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General Health and Knee Function Outcomes from Seven Days to Twelve Weeks After Spinal Anesthesia and Multimodal Analgesia for Anterior Cruciate Ligament Reconstruction

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Abstract

Background—We previously reported that continuous perineural femoral analgesia reduces pain with movement during the first 2 days after anterior cruciate ligament reconstruction (ACLR, n=270), when compared with multimodal analgesia and placebo perineural femoral infusion. We now report the prospectively collected general health and knee function outcomes in the 7 days to 12 weeks after surgery in these same patients.

Methods—At 3 points during 12 weeks after ACLR surgery, patients completed the SF-36 General Health Survey, and the Knee Outcome Survey (KOS). Generalized Estimating Equations were implemented to evaluate the association between patient-reported survey outcomes and (i) preoperative baseline survey scores, (ii) time after surgery, and (iii) 3 nerve block treatment groups.

Results—Two-hundred-seventeen patients' data were complete for analysis. In univariate and multiple regression Generalized Estimating Equations models, nerve block treatment group was not associated with SF-36 and KOS scores after surgery (all with $P \geq 0.05$). The models showed that the physical component summary of the SF-36 ($P < 0.0001$) and the KOS total score ($P < 0.0001$) increased (improved) over time after surgery and were also influenced by baseline scores.

Conclusions—After spinal anesthesia and multimodal analgesia for ACLR, the nerve block treatment group did not predict SF-36 or knee function outcomes from 7 days to 12 weeks after surgery. Further research is needed to determine whether these conclusions also apply to a nonstandardized anesthetic, or one that includes general anesthesia and/or high-dose opioid analgesia.

Implications Statement: After anterior cruciate ligament reconstruction (ACLR) with spinal anesthesia and multimodal analgesia, patients were evaluated 3 times from 7 days to

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12 weeks after surgery with (i) the SF-36, and (ii) the Knee Outcome Survey–Activities of Daily Living Scale. There were no differences in general health or knee function based on nerve block treatment group; continuous femoral nerve block analgesia was not associated with any adverse effects on patient-reported general health or knee function in the 7-day to 12-week period after ACLR.

Introduction

Patient outcomes after anterior cruciate ligament reconstruction (ACLR) have not been well described in the first few days and weeks after surgery. Continuous femoral perineural analgesia helps sustain knee analgesia during these few days¹ when included with spinal anesthesia and multimodal analgesia. However, general health and physical function outcomes up to 12 weeks after ACLR with this (or any) anesthetic-analgesic technique have not been reported. After total knee replacement^{2,3}, patients demonstrated better physical function up to 6 weeks after surgery when continuous femoral perineural analgesia was used. Therefore, we evaluated patient outcomes between 7 days and 12 weeks after ACLR, to test the hypothesis that continuous perineural femoral analgesia (versus its absence) leads to the specific aims of improved physical function and general health status, as has been demonstrated after total knee replacement.

Materials and Methods

Institutional Approval, Patient Consent, Eligibility, and Treatment Group Randomization

After achieving approval by the IRB of the University of Pittsburgh Medical Center and obtaining informed consent, ACLR patients underwent a standardized multimodal anesthesia and analgesia regimen (previously described) that included an ipsilateral hyperbaric spinal with bupivacaine.¹ These patients consented for all described study procedures and evaluations both before surgery (e.g., baseline data collection), during the day of surgery (e.g., nerve block treatment group assignment), and in the 12 weeks of follow-up after surgery (patient-reported outcome surveys described below).

Patients were eligible for participation if they were 14 to 65-years-of-age and had an ASA physical status (ASA/PS) of I-II. The patients included in this 7-day to 12-week outcomes analysis (after surgery) underwent outpatient ACLR with a single-bundle allograft, single-bundle patellar tendon autograft or a single-bundle hamstring autograft. Two-hundred-seventy patients were recruited, and exclusions after enrollment were not replaced. Patients were excluded from study enrollment based on variables previously defined in our earlier publication.¹

Patients were randomized to one of the following femoral nerve block catheter treatment groups after surgery was performed: (i) saline bolus (30 mL) plus saline infusion (270 mL at 5 mL/hr, group SbSi); (ii) levobupivacaine (0.25%) bolus with saline infusion (group LbSi), or (iii) levobupivacaine (0.25%) bolus plus levobupivacaine (0.25%) infusion (group LbLi). These details, along with the detailed descriptions of the perioperative multimodal analgesic and antiemetic care protocol, are listed in a previous manuscript.¹

Study Instruments

The SF-36^{4,5} is generally accepted as a “gold standard” of assessing general health status. The SF-36 has been used frequently to assess patients with ACL-deficient knees^{6–8}, and co-administration of the SF-36 with other knee function surveys has been recommended.⁹ The domains that the SF-36 measures are as follows: physical function, role physical, bodily pain,

general health, vitality, social function, role emotional and mental health. Through a standardized norm-scoring process, these 8 dimensions are weighted and transformed into 2 summary scores: the physical component summary (PCS) and the mental component summary (MCS).

