

COVER PAGE

Title: Adductor Canal Block versus Periarticular Bupivacaine Injection in Total Knee Arthroplasty

NCT Number: NCT02777749

07/01/2016

1. Specific Aims

In the last decade, the widespread use of regional anesthesia in total knee arthroplasty (TKA), has led to improvements in pain control, more rapid functional recovery, and reduced length of stay.¹ In recent years many surgeons have transitioned from femoral nerve blocks (proximal femoral nerve) to adductor canal blocks (distal femoral nerve) to maintain a sensory block for pain control, while minimizing any motor blockade that is typically seen in proximal femoral nerve blocks, which would hamper rehabilitation, and increase risk of falls.² In addition to regional blocks, which are typically performed in the preoperative setting, some surgeons favor an intraoperative periarticular anesthetic injection (PAI), typically with bupivacaine, either in conjunction with an adductor canal block, or independently.³⁻⁵ In theory, PAI has the advantage of a comparable sensory nerve block as an adductor canal block, without the disadvantages and risks, which include prolonged quadriceps weakness, fall risk, and neurologic dysfunction.^{3,6} The purpose of this randomized control trial is to compare the efficacy of adductor canal blocks and periarticular bupivacaine injections for pain management in patients undergoing a total knee arthroplasty.

Specific Aim: To determine whether periarticular bupivacaine injections alone are as effective as adductor canal blocks, or combined adductor canal blocks and periarticular bupivacaine injections, for post-operative pain control following TKA.

We hypothesize that standard periarticular bupivacaine injections will be as effective as adductor canal blocks for post-operative pain management following TKA. The primary outcome in this study will be pain scores in the immediate post-operative period (post-operative day 0 through post-operative day 3). Secondary outcomes include post-operative narcotic use, length of stay, range of knee flexion, and activity level. Results from this study will help determine the most appropriate regional pain management strategy for patients undergoing a TKA.

2. Research Strategy

Significance

Over 600,000 total knee arthroplasties (TKAs) are performed each year in the United States, with expectations for greater than 4 million/year by the year 2030.⁷ Since the onset of TKAs in the 1960's, there have been developments that have improved both functionality and patient satisfaction. In the last decade, a focus has been made on multimodal pain management protocols, more rapid functional recovery, reduced length of hospital stay, and minimizing side effects of treatment while maintaining function and durability.⁸ The widespread use of regional anesthesia has led to improvements in pain control, more rapid functional recovery, and reduced length of stay.¹ Femoral nerve blocks have been shown to reduce opioid consumption and decrease post-operative pain scores. More recently, surgeons have transitioned to adductor canal blocks (distal femoral nerve) to maintain a sensory block for pain control, while minimizing any motor blockade that is typically seen in proximal femoral nerve blocks, which would hamper rehabilitation, and increase risk of falls.² However, even with a more distal femoral nerve block, the risk of motor involvement is still present.

Due to this potential risk, some surgeons prefer a less invasive regional pain management strategy, such as a periarticular anesthetic injection (PAI). Unlike nerve blocks, which are typically performed by the anesthesia team in the preoperative setting, PAIs are administered intraoperatively, usually just prior to closure. In theory, PAI has the advantage of a comparable sensory block as an adductor canal block, without the disadvantages and risks, which include prolonged quadriceps weakness, fall risk, and neurologic dysfunction.³ PAIs are typically performed with bupivacaine. In addition, some surgeons administer a PAI in conjunction with an adductor canal block, preferring a multi-modal regional pain management strategy. However, whether the combined strategy enhances pain control is not proven.

This study will elucidate the differences in pain control between adductor canal blocks and PAI with bupivacaine. These results will have an immediate and meaningful clinical impact on perioperative management in TKA. In addition to increased patient satisfaction through optimized post-operative pain control, this study has the potential to lead to cost-savings through the elimination of less effective treatment strategies and decrease in hospital length of stay. Due to the prevalence of TKA, this will affect millions of people over the next few years, and has the potential for major cost-savings.

Innovation

To date, no published studies have compared adductor canal block versus PAI in TKA. This will be the first study to compare these two treatment modalities, and, therefore, has the potential to change perioperative treatment algorithms in TKA.

