The Efficacy of Continuous Bupivacaine Infiltration Following Anterior Cruciate Ligament Reconstruction

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Purpose: The purpose of this study was to determine whether continuous infiltration of a local anesthetic into the surgical wound for 48 hours will diminish the need for narcotics and improve the postoperative pain experience for patients undergoing anterior cruciate ligament (ACL) reconstruction using a patellar tendon autograft. **Type of Study:** Prospective, randomized, double-blind study with a placebo and an experimental group. **Methods:** Twenty-six patients were randomly assigned to receive either normal saline (placebo) or bupivacaine (experimental) for 48 hours. Both groups received a single intra-articular bolus injection of 35 mL of 0.25% bupivacaine and 5 mg. of morphine at the conclusion of surgery. The placebo group received an infusion of 2 mL/h of normal saline and the experimental group received an infusion of 2 mL/h of 0.25% bupivacaine, both for 48 hours. The anesthetic was infused using a disposable elastomeric pump (Baxter Healthcare, Deerfield, IL). Patients were evaluated using a pain and pain relief assessment questionnaire and visual analogue scale (VAS). Narcotic consumption was also documented. The pump was discontinued either by the patient at home or by a physical therapist. **Results:** There was a statistically significant ($P < .05$) difference in VAS pain and pain relief scores reported by patients receiving the infusion of 0.25% bupivacaine. Patients in the treatment group also consumed 37% less narcotics than the placebo group. The operating room time, tourniquet time, weight, and age of this population were similar in the 2 groups. There were no complications with the catheter technique. **Conclusion:** This report of a new technique suggests that surgical knee patients receiving local anesthetic infusion postoperatively experience less pain and require less narcotics. The disposable pump allowed administration of the medication on an outpatient basis. **Key Words:** Bupivacaine—ACL reconstruction—Continuous local anesthetic—Outpatient pain management—Elastomeric pump.

Outpatient surgery is one of the fastest growing fields in health care, particularly within the specialty of orthopedics. This is a result of improved surgical techniques, changes in orthopedic technology and recovery from anesthesia. Care of the orthopedic patient within this outpatient surgical environment requires that the surgeon and nursing staff focus on current and breakthrough methods to provide patients with improved pain management techniques. With this goal in mind, the investigators evaluated a combination bolus and continuous bupivacaine infusion technique. The primary goal was to determine whether this technique would be an improvement compared with placebo. Additional goals included evaluating the safety of the catheter in a postoperative wound and whether patients were able to safely discontinue the catheter at home.

Traditional postoperative pain management for ACL reconstruction consists of intermittent use of intravenous or subcutaneous narcotics in the early recovery phase. Unfortunately this technique is often accompanied by breakthrough pain. During this time, the neuronal pathways may become sensitized and

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sensitized neurons may interpret stimulus such as touch or temperature as pain.[1] Increased and prolonged dosages of narcotics or a similar medication may be required, and the potential for developing a chronic pain syndrome is increased.[1]

Chirwa et al.[2] demonstrated in 1989 that a local soft tissue anesthetic such as bupivacaine is usually effective for 2 hours depending on the area of infiltration and the amount of anesthetic used. Stein et al.[3] and McSwiney et al.[4] further noted that low doses of intra-articular morphine (1 to 5 mg) may prolong the analgesic effect. Therefore, researchers hypothesized that continuous low-dose infiltration of a local anesthetic for 48 hours may not only diminish the need for oral narcotics or other medications during that time, but also may further enhance recovery. The anesthetic is infused using a disposable elastomeric pump (Baxter Healthcare, Deerfield, IL). This technique has been used by the senior author (H.R.H.) with over 300 patients since 1995. Subjective reports by patients have been encouraging, but to date, no blinded, randomized, placebo-controlled trial has been published demonstrating the efficacy of this technique. The primary objective of this study is to determine if a continuous low-dose infiltration of local anesthetic into the postoperative ACL reconstruction wound will diminish the need for narcotics or other analgesic drugs, lower postoperative pain, and offer greater pain relief for 48 hours after surgery.