The Knee Outcome Survey-Activities of Daily Living Scale (KOS-ADLS)¹⁰ was developed and validated to evaluate patient-reported knee function. The 2 primary dimensions comprising the total score are symptoms (6 separate items, including pain and weakness as 2 items), and functional limitations (8 separate items, including pain during kneeling). All items in these 2 dimensions are graded by respondents on a 6-point Likert scale ranging from “Activity is not difficult” to “I am unable to perform the activity.” A separate 3-item section is included for patients to grade their global knee function assessment in 3 ways: an analog functional score between zero and 100 and 2 items featuring 4-choice Likert scale responses ranging from “severely abnormal” to “normal.”¹⁰

Data collection procedures

During the preoperative interview and after informed consent for the study was obtained, baseline survey data (SF-36 and KOS-ADLS) were obtained, as was additional demographic information (age, gender, ethnicity, height, weight, ASA/PS classification, smoking status). Surgeon, tourniquet use, tourniquet time and case duration were also recorded during the intraoperative course.

Postoperative course

At the start of the study, the surgeons’ office visits for the patients were to take place 1, 3, 7, and 12 weeks after surgery. However, this schedule was altered soon after study enrollment began. If the participant was scheduled for a surgeon’s office or physical therapy visit at the 3, 7, and 12-week time points, the surveys were administered in person. If participants’ follow-up visits were not scheduled for these time periods, then the SF-36 and KOS-ADLS surveys were mailed (with self-addressed stamped envelopes) in anticipation of these surveys being returned at the 3, 7, and 12-week points after surgery. These mailings were preceded and followed up with a reminder phone call. If the participant was not seen by the study coordinator at a scheduled office visit, then the participant was called, and a mailing to the participant’s home was arranged.

Statistical Analysis

Data were first explored to determine demographic and day-of-surgery equivalence among treatment groups of patients included in the present analysis (Table 1). Demographic variables (gender, age, race/ethnicity, Body Mass Index (BMI), smoking history, surgeon, length of surgery and use of thigh tourniquet intraoperatively) were analyzed for differences between nerve block treatment groups using one-way ANOVA (for continuous variables) or the chi-square test (for categorical variables).

Both the SF-36 and the KOS-ADLS scores were administered on several occasions after surgery. Due to the variability in response times in returning the surveys to the research team, most participants had unequally spaced survey outcomes. Since the time intervals among surveys were not equal for most patients, we present the data in 2 ways. First, we present the descriptive data acquired according to the responses completed at 3, 7, and 12 weeks for all patients who returned completed surveys at any or all of these time intervals. For each time point with this method, the range of responses was tabulated from the specific week-point (i.e., 3, 7, and 12 weeks) plus and minus 5 days from each week-point. These descriptive data are presented adjacent (Figures 1–2) to the population norm for adults of age 25–34 years with no major medical (or surgical) problems.^{4,5} The age group of 25 to 34 years represents the 95%

confidence interval of the mean age of participants in our study (Table 1). Second, we applied Generalized Estimating Equation (GEE) models to maximize the data analysis potential from all returned surveys (independent of survey return date relative to the day of surgery) and to evaluate the association among the 3 nerve block treatment groups and the SF-36 and KOS-ADLS outcomes. In other words, GEE modeling allowed us to accurately analyze all patient-reported outcome data (not just the data returned at the 3-, 7-, and 12-week time-points). We first used a univariate GEE model (with the only factor considered being the nerve block treatment group), followed by a multiple regression GEE model. In the multiple regression GEE models, we controlled for all other gathered covariate data, such as ASA/PS, race, gender, duration of surgery, smoking status, BMI, baseline SF-36 and KOS-ADLS scores. Again, the principal factor analyzed in the multiple regression GEE model was the nerve block treatment group.