Approach

Study Design:

This study will be a randomized control trial. There will be 3 study groups:

- 1) Adductor canal block alone (ACB)
- 2) Periarticular Standard Bupivacaine alone (SB)
- 3) Adductor canal block + Periarticular Standard Bupivacaine (ACB+SB)

There will be 50 patients in each study group, for a total of 150 enrolled patients. The study population will be 150 consecutive patients undergoing a unilateral primary total knee arthroplasty under the care of the two senior arthroplasty surgeons at this institution. Patients will be enrolled pre-operatively at the pre-operative clinic visit, and randomized at that time to one of the five groups. As is standard of care, the adductor canal blocks (15 cc's of 0.5% bupivacaine) will be performed by the regional pain anesthesia team in the pre-operative block area, just prior to surgery. As is standard of care, the periarticular injections (50 cc's of bupivacaine) will be performed intraoperatively, prior to wound closure, by the performing surgeon. Floor staff and therapists will be blinded to the treatment group. Patients will be blinded to the intraoperative medication (SB versus LB), but not the pre-operative block. Neither the surgeon nor surgical team (including anesthesiology) will be blinded to the treatment group.

Post-operatively, visual analog scale (VAS) pain scores will be recorded two times/day from POD0 through POD3. This will be the primary outcome. Secondary outcomes monitored in the immediate post-operative period will include:

Activity level: Steps taken in daily physical therapy sessions will be recorded.

Opioid consumption: All patients will have the same opioid pain medications offered on an as needed basis. The amount of opioid consumption will be recorded. In addition, all patients will receive toradol, and then celecoxib as part of the standard of care multi-modal pain management for TKAs at this institution.

Range of knee flexion: Range of knee flexion, for both passive and active motion, will be recorded prior to discharge, and at 3 week follow-up for all groups.

Length of stay: Total length of hospital stay from time of surgery through time of discharge will be recorded. In addition, location of discharge (home versus rehabilitation center), will be recorded.

Inclusion Criteria

All patients undergoing a unilateral primary total knee arthroplasty under the care of the two senior arthroplasty surgeons.

Potential Difficulties and Limitations

A large randomized clinical trial creates the potential for coordination issues. The study locations include the preoperative area, operating room, inpatient floor, and outpatient office. In order to ensure seamless coordination between study staff and the care team, we will have a designated study coordinator. The study coordinator will ensure that study execution and data collection with appropriate timing and location. Any issues that arise at the beginning of the study, will be addressed immediately by coordinating frequent research team meetings.

Statistical Procedures:

A power analysis reveals that 50 patients per group will be adequately powered to identify a VAS difference of 0.5 between groups, with $\beta=0.8$. VAS pain scores and continuous measures will be compared with unpaired student t-tests. Narcotic equivalents will be compared with a Mann-Whitney U test. Statistical significance will be defined as $p<0.05$.

1. Paul JE, Arya A, Hurlburt L, Cheng J, Thabane L, Tidy A, Murthy Y. Femoral nerve block improves analgesia outcomes after total knee arthroplasty: a meta-analysis of randomized controlled trials. *Anesthesiology*. 2010;113(5):1144-1162. doi:10.1097/ALN.0b013e3181f4b18.
2. Grevstad U, Mathiesen O, Valentiner LS, Jaeger P, Hilsted KL, Dahl JB. Effect of adductor canal block versus femoral nerve block on quadriceps strength, mobilization, and pain after total knee arthroplasty: a randomized, blinded study. *Reg Anesth Pain Med*. 2015;40(1):3-10. doi:10.1097/AAP.0000000000000169.

3. Wang C, Cai X-Z, Yan S-G. Comparison of Periarticular Multimodal Drug Injection and Femoral Nerve Block for Postoperative Pain Management in Total Knee Arthroplasty: A Systematic Review and Meta-Analysis. *J Arthroplasty*. 2015;30(7):1281-1286. doi:10.1016/j.arth.2015.02.005.
4. Schroer WC, Diesfeld PG, LeMarr AR, Morton DJ, Reedy ME. Does Extended-Release Liposomal Bupivacaine Better Control Pain Than Bupivacaine After TKA? A Prospective, Randomized Clinical Trial. *J Arthroplasty*. June 2015. doi:10.1016/j.arth.2015.01.059.
5. Berry J. Audience response-practice norm/trends. 22nd Annual Meeting of the American Association of Hip and Knee Surgeons. *American Association of Hip and Knee Surgeons*. November 2012.
6. Jeng CL, Torrillo TM, Rosenblatt MA. Complications of peripheral nerve blocks. *Br J Anaesth*. 2010;105 Suppl 1:i97-i107. doi:10.1093/bja/aeq273.
7. Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. *JAMA*. 2012;308(12):1227-1236. doi:10.1001/2012.jama.11153.
8. Berend ME, Berend KR, Lombardi AV. Advances in pain management: game changers in knee arthroplasty. *Bone Joint J*. 2014;96-B(11 Supple A):7-9. doi:10.1302/0301-620X.96B11.34514.