Evaluation of Postoperative Bupivacaine Infusion for Pain Management After Anterior Cruciate Ligament Reconstruction

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Purpose: Postoperative pain control has received increasing attention by health care providers in the new millennium. In fact, pain was called the "sixth vital sign" by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 2001. The continued challenge of effective, safe analgesia in the outpatient setting has promoted the use of various devices designed to deliver local anesthetic directly to the surgical site. We endeavored to evaluate the efficacy of one such device currently in use. **Type of Study:** Prospective, randomized, placebo-controlled, double-blinded study. **Methods:** In this study, 49 consecutive patients were prospectively enrolled and randomly assigned to 1 of 3 groups after anterior cruciate ligament (ACL) reconstruction. Patients and investigators were blinded to group assignment. Group 1 (control group) received no catheter. Group 2 (placebo group) received an infusion catheter filled with saline. Group 3 (experimental group) received the same catheter filled with 0.25% bupivacaine solution. All patients received an ipsilateral femoral nerve block with 30 mL 0.25% bupivacaine and 20 mL 0.25% bupivacaine intra-articular injection. Patients recorded narcotic consumption and pain levels on visual analogue scales twice a day for 4 days after surgery. The catheters were removed on day 4 and physical therapy performance was recorded. The patients were then asked to continue to record pain ratings and medication consumption for an additional 4 days after catheter removal. All patients underwent bone–patellar tendon–bone ACL reconstruction by the senior author (P.D.F.). Seven patients were excluded from the study for ineffective femoral nerve block or catheter disconnection or occlusion. Narcotic consumption and the maximum, minimum, and median pain ratings were analyzed by analysis of variance. **Results:** Median pain ratings show lower pain levels ($P < .03$) for both catheter groups versus the control group. No significant differences were found between the catheter groups for the median pain ratings, but lower maximum pain ratings were seen in the bupivacaine group compared with both placebo and no-catheter control subjects. Postoperative narcotic consumption was also lower in both catheter groups versus control subjects ($P < .03$). Physical therapy data revealed no difference in range of motion on postoperative day 4. More patients were able to perform straight leg raises during the first therapy session in both the saline placebo catheter group (70%) and bupivacaine group (72%) compared with the control group (50%). **Conclusions:** The data suggest some element of placebo benefit at median pain ratings but a protective effect of the bupivacaine at maximum pain levels. **Key Words:** ACL reconstruction—Pain management—Bupivacaine infusion catheter.

Orthopaedic surgeons routinely perform anterior cruciate ligament (ACL) reconstructions in an outpatient setting rather than admit the patient to the hospital postoperatively. The continued challenge of effective, safe analgesia in the outpatient setting has promoted the use of various devices designed to deliver local anesthetic directly to the surgical site. Anecdotal reports describe good pain control with bupivacaine catheters.[1-3] Previous studies that have attempted to analyze the efficacy of these devices have failed to do so in a truly controlled manner. To our knowledge, no prospective, randomized, placebo-controlled, double-blinded study of postoperative analgesia provided by a bupivacaine infusion catheter in orthopaedic surgery has been conducted. We present

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our data of the first study of this type used in the setting of ACL reconstruction.

The purpose of this study was to evaluate the efficacy of a continuous bupivacaine infusion pump. This pump delivers anesthetic agents intra-articularly after ACL reconstruction. We examined the adequacy of pain control as reflected by visual analogue scores and patient narcotic consumption in the immediate postoperative period, both with the catheters in place and after they were removed. We also evaluated each patient's performance during the first physical therapy session.

We hypothesize that the use of a Painbuster continuous infusion pump (I-Flow, Lake Forest, CA) to deliver 0.25% bupivacaine to the surgical site would result in better pain control in the postoperative period, as reflected by patients' reports of visual analogue scales and oral narcotic consumption. Based on previous work,[4] we predict that that effective, lasting postoperative anesthetics may result in improved initial physical therapy performance during the early therapy sessions.