It should be noted that the KOS-ADLS (but not the SF-36) was also administered to patients 1 week after surgery at the follow-up visit with the surgeon. These 1-week KOS-ADLS data are included in the multiple regression GEE equations for the KOS-ADLS.

$P < 0.05$ was considered statistically significant. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS for Windows, version 14.0, Chicago, IL) and SAS (version 9.1.3, SAS Institute Inc., Cary, NC). In this current study of 7-day to 12-week patient-reported outcomes, our inclusion rate was 80%, which matched the 80% power/sample size threshold required for interpretation.¹

Results

Recruitment began in July 2001, and study follow-ups were completed by January 2005. Two-hundred-seventy patients consented to participate in the study. Thirty-five of the 270 recruited patients were excluded before the end of the day of surgery, with the reasons for exclusions having been detailed previously.¹ Of the remaining 235 patients, 210 had complete baseline SF-36 data, and 217 had complete KOS-ADLS baseline data (i.e., no missing data entries). There were no demographic differences among treatment groups (Table 1) with respect to gender, age, race/ethnicity, BMI, ASA/PS, smoking history, use of thigh tourniquet or length of surgery. These 210 and 217 patients, respectively, had also at least 1 completed postoperative survey, yielding a total of 523 SF-36 surveys analyzed, and 745 KOS-ADLS surveys analyzed. The response rates (i.e., participants returning at least 1 completed survey during the postoperative course) on the SF-36 and KOS-ADLS did not significantly differ between nerve block treatment groups; the overall response rate was 99%.

Descriptive SF-36 data are presented in Figures 1 and 2 next to population norm^{4,5} data for the baseline, 3-week, 7-week and 12-week epochs.

Baseline data (n=217) for KOS-ADLS survey data were comprised of a mean total score of 69.96 (standard deviation = 19.94). There were no differences in baseline KOS-ADLS scores among nerve block treatment groups (data not shown).

The GEE results (Table 2) show that in both univariate and multiple regression models, nerve block treatment group was not significantly associated with SF-36 or KOS-ADLS outcomes (all with $P \geq 0.05$). The multiple regression GEE model (Table 3) that considered covariates only (i.e., not evaluating the nerve block treatment group as a factor, but instead as a covariate) showed that both the PCS of the SF-36 ($P < 0.0001$) and the KOS-ADLS total score ($P < 0.0001$) increased over time after surgery. Baseline SF-36 PCS scores were a positive predictor of postoperative PCS scores, which was also true for the KOS-ADLS scores. Increasing patient age was a predictor of lower postoperative PCS scores, but age did not influence KOS-ADLS scores.

Discussion

When the described spinal anesthetic (with multimodal analgesia) was used for patients undergoing ACLR, and when factoring the described perineural catheter treatment group, there were no statistically significant differences in general health status and knee function outcomes from 7 days to 12 weeks after surgery. More specifically, there were no differences in SF-36 or KOS-ADLS scores based on the nerve block treatment group considered in isolation (univariate GEE analysis) or when controlling for demographic covariates (multivariable GEE analysis). The same conclusion cannot be declared for ACLR patients undergoing any other anesthetic plan (e.g., general anesthesia [GA] with high-dose opioid analgesia, *versus* spinal anesthesia, multimodal analgesia, with or without a perineural femoral catheter). To reach this conclusion addressing GA-based anesthetic care plans, additional research would be needed.

It is clinically accepted that ACLR is not as invasive as total knee replacement. Therefore, it is logical that patients undergoing less invasive knee surgery may derive less long-term benefit after a continuous femoral perineural catheter than when compared with a more invasive surgery (such as total knee replacement with GA^{2,3} and the same perineural catheter). As described above, the hypothesis for ACLR patients needs to be re-tested in GA contexts that do not include spinal anesthesia and/or multimodal analgesia before drawing such conclusions.

Unlike inpatients undergoing total knee replacement^{2,3} (and physical therapist-reported patient outcome in the hospital), patient-reported outcomes measures are a more appropriate methodology for outpatients. However, intermediate-term outcomes measures had, to that point, been unexplored in our subspecialty. To our knowledge, this is the first study that used validated general health and extremity function outcomes that measure the effects of nerve blocks (including continuous nerve block infusions with local anesthetics) on patient outcomes in the 7-day to 12-week period after surgery, in the setting of an anesthesia care protocol consisting of spinal anesthesia and multimodal analgesia.