METHODS

Subjects

Patients undergoing ACL reconstruction with a patellar tendon autograft, using an endoscopic approach through a single anterior incision, were prospectively randomized using a computer-generated list. Each patient had a 50% chance of receiving either placebo or bupivacaine. The surgeon, staff, and patients were blinded to which treatment the patient received.

Patients undergoing concurrent chondroplasty or meniscus resection or repair were included if additional incisions were not made. Conversely, patients having an incision for additional procedures such as repair or reconstruction of other ligaments were excluded. Patients with a history of chronic pain, drug abuse, or alcoholism were also excluded from the study.

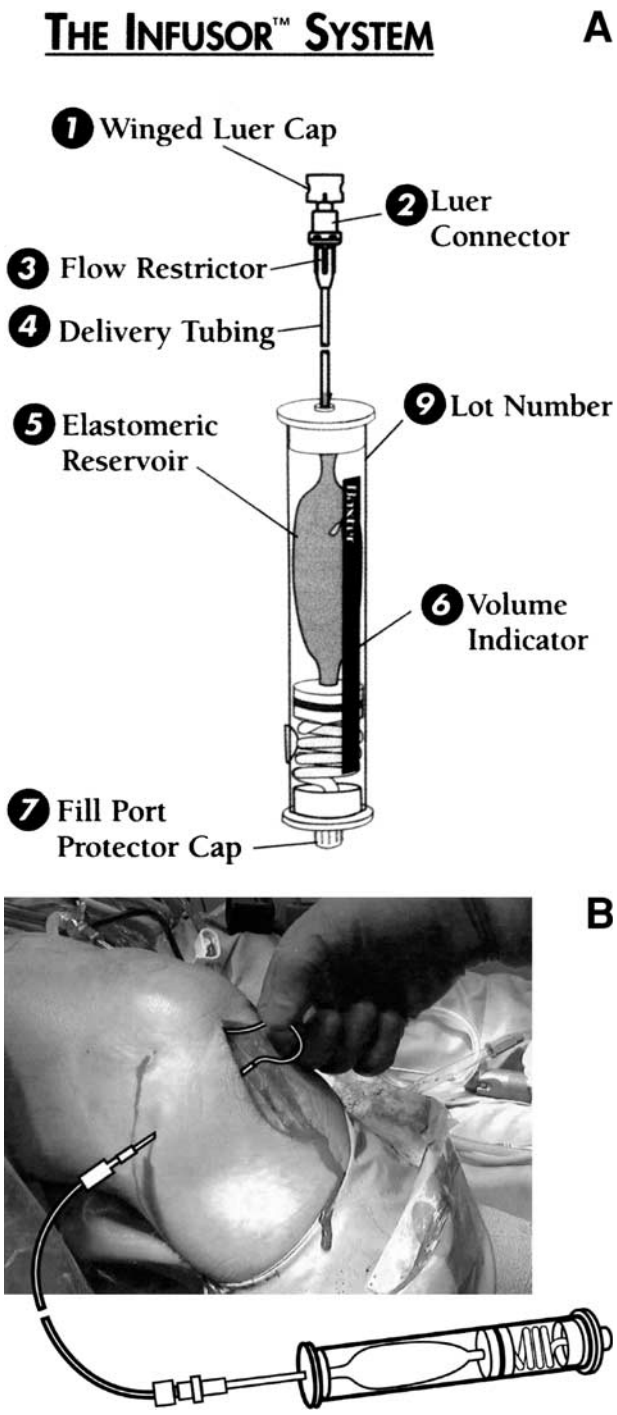

FIGURE 1. (A) The infusor consists of pressure applied by an elastomeric reservoir flowing through a restrictor that controls the rate of infusion. (B) The catheter is placed in the patella tendon defect.