METHODS

In this study, 49 consecutive patients who prospectively enrolled were randomly assigned to 1 of 3 groups after ACL reconstruction. The randomization process was a random number draw conducted in the operating suite by a circulating nurse, and the group assignment and patient identification were recorded in a separate sealed notebook. Group 1 (control group) received no catheter, group 2 (placebo group) received an infusion catheter with saline, and group 3 (experimental group) received the same catheter filled with 200 mL 0.25% bupivacaine solution without epinephrine. Both patient and investigators were blinded to the catheter contents and group assignment. All patients received an ipsilateral nerve stimulator-guided femoral nerve block with 30 mL 0.25% bupivacaine before surgery, as well as 20 mL 0.25% bupivacaine intra-articular injection at the completion of the surgical procedure. The catheters were placed in the anterior joint space through a lateral puncture. Preoperatively, all patients were examined carefully under anesthesia, and a systematic diagnostic arthroscopy was performed before ACL reconstruction. Patients with significant associated injuries to the knee were excluded from the study, because these injuries represent potential confounding elements with respect to outcome parameters and pain assessments. Injuries that were excluded from the study were an incompetent posterior cruciate ligament (PCL) or PCL rupture; collateral ligament injury or frank instability to varus or valgus; fracture of femur, tibia, or fibula; an osteochondral defect greater than 5 mm; or grade II or greater chondrosis. The senior author (P.D.F.) reconstructed all ACLs using autologous ipsilateral bone–patellar tendon–bone graft with a single midline incision and 2 anterior portals. No patients involved with Workers' Compensation cases were included in the study. Seven patients were excluded from the study for ineffective femoral nerve block (4 patients), and catheter disconnection or occlusion (3 patients).

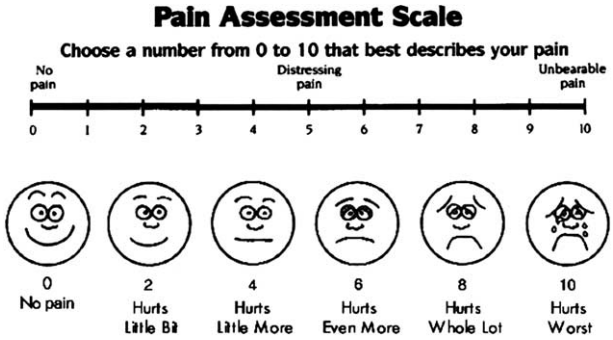

FIGURE 1. Pain assessment scale.

After the femoral nerve block and intra-articular bupivacaine wore off, postoperative pain management protocol for all patients included hydrocodone/acetaminophen, 5 mg/500 mg, orally every 4 hours as needed and ibuprofen, 800 mg, orally 3 times a day. In addition, all patients were instructed to rest, ice, and elevate the immobilized leg during the immediate postoperative period. Patients recorded medication consumption and pain levels twice a day for 4 days after surgery. Responses were recorded on visual analogue scales previously used and tested for reproducibility (Fig 1). [5]

The catheters were removed on day 4, and initial physical therapy performance was recorded on that day by 1 of 3 randomly assigned certified physical therapists. The therapists were blinded to patient group assignment. They recorded information regarding the condition of the catheter to confirm function (bulb volume, catheter connectivity, signs of infection). In addition, they recorded initial therapy performance, including each patient's range of motion and ability to perform straight leg raises. The patients were then asked to continue to record pain ratings and medication consumption for an additional 4 days after catheter removal. The data were analyzed using Instat