The SF-36 has been used several times in previous publications to assess anesthesia-specific outcomes. Carli et al. showed that adding a thoracic epidural to a standardized anesthetic–analgesic–rehabilitation care plan for colonic surgery showed improved SF-36 outcomes at 3 and 6 weeks after surgery (when compared with patients only treated with IV patient-controlled opioids).¹¹ In another study, Shyong et al. showed that the use of intraoperative and/or perioperative beta blockers led to improved SF-36 PCS scores (primarily through reduced bodily pain) 72 hours postoperatively, when compared with patients not receiving beta blockers (n=59, all patients 65 years or older).¹²

The 2 outcome studies in the previous paragraph (showing clinical differences in SF-36 outcomes based on perioperative anesthetic intervention) are offset by 2 reports of no difference in SF-36 outcomes. First, Wurm et al. showed no differences in SF-36 outcomes at 1 and 7 days postoperatively, but this study did not describe its basis of sample size determination (interscalene block performed preoperatively versus postoperatively, n=102).¹³ In a more recent study, no SF-36 differences were seen at 12 weeks postoperatively when comparing spinal anesthesia and GA for vaginal hysterectomy.¹⁴

A potential limitation of this study is that neither the SF-36 nor KOS-ADLS specifically addresses symptomatic outcomes associated with regional anesthesia procedures, such as peripheral nerve blocks (paresthesiae, or other symptoms associated with sensorimotor nerve damage). However, we recorded patients' postoperative symptoms during this time on other case report forms, and all such symptoms (which were rare and generally not present at baseline) resolved by the 12-week period (usually much sooner). Such symptoms are considered rare, and the course of such complications typically resolves within a 6-month period.¹⁵

Our data show no outcome differences (i.e., 2-tailed) in the 7 days to 12 weeks after ACLR; therefore, there is no evidence to conclude that a femoral nerve block should be withheld based on adverse general health or knee function outcomes in the 7 days to 12 weeks after surgery. This finding serves as an addendum to our earlier report¹ that the femoral perineural catheter yields (i) a clinically significant improvement in numeric rating scores for pain with movement and (ii) lower opioid consumption, in the first 2 days after surgery.

The question then becomes, if such a labor-intensive intervention¹⁶ yields a significant 2-day benefit and no long-term detriment (but no apparent long term benefit either), then is the intervention worthwhile? When considering pharmacoeconomic research addressing regional anesthesia and analgesia over the past decade, our patient care outcomes achieved in this protocol appear to warrant the labor-intensive intervention, when considering the context of the ambulatory surgery care process, described further below.

Patients ascribe value to the avoidance of nausea, vomiting and pain.¹⁷ The Joint Commission for the Accreditation of Healthcare Organizations mandates the evaluation of pain as the fifth vital sign¹⁸ and implies that the avoidance of moderate-to-severe pain is an important patient care objective. The National Institutes of Health defines moderate to severe pain as “5 or higher” on a zero-to-10 scale.¹⁹ Since 75% of our study’s patients’ treatment infusion group (i.e., not the placebo infusion groups) accomplished this pain management-related public health objective¹, then the intervention appears to be worthwhile on that parameter. We have reported a low incidence of nausea and vomiting both on the day of surgery and through the first 4 days after surgery²⁰ in the context of regional anesthesia and multimodal analgesia-antiemesis, accomplishing described patient-oriented objectives both in-hospital and at home. After the day of surgery, the antiemetic benefits were not traceable to the perineural infusion, per se, but instead to the establishment and maintenance of analgesic and antiemetic “momentum,” in that the previous days’ symptoms were predictive of the next day’s symptoms when considered as covariates with the nerve block catheter treatment group. Therefore, the femoral perineural catheter may not necessarily provide additional value beyond spinal anesthesia and multimodal analgesia-antiemesis for the context of nausea and/or vomiting in hospital or after discharge.

