or 0.25% bupivacaine at 2 mL/hour reported reduced pain VAS scores and narcotic consumption in the bupivacaine group compared with the saline group.⁶ A prospective, randomized, blinded study of infusion pumps after subacromial decompression in 60 patients reported similar findings.⁷ These studies are well designed and randomized, but like our study, rely heavily on patient reporting of narcotic consumption.

Several recent infusion pump studies, which include

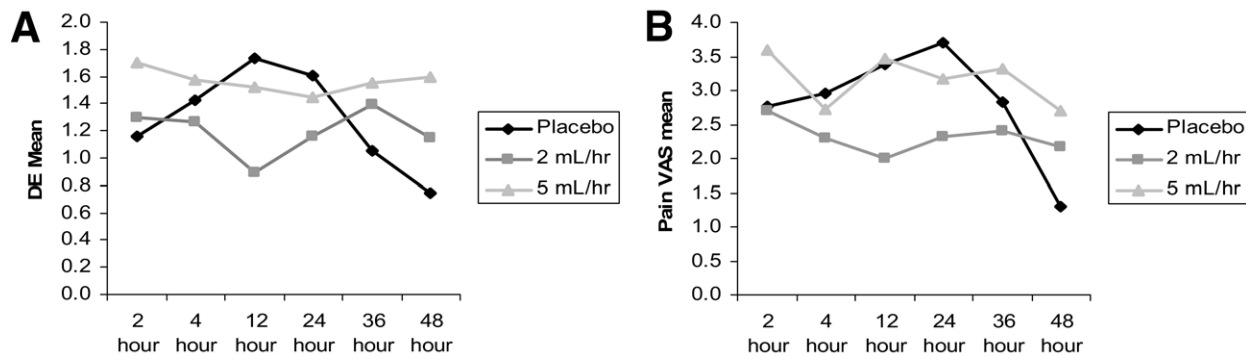


FIGURE 4. (A) Mean DE at each time point. Significant at 12-hour point between placebo group and 2-mL group ($P = .005$). (B) Mean pain VAS at each time point. Significant between placebo group and 2-mL group at 12 hours ($P = .03$) and at 24 hours ($P = .04$) and near significance between 2-mL group and 5-mL group at 12 hours ($P = .055$).

a variety of arthroscopic procedures, show mixed results. A prospective, randomized study of 50 patients undergoing a range of arthroscopic shoulder procedures with patients receiving either 0.5% bupivacaine or saline at 2 mL/hour reported lower pain scores and decreased use of oral pain medication in the bupivacaine group at all recorded times over the first postoperative week. The interval of greatest pain was identified as the second postoperative day.¹¹ Another study comparing subacromial infusion with intravenous injection after arthroscopic shoulder surgery reported lower VAS scores in the subacromial group, but found no significant differences between groups.¹² Alternatively, Quick and Guanche⁸ found that infusion pumps were not efficacious in a randomized, controlled study of 50 patients undergoing either subacromial decompression or arthroscopic labral repair. Bupivacaine (0.5% with epinephrine) infused at 2 mL/hour was compared with the control group that had the catheter simply taped on the skin and concealed. Narcotic consumption, subjective pain scores, and recovery of motion were not different in the 2 groups.

Studies to date on infusion pump use after rotator cuff repair have been after open surgery. Duralde, McCollam, and Scherger¹³ presented a study of 58 patients who underwent open rotator cuff repair randomized to receive either an interscalene block or an infusion pump delivering 0.25% bupivacaine at 5 mL/hour. One complication requiring hospital admission was reported in a patient who received an interscalene block. Both modalities were reported to be effective at reducing pain. Another study of 50 patients with open acromioplasty and rotator cuff repair randomized to receive 0.25% bupivacaine or saline at 6 mL/hour

reported no effect on postoperative pain or narcotic use.¹⁴

Our study was limited by the low numbers of patients enrolled, providing only a 60% power for our study. A larger patient cohort would have provided a larger power, perhaps providing more conclusive results.

Although the animal studies have indicated a connection between chondrolysis and bupivacaine,³⁻⁵ no human studies yet have corroborated these findings. Hansen's¹ report indicates that intra-articular infusions of bupivacaine may be associated with postarthroscopic glenohumeral chondrolysis. Our use of the bupivacaine infusion pump in shoulders predates these studies; however, more research is warranted into the effects of bupivacaine infusion in shoulders.

The senior author has used infusion pumps for the majority of shoulder arthroscopies and arthroscopic-assisted ACL reconstructions since 1994. In more than 500 cases, no deep infection and no case of bupivacaine toxicity has been reported. A randomized clinical study assessing the usefulness of the infusion pump in ACL reconstruction was similar in design to the current study, yet showed an overall decrease in narcotic consumption and pain VAS scores of approximately 30% with the use of the infusion pump.¹⁵ Rotator cuff repair may not be a good model for assessing the usefulness of the infusion pump, because in our experience pain is highly variable among patients after this procedure.

CONCLUSIONS

This study neither supports nor refutes the use of infusion pumps. We hypothesized that the placebo

group would experience greater pain than the 2-mL group or the 5-mL group. However, a nonsignificant trend toward the contrary occurred. A nonsignificant trend toward less pain in the 2-mL group than in the 5-mL group was found.

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