TABLE 1. *Patient Characteristics*

Subject No.	Group Assignment	Sex	Operative Side	Age	Associated Injury	Additional Treatment
1	No catheter	M	R	32	mmt	pmm
2	Saline catheter	M	L	43		
3	No catheter	F	L	32	mmt	mm repair
4	Bupivacaine catheter	M	R	39		
5	Saline catheter	F	R	16		
6	No catheter	M	R	17		
7	No catheter	M	L	17	lmt	plm
8	Bupivacaine catheter	F	L	42		
9	Saline catheter	M	R	19	mmt	pmm
10	Bupivacaine catheter	M	L	16		
11	No catheter	F	L	45		
12	Bupivacaine catheter	M	R	30		
13	Saline catheter	M	L	38	mmt	pmm
14	No catheter	F	L	46		
15	Saline catheter	M	R	42		
16	No catheter	M	R	41		
17	Bupivacaine catheter	F	L	46		
18	No catheter	F	L	23		
19	Bupivacaine catheter	F	R	18	lmt	plm
20	Bupivacaine catheter	M	L	43		
21	Saline catheter	F	R	50		
22	No catheter	F	L	30		
23	Saline catheter	F	L	44		
24	No catheter	M	L	43	mmt	pmm
25	Bupivacaine catheter	F	L	29	mmt	pmm
26	Bupivacaine catheter	F	R	33		
27	No catheter	M	R	22		
28	Bupivacaine catheter	F	R	15		
29	Saline catheter	F	R	21	mmt	pmm
30	No catheter	M	R	42	mmt	pmm
31	Bupivacaine catheter	F	L	22	mmt	mm repair
32	Bupivacaine catheter	M	L	19		
33	Saline catheter	M	L	33		
34	Saline catheter	F	R	40	mmt	pmm
35	Bupivacaine catheter	M	L	35	mmt	pmm
36	Bupivacaine catheter	M	L	37		
37	No catheter	F	L	34		
38	Bupivacaine catheter	M	R	50	lmt	plm
39	Saline catheter	M	L	28	mmt	mm repair
40	Saline catheter	F	R	31	mmt, lmt	pmm, plm
41	No catheter	M	L	19		
42	Bupivacaine catheter	M	R	37	mmt	pmm

Abbreviations: mmt, medial meniscal tear; lmt, lateral meniscal tear; pmm, partial medial meniscectomy; plm, partial lateral meniscectomy; mm repair, medial meniscal repair with meniscal arrow.

(Graphpad Software, San Diego, CA) by analysis of variance.

RESULTS

The 3 groups were well matched with regard to age, gender, and affected side (Tables 1 and 2). Of the 42 patients remaining, none experienced readmission, infection, wound complications, excessive swelling, or bupivacaine toxicity.[6] No significant differences were found in tourniquet times or recovery room medications given to patients.

Pain Rating Data

Minimum, maximum, and median pain ratings were compared among the 3 groups. The bupivacaine infusion catheter (experimental group) patients reported

TABLE 2. *Patient Characteristics: Patients Were Well Matched for Gender, Age, Operative Side, and Incidence of Associated Meniscal Injury*

Group	No.	Male	Female	Right	Left	Mean age (y)	Assoc Injury
No catheter	14	8	6	5	9	29.6 ± 11	5 (35%)
Saline catheter	12	6	6	7	5	30.7 ± 11	6 (50%)
Marcaine catheter	16	9	7	7	9	29.8 ± 11	7 (43%)
Totals	42	23	19	19	23	30.0 ± 11	18 (42%)

lower maximum pain than the placebo or control groups while the catheters were in place ($P < .03$). This difference normalizes during days 5 to 8 after catheter removal. The patients in the bupivacaine group reported higher maximum pain after removal, and the control and saline groups had lower maximum ratings after catheter removal (Fig 2).

Lower median pain ratings ($P < .05$) were found for both the placebo and bupivacaine infusion groups when compared with the groups with no catheter. This difference did not persist after the catheters were removed (Fig 3).

A trend was found for lower minimum pain ratings for the bupivacaine infusion group compared with both the saline control group and the group with no catheters, but this relationship was reversed after catheter removal. It was not statistically significant (Fig 4).

Medication Consumption Data

Less narcotic medication was used by the saline group than the group with no catheter ($P < .05$). The bupivacaine group also showed a trend to use less narcotic medication than the group without a catheter, but this was not statistically significant (Fig 5). The 3 groups maintained this relationship after catheter removal on day 4. A review of ibuprofen medication consumption showed that all patients were compliant with 3 times a day ibuprofen consumption around the clock.

Physical Therapy Data

A χ-square test for trend showed a statistically significantly higher percentage of patients able to perform straight leg raises during the first therapy session in both the saline placebo group (70%) and the bupivacaine group (72%) when compared with the no-catheter control group (50%).