From a hospital efficiency standpoint, hospital cost savings have been reported²¹ when patients bypass the phase-I postanesthesia care unit immediately after surgery²², which is more reliably achieved after regional anesthesia with a sustained regional analgesic technique in place.^{21, 23–27} Therefore, our study’s patients with a perineural femoral catheter may not necessarily have additional value when compared with a simpler single-injection femoral nerve block. Standardization of patient throughput criteria has been recommended to capitalize on the hospital-based benefits of regional anesthesia^{16,21,22,25–27}, as well as to enhance the comparability of outcomes studies.^{16,28} Finally, the costs of avoided unplanned hospital admission²¹ and pain-related hospital readmission²⁹ have been elucidated. One levobupivacine infusion patient in our study returned to the emergency department for extrapyramidal symptoms³⁰ and pain control after a hamstring autograft (the sciatic nerve was not blocked preoperatively per protocol); there were no other unplanned hospital admissions, readmissions or emergency room visits for pain control throughout our study. Therefore, the inconvenience of perineural catheter placement for the practitioner appears to be offset by the myriad health care system benefits, as well as patient benefits in the first few days after surgery, with no apparent patient-reported long-term detriment based on validated outcome surveys. We routinely administer sciatic single-injection nerve blocks for our ACLR patients undergoing hamstring autografts³¹, but did not for this study.

One interesting finding in the multiple regression GEE model (Table 2) was that the LbLi patient group showed a trend ($P=0.05$) toward better scores on the MCS (i.e., mental component summary) than did the placebo SbSi group. Although this trend may reflect an artifact of

multiple analyses, the finding may prove to be of value for future hypothesis generation, for example, when comparing more disparate anesthesia-analgesia care plans. Another interesting finding noted in Table 3, from the standpoint of epidemiology and public health, was that smoking status was associated with lower patient-reported SF-36 MCS scores during the 7-day to 12-week period after the described surgery and anesthetic.

One limitation of this study is that postoperative rehabilitation regimens, although standardized at the level of surgeons' printed instructions to their surgical patients, could be monitored neither for individual therapist compliance to the written protocols, nor for patient compliance to the written protocols and/or the physical therapy objectives given by individual patients' specific therapists. We do not foresee this methodologic barrier ever being overcome in study designs such as this with large patient samples. In fact, our experience early in the study was that requiring patients to undergo a centralized physical therapy program on site at the surgeons' outpatient clinic and physical therapy center (as a condition for study inclusion) led to no patient recruitment for the first several months of study enrollment.

In conclusion, this triple-blinded, prospective, randomized, clinical trial addressed patient-reported general health status and knee function outcomes. For the period of 7 days to 12 weeks after ACLR surgery, these outcome data did not show any differences based on nerve block treatment group superimposed upon the described anesthetic-analgesic-antiemetic care plan. It is reassuring that, given the previously described¹ short-term benefits of continuous femoral perineural analgesia, this treatment had no patient-reported detriments during the described time frame, based on the parameters measured by 2 validated patient outcome surveys (SF-36, and KOS-ADLS).

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References

1. Williams BA, Kentor ML, Vogt MT, Irrgang JJ, Bottegal MT, West RV, Harner CD, Fu FH, Williams JP. Reduction of verbal pain scores after anterior cruciate ligament reconstruction with two-day continuous femoral nerve block: A randomized clinical trial. *Anesthesiology* 2006;104:315–27. [PubMed: 16436852]
2. Capdevila X, Barthelet Y, Biboulet P, Ryckwaert Y, Rubenovitch J, d'Athis F. Effects of perioperative analgesic technique on the surgical outcome and duration of rehabilitation after major knee surgery. *Anesthesiology* 1999;91:8–15. [PubMed: 10422923]