TABLE 1. *Demographics*

Group	N	Age (yr)*	Sex	Operating Room Time (min)†	Tourniquet Time (min)‡	PACU Time (hs)‡
Placebo	14	36.0 range, 24-46	F = 6 M = 8	111 range, 83-148	55 range, 34-73	2.23 range, 1.2-4.0
Bupivacaine	12	36.7 range, 25-49	F = 1 M = 11	118 range, 85-153	64 range, 46-92	1.75 range, 1.0-2.8

*$P = .39$.
†$P = .21$.
‡$P = .06$.

Methods

At the end of the surgery, both groups had a 20-gauge catheter tunneled subcutaneously to the donor site of the patellar tendon and the anterior fat pad. A bolus injection consisting of 25 mL of 0.25% bupivacaine and 5 mg of morphine was injected into the patellar tendon donor site and intra-articular space. The patient was then randomized to the placebo or experimental group in the operating room. Patients, nurses, and investigators were blinded as to treatment. The placebo group received an infusion of normal saline (NS) infused at 2 mL/h for 48 hours, and the experimental group received 0.25% bupivacaine infused at 2 mL/h for 48 hours. The infusor consisted of pressure applied by an elastomeric reservoir (balloon); flow was metered (at a rate of 2 mL/h) by an inline restrictor attached to the infusion (Fig 1). Patients were instructed on removal of the device preoperatively and at hospital discharge. They were instructed to remove the catheter from the wound themselves at 48 hours or before if the infusor was empty. In addition, patients routinely work with a physical therapist between 24 and 48 hours postoperatively and were able to have a therapist discontinue the catheter at that time.

Patients were asked by a nurse to assess their level of pain on awakening in the Post Anesthesia Care Unit (PACU), and at 2, 4, 12, 18, 24, 36, and 48 hours after surgery. A visual analogue scale (VAS) and word descriptors were used for pain and pain relief assessment. Pain and pain relief scores and narcotic use was recorded by the study coordinator (P.A.P.) while the patients were in the hospital, and then by the patient at home. The short form pain questionnaire described by Melzack[5] was used. This consists of a 10-cm line with 0 at one end representing "no pain" and 10 at the other end representing "worst possible pain." A similar line is used to measure pain relief, with 0 at one end representing "no relief" and 10 at the other end representing "complete relief."

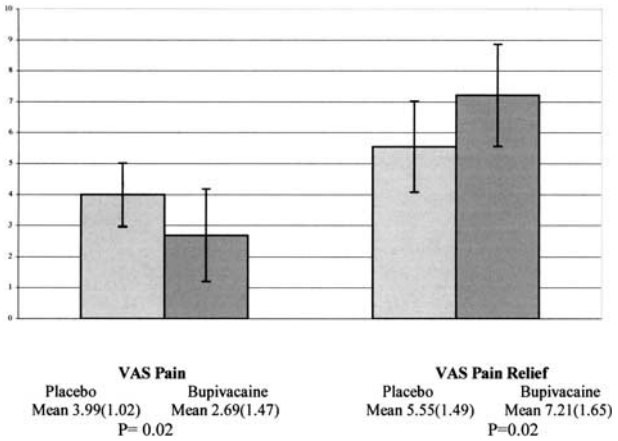

FIGURE 2. VAS pain and pain relief scores.

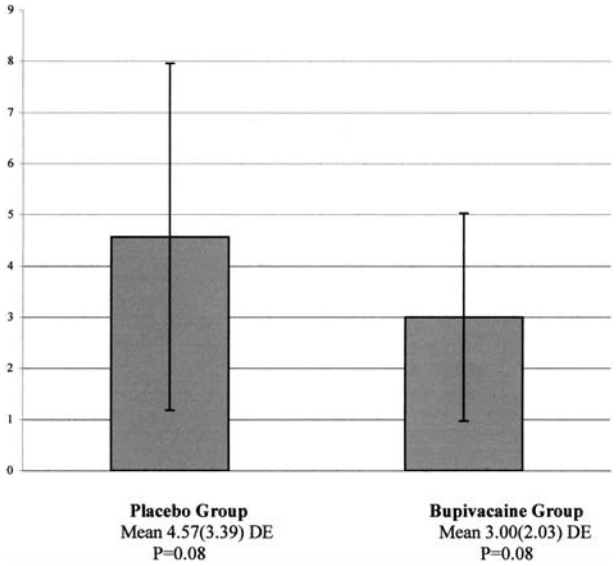

FIGURE 3. Total dose equivalent (DE) of narcotics is shown.