With rare exceptions (7%), all patients were able to achieve full extension at the first therapy session on postoperative day 4. A slightly higher arc of flexion for the bupivacaine group (71°) versus the saline (56°) and control (60°) groups was seen, but this difference was not statistically significant. All patients were able

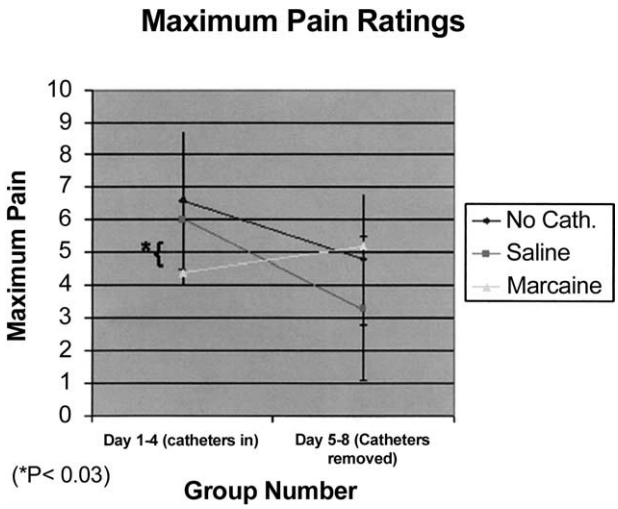

FIGURE 2. Average maximum pain ratings for control, saline, and bupivacaine groups for days 1 to 4 (with catheters) and days 5 to 8 (without catheters).

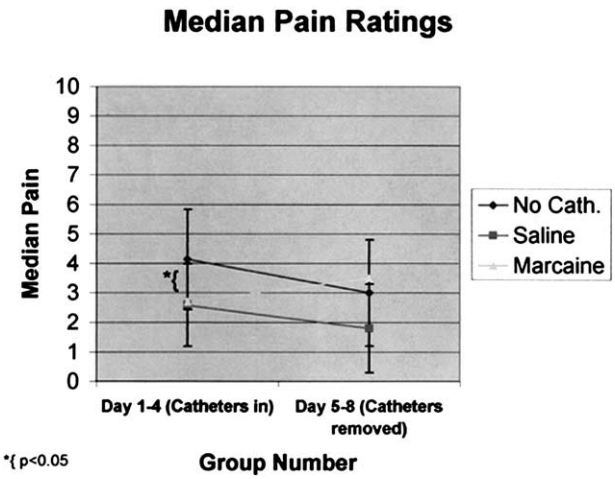

FIGURE 3. Median pain ratings for control, saline, and bupivacaine groups for days 1 to 4 (with catheters) and days 5 to 8 (without catheters).

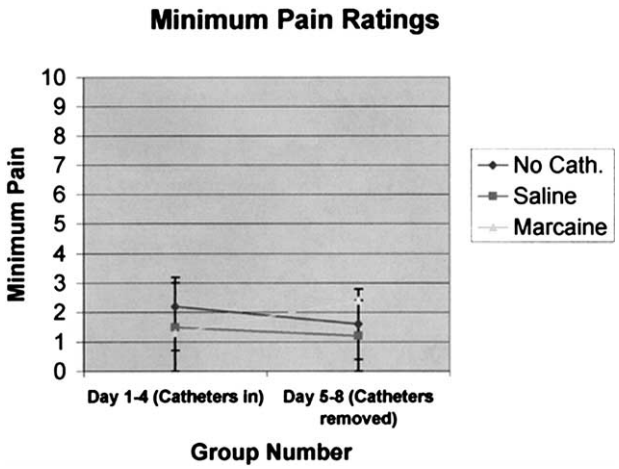

FIGURE 4. Minimum pain ratings for control, saline, and bupivacaine groups for days 1 to 4 (with catheters) and days 5 to 8 (without catheters).

to achieve full extension and almost 90° flexion by postoperative day 8.