3. Singelyn FJ, Deyaert M, Pendeville E, Gouverneur JM. Effects of intravenous patient-controlled analgesia with morphine, continuous epidural analgesia, and continuous three-in-one block on postoperative pain and knee rehabilitation after unilateral total knee arthroplasty. *Anesth Analg* 1998;87:88–92. [PubMed: 9661552]
4. Ware, JE.; Kosinski, M.; Kemoun, G. SF-36 physical and mental health summary scales: a user's manual, Fifth printing Edition. Boston, MA: Health Assessment Lab; 1994.
5. Ware, JE.; Snow, KK.; Kosinski, M.; Gandek, B. SF-36 health survey: manual & interpretation guide, Second printing Edition. Boston, MA: The Health Institute; 1997.
6. Ferrari JD, Bach BR Jr, Bush-Joseph CA, Wang T, Bojchuk J. Anterior cruciate ligament reconstruction in men and women: An outcome analysis comparing gender. *Arthroscopy* 2001;17:588–96. [PubMed: 11447545]
7. Thomee P, Wahrborg P, Borjesson M, Thomee R, Eriksson BI, Karlsson J. A new instrument for measuring self-efficacy in patients with an anterior cruciate ligament injury. *Scand J Med Sci Sport* 2006;16:181–7.
8. Shapiro ET. The use of a generic, patient-based health assessment (SF-36) for evaluation of patients with anterior cruciate ligament injuries. *Am J Sport Med* 1996;24:196–200.
9. Johnson DS, Smith RB. Outcome measurement in the ACL deficient knee--what's the score? *Knee* 2001;8:51–7. [PubMed: 11248569]
10. Irrgang JJ, Snyder-Mackler L, Wainner RS, Fu FH, Harner CD. Development of a patient-reported measure of function of the knee. *J Bone Joint Surg* 1998;80-A:1132–45. [PubMed: 9730122]
11. Carli F, Mayo N, Klubien K, Schrickler T, Trudel J, Belliveau P. Epidural analgesia enhances functional exercise capacity and health-related quality of life after colonic surgery: results of a randomized trial. *Anesthesiology* 2002;97:540–9. [PubMed: 12218518]
12. Shyong EQ, Lucchinetti E, Tagliente TM, Hossain S, Silverstein JH, Zaugg M. Interleukin balance and early recovery from anesthesia in elderly surgical patients exposed to beta-adrenergic antagonism. *J Clin Anesth* 2003;15:170–8. [PubMed: 12770651]
13. Wurm WH, Concepcion M, Sternlicht A, Carabuena JM, Robelen G, Goudas LC, Strassels SA, Carr DB. Preoperative interscalene block for elective shoulder surgery: Loss of benefit over early postoperative block after patient discharge to home. *Anesth Analg* 2003;97:1620–6. [PubMed: 14633531]
14. Sprung J, Sanders MS, Warner ME, Gebhart JB, Stanhope CR, Jankowski CJ, Liedl L, Schroeder DR, Brown DR, Warner DO. Pain relief and functional status after vaginal hysterectomy: intrathecal versus general anesthesia. *Can J Anaesth* 2006;53:690–700. [PubMed: 16803917]
15. Brull R, McCartney CJL, Chan VWS, El-Beheiry H. Neurological complications after regional anesthesia: contemporary estimates of risk. *Anesth Analg* 2007;104:965–74. [PubMed: 17377115]
16. Williams BA. Potential economic benefits of regional anesthesia for acute pain management: the need to study both inputs and outcomes. *Reg Anesth Pain Med* 2006;31:95–9. [PubMed: 16543093]
17. Macario A, Weinger M, Carney S, Kim A. Which clinical anesthesia outcomes are important to avoid? The perspective of patients. *Anesth Analg* 1999;89:652–8. [PubMed: 10475299]
18. Solovy A. Pain management. Tools for implementing JCAHO's new standards. *Hospitals & Health Networks* 2000;74:57–63. [PubMed: 11192675]
19. AHCPR. Clinical Practice Guideline. AHCPR Pub No. 92–0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; Feb. 1992 Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma.
20. Williams BA, Kentor ML, Irrgang JJ, Bottegall MT, Williams JP. Nausea, vomiting, sleep, and restfulness upon discharge home after outpatient anterior cruciate ligament reconstruction with regional anesthesia and multimodal analgesia/antiemesis. *Reg Anesth Pain Med* 2007;32:193–202. [PubMed: 17543813]
21. Williams BA, Kentor ML, Vogt MT, Vogt WB, Coley KC, Williams JP, Roberts MS, Chelly JE, Harner CD, Fu FH. The economics of nerve block pain management after anterior cruciate ligament reconstruction: Significant hospital cost savings via associated PACU bypass and same-day discharge. *Anesthesiology* 2004;100:697–706. [PubMed: 15108988]