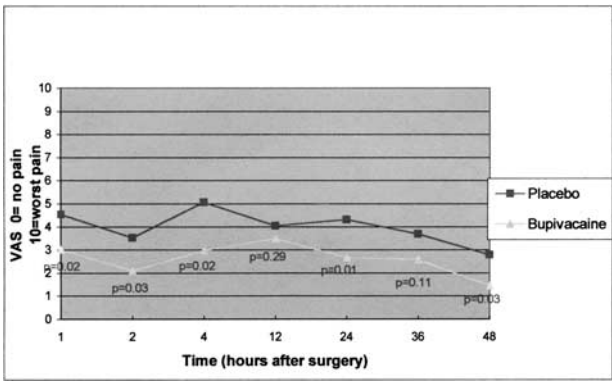

FIGURE 4. VAS pain scores at time intervals.

Narcotics were converted to a dose equivalency (DE) system with conversion factors from Drug Facts and Comparisons.[6] For example, 10 mg of morphine sulfate equals 1 DE. This includes supplemental or rescue narcotics. Knee range of motion was recorded by the therapist for the first 3 postoperative visits.

Data analysis consisted of both descriptive statistics and a student t-test assuming unequal variances. Alpha level was set at 5% with a power of 90% for a desired sample size of 30 patients for each group based on the power analysis. The efficacy of the 48 hour total pain and pain relief measurement and total narcotic usage for that same period were examined. However, because this was a preliminary evidence-based outcomes study, results were analyzed prior to completing data collection for the desired number of patients for each group. Statistical significance was achieved for the primary outcomes of pain and pain relief measurement.

RESULTS

Twenty-six patients were enrolled in the study and signed a Human Subjects Committee approved consent form. There was no difference in the demographic characteristics of the two groups (Table 1). Fifty percent of patients in each group had ACL reconstruction alone and 50% in each group had ACL reconstruction with either lateral or medial meniscus repair. A statistically significant difference ($P < .05$) was noted in the VAS pain scores (4.0 *v* 2.7) and VAS pain relief scores (5.6 *v* 7.2) in the patients receiving the infusion of 0.25% bupivacaine compared with the placebo group for the 48 hour period (Fig 2). Patients in the bupivacaine group also consumed 37% less narcotics (3.0 DE) than those in the placebo group (4.6 DE; $P = .08$; Fig 3). The VAS pain score was consistently lower and the VAS pain relief score was consistently higher in the bupivacaine group (Figs 4 and 5).

Seventy-nine percent of patients terminated the infusor when it was empty; the remaining 27% terminated it at three-quarters empty. The average time the infusor was in place was 46.0 hours. Fifty-four percent of the infusors were discontinued by the patient, and 42% were discontinued by a physical therapist. In one case, a family member or significant other discontinued the infusor.

One patient experienced a wound hematoma and 1 experienced a superficial wound infection distant from the catheter site. Ninety-two percent of the patients reported no problems or malfunctions with their pump and 1 patient reported leakage at the catheter connection site. One patient changed his mind and pulled the pump out prior to 48 hours. However, there were no complications related to the medication or the pump. Neither the placebo group nor the experimental group demonstrated a difference in range of motion in the knee.