DISCUSSION

Outpatient ACL reconstruction has improved overall patient satisfaction and allowed earlier return to work or athletic competition.[7] In addition, the reduced consumption of hospital resources may save between $3,000 and $5,000[8,9] in costs per case. Although outpatient management of ACL reconstruction has been shown to be safe,[7,10] postoperative pain management continues to be a challenge. One series reported a repeat admission rate as high as 6.1% for problems with pain control.[11]

Postoperative pain control has generated increasing attention in the new millennium. In 2001, pain was named the "sixth vital sign" by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and documentation of postoperative pain assessment by health care providers is now a required feature of medical records.[12]

In several controlled studies, patients report poor pain control in situations in which local anesthetic or spinal anesthetic (0.25% bupivacaine) is not used, resulting in larger consumption of oral narcotic medication.[4,13] In situations in which local anesthetic was used, pain was much better controlled. In these situations, patients required less oral pain medication but only for the duration of the local anesthetic effect.[13-15] Continuous infusion of local anesthetic has been used to provide a lasting interscalene nerve block in patients undergoing shoulder surgery.[16,17] This resulted in higher comfort levels and less narcotic consumption while the nerve block was in effect.

In addition to increased patient satisfaction and decreased narcotic consumption, adequacy of postoperative pain control has correlated with physical therapy progress and functional outcome, including range of motion and ability to perform straight leg raises after ACL reconstruction.[4] In fact, postoperative bupivacaine blocks have been shown to improve postoperative function and rehabilitation success after shoulder surgery.[18,19] Clearly, safe, effective, postoperative pain control after ACL reconstruction is important for patient outcome, surgery costs, and patient satisfaction.

The continued challenge of providing safe, effective, lasting postoperative analgesia has led to the increased use of local anesthetic-infusion catheters. These typically involve a small elastomeric bulb containing a quantity of infusible local anesthetic, such as bupivacaine and a flow-regulated catheter that is inserted into the wound. Previously reported trials of the use of an infusion catheter in orthopaedic surgery have been promising. In 2000, Savoie et al.[20] reported on a series of 62 patients with either a saline catheter or bupivacaine catheter after arthroscopic subacromial decompression. They found lower pain levels in those patients with bupivacaine catheters. However, that series did not include a group without a catheter as a control, which makes evaluating the magnitude of any placebo effect from the catheter itself difficult.[20] Sev-

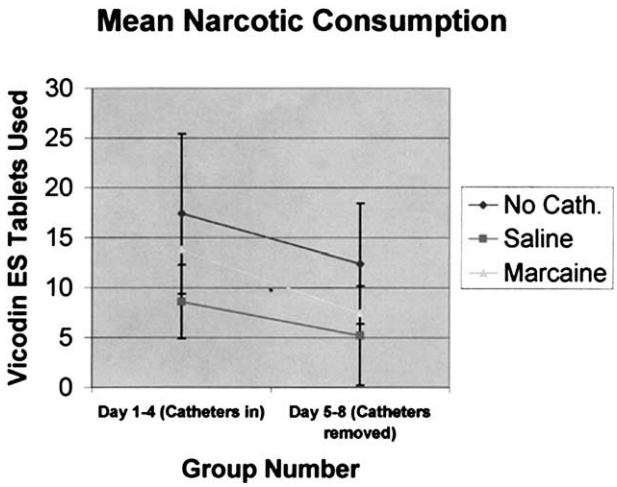

FIGURE 5. Mean narcotic use for control, saline, and bupivacaine groups for days 1 to 4 (with catheters) and days 5 to 8 (without catheters). Vicodin ES tablets are Vicodin extra strength (hydrocodone, 7.5 mg; acetaminophen, 750 mg).

eral other anecdotal reports of pain control success after arthroscopic Bankart repair, arthroscopic rotator cuff repair,[1,2] and arthroscopic-assisted ACL reconstruction[3] have been published. However, these studies, although promising, do not present placebo-controlled data. To our knowledge, our data represent the first published results of a prospective, randomized, double-blinded, placebo-controlled evaluation of a bupivacaine infusion catheter device after ACL reconstruction.