22. Williams BA. For outpatients, does regional anesthesia truly shorten the hospital stay, and how should we define postanesthesia care unit bypass eligibility? *Anesthesiology* 2004;101:3–6. [PubMed: 15220763]
23. Williams BA, DeRiso BM, Figallo CM, Anders JW, Engel LB, Sproul KA, Ilkin H, Harner CD, Fu FH, Nagarajan NJ, Evans JH 3rd, Watkins WD. Benchmarking the perioperative process: III. Effects of regional anesthesia clinical pathway techniques on process efficiency and recovery profiles in ambulatory orthopedic surgery. *J Clin Anesth* 1998;10:570–8. [PubMed: 9805698]
24. Williams BA, DeRiso BM, Engel LB, Figallo CM, Anders JW, Sproul KA, Ilkin H, Harner CD, Fu FH, Nagarajan NJ, Evans JH 3rd, Watkins WD. Benchmarking the perioperative process: II. Introducing anesthesia clinical pathways to improve processes and outcomes and to reduce nursing labor intensity in ambulatory orthopedic surgery. *J Clin Anesth* 1998;10:561–9. [PubMed: 9805697]
25. Williams BA, Kentor ML, Williams JP, Figallo CM, Sigl JC, Anders JW, Bear TC, Tullock WC, Bennett CH, Harner CD, Fu FH. Process analysis in outpatient knee surgery: Effects of regional and general anesthesia on anesthesia-controlled time. *Anesthesiology* 2000;93:529–38. [PubMed: 10910504]
26. Williams BA, Kentor ML, Williams JP, Vogt MT, DaPos SV, Harner CD, Fu FH. PACU bypass after outpatient knee surgery is associated with fewer unplanned hospital admissions but more phase II nursing interventions. *Anesthesiology* 2002;97:981–8. [PubMed: 12357168]
27. Williams BA, Kentor ML, Vogt MT, Williams JP, Chelly JE, Valalik S, Harner CD, Fu FH. Femoral-sciatic nerve blocks for complex outpatient knee surgery are associated with less postoperative pain before same-day discharge: a review of 1200 consecutive cases from the period 1996 - 1999. *Anesthesiology* 2003;98:1206–13. [PubMed: 12717143]
28. Liu SS, Strodtbeck WM, Richman JM, Wu CL. A comparison of regional versus general anesthesia for ambulatory anesthesia: a meta-analysis of randomized controlled trials. *Anesth Analg* 2005;101:1634–42. [PubMed: 16301234]
29. Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *J Clin Anesth* 2002;14:349–53. [PubMed: 12208439]
30. Skledar SJ, Williams BA, Vallejo MC, Dalby PL, Waters JH, Glick R, Kentor ML. Eliminating postoperative nausea and vomiting in outpatient surgery with multimodal strategies including low doses of nonsedating, off-patent antiemetics: is “zero tolerance” achievable? *The Scientific World Journal* 2007;7:959–77.
31. Williams BA, Matusic B, Kentor ML. Regional anesthesia procedures for ambulatory knee surgery: effects on in-hospital outcomes. *Int Anesthesiol Clin* 2005;43:153–60. [PubMed: 15970752]

Figure 1.

Descriptive data of anterior cruciate ligament (ACL) reconstruction patients' scores on the component summaries (physical and mental; PCS and MCS, respectively) of the SF-36 at preoperative baseline, and at 3, 7, and 12 weeks after surgery, in comparison with population norms. All patients received regional anesthesia and multimodal analgesia for their anesthetic and pain management care plan. The population norm represents the age group from 25 to 34 years, which is the 95% confidence interval of the mean age of patients in this study. Preoperative baseline PCS as well as these values for 3, 7, and 12 weeks appear lower than those for population norms. MCS scores perioperatively did not appear to differ from population norms in this data presentation.

Figure 2.

Descriptive data of anterior cruciate ligament (ACL) reconstruction patients' scores on the 8 dimensions of the SF-36 at preoperative baseline, and at 3, 7, and 12 weeks after surgery, in comparison with population norms. The population norm (blue) represents the age group from 25 to 34 years, which is the 95% confidence interval of the mean age of patients in this study. Preoperative baseline physical function (PF), role physical (RP), and bodily pain (BP) appear to be lower than those for population norms. General health (GH), vitality (VT), social function (SF), role emotional (RE), and mental health (MH) approximate the population norm throughout the preoperative and postoperative course with the exception of SF and RE at 3 weeks after surgery, which both appear to lag behind all other assessment time periods. Interestingly, MH in this ACL patient population appears to lag behind the MH of population norms throughout the perioperative course.