DISCUSSION

Continuous infiltration of local anesthetic is one method of providing pain relief for 48 hours postoperatively. The total dose of local anesthetic remained within safe and acceptable limits. For example, the bolus injection of 25 mL of 0.25% bupivacaine or 62.5 mg plus 0.25% at 2 mL/h for the first 24 hours (120 mg) equals 182.5 mg in a 24-hour period. This does not exceed the published recommended limit of 400 mg for the first 24 hours.[7] The addition of 0.25% bupivacaine at 2 mL/h from 24 to 48 hours equates to a 302.5 mg total for the 48-hour period, still below the

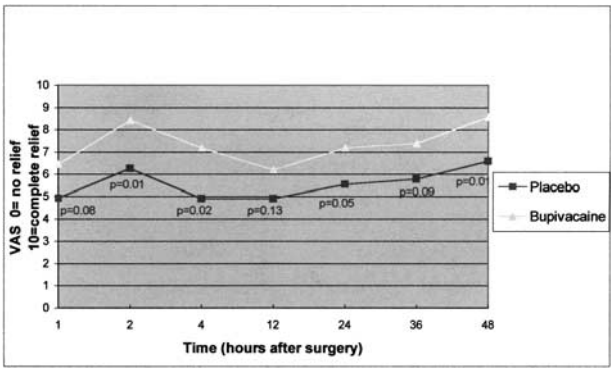

FIGURE 5. VAS pain relief score at time intervals.

per 24-hour maximum recommended dose. This technique was well received by patients and by nursing staff. It required no manipulation by the patient or staff until it was removed at approximately 48 hours.

The bolus administration of 5 mg of morphine may extend the effect of the initial bolus injection of bupivacaine[3,4] in both the placebo and experimental group.

The patellar tendon donor site was chosen for initial infusion of the anesthetic to minimize the risk of an intra-articular infection. This practice has now been performed in more then 300 patients, with no reports of deep infections. One patient in this study developed a superficial suture abscess that did not communicate with the catheter site and responded to local debridement of the suture and oral antibiotics. Historically, the surgeons participating in this study routinely administered a prophylactic dose of cephazolin 1 g intravenously at the beginning of the surgical procedure. This practice was continued during the study.

Recent information on neurosensory mapping for the knee suggests that the anterior knee is very sensitive in relation to other sites.[8] Further studies may be helpful to determine optimal catheter placement sites. The flow rate of 2 mL/h was also chosen to minimize toxicity and for the commercial availability of pumps.

CONCLUSIONS

No previously published study reports on the efficacy and safety of this procedure in spite of the popular use of this technique. This initial report suggests that continuous administration of bupivacaine for 48 hours results in decreased pain levels and greater pain relief reported by patients. There was a trend toward reduced narcotic consumption, but this was not significant. This technique has also been used on an outpatient basis with patients successfully discontinuing the pump at home. This study can provide a basis for expanded study and use of this technique in ACL reconstruction, as well as in other operative joint procedures.

REFERENCES

1. Woolf CJ, Chong M-S. Preemptive analgesia-treating postoperative pain by preventing the establishment of central sensitization. *Anesth Analg* 1993;77:362-379.
2. Chirwa SS, MacLeod BA, Day B. Intraarticular bupivacaine (Marcaine) after arthroscopic meniscectomy: A randomized double-blind controlled study. *Arthroscopy* 1989;5:33-35.
3. Stein C, Comisel K, Haimerl E, et al. Analgesic effect of intra-articular morphine after arthroscopic knee surgery. *N Engl J Med* 1991;325:1123-1126.
4. McSwiney MM, Joshi GP, Kenny P, McCarroll SM. Analgesia following arthroscopic knee surgery: A controlled study of intra-articular morphine, bupivacaine or both combined. *Anaesth Intensive Care* 1993;21:210-213.
5. Melzack R. The short-form McGill Pain Questionnaire. *Pain* 1987;30:191-197.
6. Hebel SK, Burnham TH, eds. *Drug Facts and Comparisons*. St. Louis, MO: Facts and Comparisons, 1996:242b.
7. Abbott Laboratories. Bupivacaine Hydrochloride Injection and Bupivacaine Epinephrine Injection Package Inserts. North Chicago, IL: Abbott Laboratories, 1998.
8. Dye SF, Vaupel GL, Dye CC. Conscious neurosensory mapping of the internal structures of the human knee without intraarticular anesthesia. *Am J Sports Med* 1998;26:773-777.