Pain Rating Data

To better understand the specific effect of bupivacaine infusion, we analyzed our data by examining the maximum, minimum, and median pain ratings reported by patients. Some pain rating studies[4,14,15] have only evaluated mean or median pain ratings, which may not fully characterize patients' experience of postoperative pain. This experience often produces moments of "spiking" pain. By stratifying the data as we have, we are better able to describe the quality of pain relief offered by bupivacaine infusion.

Maximum pain ratings for days 1 to 4 show a statistically significant benefit of bupivacaine treatment compared with saline and no catheter controls. The fact that this relationship changes after catheter removal (days 5 to 8) suggests an independent effect of bupivacaine in lowering the maximum pain experienced by patients after surgery. Researchers would expect patients to report progressively lower pain in the saline and control groups as time passed (day 4 *v* day 8) after surgery, and our data show this gradual decrease. Conversely, after removing a pain-reducing instrument, an increase in pain ratings could be expected from patients who had their bupivacaine infusions stopped. We noted this increase in maximum pain ratings in the bupivacaine groups after removal of the catheter, which suggests that bupivacaine infusion has the ability to protect patients from spikes of maximum pain. This protective effect was not seen in the placebo group.

Analysis of the median pain reports indicates equal benefit for both the saline and bupivacaine catheter groups compared with the group without an infusion catheter. Again, we saw a slight increase in pain ratings from the bupivacaine group after catheter removal, whereas the saline and control groups maintained a parallel relationship, trending lower as time progressed.

The minimum pain rating data show a similar trend of comparatively lower initial bupivacaine ratings that are lost on catheter removal. This trend is not statistically significant. For all 3 data groups (maximum, minimum, and median), the saline and control groups maintain a parallel relationship, suggesting that they respond similarly as time progresses. People tend to have less pain further from surgery. In all 3 data groups (maximum, minimum, median), however, increased pain ratings are seen in the bupivacaine catheter groups after the catheters are removed. This result suggests the removal of a pain-ameliorating element.

In the higher pain ratings (maximum pain), we see the greatest independent benefit for bupivacaine. This is our only statistically shown benefit of bupivacaine infusion over saline infusion. We believe this represents a protective effect of the bupivacaine infusion to prevent the spikes of extreme pain that patients experience. This anesthetic benefit is not as visible at lower pain levels, possibly because of patients' belief in the benefit of a catheter itself. This could correspond with a tendency to report lower pain ratings. This study suggests some element of placebo effect from the presence of a catheter at lower pain levels, but also shows the protective effect of bupivacaine from spikes of extreme (maximum) pain.

Physical Therapy Data

Previous work has shown a strong correlation between postoperative pain and an inability to perform straight leg raises.[4] In our data series, the patients with saline and bupivacaine catheters were both more likely to be able to perform a straight leg raise compared with the group with no catheter. This greater ability to perform straight leg raises in the bupivacaine and saline catheter patients may be because of a higher motivation in these patients caused by their belief in the benefit of the catheter. Anecdotal reports from our therapy department describe patients' increased effort and excitement about "getting the juice," referring to the catheter contents, regardless of type of infusion. Being motivated by the presence of a catheter may represent a placebo effect. Our findings do not necessarily contradict earlier work correlating pain and straight leg raise ability, because in some ranges of pain, high levels of motivation can overcome pain.

Narcotic Consumption Data

As would be expected, the saline and no catheter groups required less narcotic medication as time passed after surgery. After removal of the bupivacaine catheters, the patients did not report a statistically significantly higher amount of narcotic medication

consumption, despite reporting higher pain. The lower narcotic consumption in the saline group versus the control group may have been caused by patient expectations that they would require less pain medication.

In summary, our data for median pain ratings suggest some element of placebo benefit to undergoing postoperative catheter placement in the knee. However, bupivacaine infusion does appear to have a protective effect at maximum pain levels. The patients' belief in the benefit of the catheter itself, regardless of its contents, may promote lower narcotic consumption and a higher motivation to perform therapy tasks. The ability of the bupivacaine infusion to protect patients from spikes of maximum pain appears to be independent of saline placebo and could represent a real benefit offered by bupivacaine infusion.

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