Table 1

Demographic data

Variable	Total
N	217
Age, mean (95% CI)	28 (26, 29)
ASA/PS II (% within categories)	40 (18%)
Female (% within categories)	92 (42%)
Not Caucasian (including African-American, Asian, Hispanic, and from India)	24 (11%)
Smoker	15 (7%)
Body Mass Index, mean (95% CI)	26 (25, 26)
Length of surgery, min (95% CI)	111 (106, 116)
Thigh tourniquet used (% within categories)	103 (47%)
Baseline SF-36 PCS score (95% CI)	40 (39, 42)
Baseline SF-36 MCS score (95% CI)	55 (54, 56)
Baseline KOS-ADLS score (95% CI)	70 (67, 72)

ASA/PS: American Society of Anesthesiologists' Physical Status classification

95% CI: 95% confidence interval

PCS: physical component summary; MCS: mental component summary;

KOS-ADLS: Knee Outcome Survey–Activities of Daily Living total score

There were no significant demographic differences based on femoral nerve block catheter treatment group (data not shown)

Table 2

Univariate and Multivariable GEE models, and results of SF-36 and KOS-ADLS survey outcomes based on nerve block treatment group

Outcomes	GEE model independent variable	Univariate model P values	Multivariable model P values
SF36-PCS	LbLi vs. placebo SbSi	0.65	0.89
SF36-PCS	LbSi vs. placebo SbSi	0.98	0.96
SF36-PCS	LbLi vs. LbSi	0.65	0.90
SF36-MCS	LbLi vs. placebo SbSi	0.07	0.05
SF36-MCS	LbSi vs. placebo SbSi	0.67	0.71
SF36-MCS	LbLi vs. LbSi	0.12	0.10
KOS-ADLS	LbLi vs. placebo SbSi	0.06	0.32
KOS-ADLS	LbSi vs. placebo SbSi	0.17	0.15
KOS-ADLS	LbLi vs. LbSi	0.58	0.67

GEE: Generalized Estimating Equations. Univariate equations only considered nerve block treatment group without covariates. Multivariable equations controlled for the covariates of age, gender, body mass index, race, smoking status, time (days) since surgery, duration of surgery, tourniquet use during surgery, and baseline preoperative SF-36 or KOS-ADLS scores (preoperative PCS for the PCS analysis; preoperative MCS for the MCS analysis, and preoperative KOS-ADLS for the KOS-ADLS analysis).

PCS: physical component summary of the SF-36 General Health Survey; MCS: mental component summary of the SF-36 General Health Survey; KOS-ADLS: Knee Outcome Survey-Activities of Daily Living Scale; SbSi: Saline bolus, Saline infusion;

LbSi: Levobupivacaine bolus, Saline infusion; LbLi: Levobupivacaine bolus, Levobupivacaine infusion

Table 3
Multiple regression GEE Model: Results of Association of SF-36 PCS and MCS scores, and KOS-ADLS scores

Independent Variable	Parameter	Point Estimate	SE	95% CI	Z-score	P value
SF-36 PCS	Intercept	24.83	4.59	15.85–33.82	5.42	<0.0001
	Days since surgery	0.16	0.009	0.14–0.18	18.97	<0.0001
	Age	–0.11	0.052	–0.22–0.013	–2.21	0.027
	Baseline PCS	0.19	0.056	0.083–0.303	3.44	0.0006
SF-36 MCS	Intercept	21.57	4.97	11.83–31.30	4.34	<0.0001
	Smoker (versus nonsmoker)	–4.10	1.75	–0.67–7.53	–2.34	0.019
	Baseline MCS	0.54	0.052	0.44–0.64	10.45	<0.0001
KOS-ADLS	Intercept	35.062	9.580	16.286–53.839	3.66	0.0003
	Days since surgery	0.305	0.020	0.265–0.345	14.93	<0.0001
	Baseline KOS-ADLS	0.272	0.047	0.181–0.363	5.86	<0.0001

GEE: Generalized Estimating Equations; PCS: Physical Component Summary; MCS: Mental Component Summary; KOS-ADLS: Knee Outcome Survey–Activities of Daily Living Scale; SE: standard error; CI: confidence interval.

This model is to be interpreted as follows. SF-36 PCS score after surgery (i) was higher with a higher Baseline PCS score before surgery, (ii) increased over time after surgery; and (iii) was lower with increased patient age. SF-36 MCS after surgery was (i) higher with a higher Baseline MCS score before surgery; and (ii) lower for smokers. KOS-ADLS score after surgery (i) was higher with a higher Baseline KOS-ADLS score before surgery, and (ii) increased over time after surgery.

In all three GEE models, days since surgery, baseline score, age, and smoking status were included along with the following covariates: graft type, nerve block treatment group, body mass index, gender, race, duration of surgery, and use of a thigh tourniquet during surgery. Only variables significantly associated with PCS, MCS, or KOS-ADLS scores after surgery are provided to minimize the complexity of data presentation.