The Effect of Regional Anesthesia and Periarticular Injection and Versus Periarticular Injection Alone on Early Recovery after Total Knee Arthroplasty: A Prospective Randomized Trial

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Purpose

The purpose of the study is to compare two types of perioperative analgesic modalities, adductor canal block plus interspace between popliteal artery and capsule of the knee (IPACK) block and periarticular injection versus periarticular injection alone, to determine their relative efficacies with regard to pain relief and functional outcomes in the early postoperative period following primary total knee arthroplasty.

Hypothesis

We hypothesize that periarticular injection alone will be non-inferior in terms of pain scores, opioid consumption, and objective functional recovery metrics compared to periarticular injections with the addition of regional anesthesia (adductor canal block plus IPACK block.

Background

The widespread adoption of multimodal analgesia in contemporary total knee arthroplasty (TKA) has led to improvements in perioperative pain control, expedited recovery times, and shorter hospital stays[1–3]. Periarticular injections (PAIs), adductor canal blocks (ACBs), and interspace between popliteal artery and capsule of the knee (IPACK) blocks are commonly utilized as part of contemporary multimodal analgesia protocols, but their relative efficacies in improving early recovery after TKA has yet to be definitively elucidated[4]. There are a few known potential drawbacks of ACBs and IPACKs including surgical delay due to administration timing, increased costs, and small risks associated with a regional block. Both regional anesthesia and PAI have been found to be effective alone in improving pain and opioid consumption, but there is limited data on whether there is an additive benefit of providing both treatments for patients undergoing primary TKA. Therefore, the purpose of our study is to compare the efficacy of regional anesthesia and PAI vs. PAI alone for pain management and functional recovery in the early postoperative period following TKA.

Design

Prospective randomized trial

Treatment Groups

All ACBs will be administered as a single shot preoperatively in the holding area on the day of surgery by the regional anesthesia team and PAIs will be administered intraoperatively by the treating orthopaedic surgeon.

Group 1: regional anesthesia (ACB + IPACK) and PAI
Group 2: PAI alone

Inclusion Criteria
Age > 18 years
Primary unilateral total knee arthroplasty
BMI<45
Primary diagnosis of osteoarthritis
Patient owns smartphone capable of running the patient engagement platform and wearable activity monitor
Robotic-assisted surgery

Exclusion Criteria
Preexisting functionally limiting neurologic disorders
hepatic or renal insufficiency
history of unprovoked venous thromboembolism
Inability to complete baseline functional testing
Chronic opioid or gabapentin and pregabalin use (chronic defined as use >5 days per week prior to the surgical procedure)
Allergy or intolerance to trial medications
Planned admission to a postoperative rehabilitation facility
Planned general anesthesia
Receiving Workers' Compensation or disability payments

Primary Outcome
Mean VAS pain score for 2 weeks postoperatively

Secondary Outcomes
Daily opioid consumption
Daily VAS score at rest
Daily step count during the first 14 days postoperatively
Length of stay
Complications
Knee range of motion
Oxford Knee Score
Sleep quality

Power Analysis
A prior study by Grosso et al. identified a VAS pain score with ACB alone to have an average of 3.8 (standard deviation of 2.7) over the first 3 post-operative days[2]. Moreover, they identified a mean VAS pain score of 2.75 (standard deviation of 2.3) among those receiving an ACB and PAI over the first 3 post operative days. Assuming a common within-group assessment in the

proposed study, the Cohen's d effect size of 0.42 was calculated for use in an a priori power analysis. With a power of 80% at a 2-sided alpha of 0.05 and 1:1 allocation, a power analysis resulted in 90 subjects required for each arm of the study (180 subjects total). Accounting for unknown contributing factors that may lead to exclusion of patients from the study, 200 subjects (100 in each arm) will be enrolled in this trial. We will plan to do a midterm analysis once 100 patients have been enrolled.

Methodology

Randomization and Interventions

Patients will be randomized to receive a PAI with or without regional anesthesia using a computerized formal probability model with block design and 1:1 allocation ratio. This will occur in the clinic when the patient is indicated for surgery. Only those patients that are randomized to the regional anesthesia group will be billed for regional anesthesia. Regional anesthesia will be administered by an anesthesiologist and staff working under his/her supervision using standard of care techniques. All patients will be issued and trained on a patient engagement platform (PEP) (FocusMotion, Santa Monica, CA) and a wearable activity monitor (FitBit Inspire HR, FitBit, San Francisco) at study recruitment[5,6]. The wearable activity monitor will be provided free of charge to the patients.

. The periarticular injections will be given by the surgeon intraoperatively using standard of care techniques.

Data Collection

Patients will be instructed to begin using the PEP and wearable activity monitor 2 weeks before surgery for baseline data collection and continue use for 14 days postoperatively. Patient reported outcome measures including the Oxford Knee Score (OKS) and Forgotten Joint Score (FJS), will be collected preoperatively via the PEP. Intraoperative and in-hospital data will be collected prospectively by surgeons and nursing staff. Mean running averages for daily VAS pain scores and opioid consumption as measured by morphine milligram equivalent (MME) will be calculated. Fourteen days of postoperative biometric data collected from the wearable activity monitor will include sleep duration, sleep quality, sleep disturbances, step count, as well as maximum resting heart rate.

Enrollment

We are planning for 1 enrolling site, Barnes Jewish West County Hospital.

Risks, Benefits

Total knee arthroplasty patients are routinely given PAI with or without the addition of regional anesthesia as standard of care; this decision is primarily based upon surgeon preference. Therefore, participation in this study does not involve any additional risk. However, whether the addition of regional anesthesia provides a clear clinical benefit is unknown, and thus there is no true standard for this important aspect of patient care. There are known risks related to both local blocks alone as well as local blocks with the addition of a regional blocks, but the benefits of pain control, reduced opioid consumption, and enhanced functional recovery are believed to outweigh these risks.

Breach of confidentiality and/or privacy is a risk of the study. Below is a description of the procedure for maintaining confidentiality. There is no direct benefit to the participants in this study.

Procedures for Maintaining Confidentiality

A breach of confidentiality and/or privacy is a risk of this study. To prevent this and protect patient identity and information, all collected data will be deidentified and stored electronically in password-protected files. All information will be collected and reviewed by the research team only. Data will be maintained on a password-protected computer.

References

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