



**Expanding the peri-operative surgical home model: ERAS TKR with a
transitional pain service (TeleTPS)- Continuous adductor canal catheter
versus adductor canal block for total knee arthroplasty, a randomized double-
blinded controlled trial**

FUNDER: Anesthesiology Research Department

PROTOCOL NO.: 2017-1858

VERSION & DATE: Version 1, 06/09/2023

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PROTOCOL SYNOPSIS

Protocol Title:	Expanding the peri-operative surgical home model: ERAS TKR with a transitional pain service (TeleTPS)- Continuous adductor canal catheter versus adductor canal block for total knee arthroplasty, a randomized double-blinded controlled trial
Protocol Number:	2017-1858
Protocol Date:	06/09/2023
Sponsor:	Anesthesiology Department
Principal Investigator:	David Kim, MD
Products:	AmbIT Pump and MediBag – Summit (Manufacturer) Arrow, FlexBlock CPNB Kit – Teleflex (Manufacturer)
Objective:	The purpose of this study is to conduct a randomized controlled trial on patients undergoing unilateral total knee arthroplasty to compare the benefits of receiving an adductor canal catheter versus a single-shot adductor canal block with and additive (dexamethasone).
Study Design:	Randomized Clinical Trial
Enrollment:	60
Subject Criteria:	<p>Inclusion:</p> <ul style="list-style-type: none">• Patients with osteoarthritis scheduled for a primary total knee arthroplasty with a participating surgeon• Age 18 to 75 years• Planned use of regional anesthesia• Ability to follow study protocol• English speaking (secondary outcomes include questionnaires validated in English only)• Patients of participating surgeons: Drs. Mayman, Jerabek, Della Valle, Alexiades, Blevins, Chalmers, Ast, Carli, Ranawat• Lives within two hours of the hospital• Has a smartphone <p>Exclusion:</p> <ul style="list-style-type: none">• Hepatic or renal insufficiency• Younger than 18 years old and older than 75• Patients undergoing general anesthesia• Allergy or intolerance to one of the study medications• BMI > 40• Diabetes• ASA of III,IV• Chronic gabapentin/pregabalin use (regular use for longer than 3 months)• Patients with chronic pain (from a referral to chronic pain service) or a pain catastrophizing scale (PCS) > 30

	<ul style="list-style-type: none">• Chronic opioid use (taking opioids for longer than 3 months, or daily oral morphine equivalent of >5mg/day for one month)• Patients with severe valgus deformity or flexion contracture• Patients unable to follow home catheter instructions and unwilling to go home with an infusing catheter• Patients who have no home caregivers in the event if a catheter is to be sent home with the patient• Patients with planned stay at rehab facility (to avoid medical device being tampered with at the rehab facility)• Non English speakers (secondary outcomes include questionnaires validated in English only)
Study Duration:	<ul style="list-style-type: none">• 1 year
Data Collection:	<p>Sources: EPIC, Medical Records, and Patient Reported.</p> <p>Variables: Name, DOB, Race, Gender, BMI, NRS (at rest and with movement), Opioid consumption, Time to reach discharge, Physical Therapy, Nerve Block success, Patient satisfaction, Knee Injury and Osteoarthritis Outcome Score (KOOS) Junior, Blinding assessment, ORSDS, LANSS, PCS, COMM, PDI</p>
Statistical Analysis:	<p>Proposed analysis: Two-sample t-test or Wilcoxon rank-sum test</p> <p>Interim analysis planned? No</p> <p>Alpha level: .05</p> <p>Beta or power level: .80</p> <p>Number of groups being compared: 2</p> <p>Resulting number per group: 30</p> <p>Total sample size: 60</p>

1.0 INTRODUCTION

Adductor canal blocks (ACB) have been shown to effectively provide adequate analgesia without compromising the quadriceps strength. IPACK (interspace between the popliteal artery and capsule of the posterior knee) has been shown to optimize the pain relief by providing analgesia to the posterior compartment of the knee without compromising foot strength. The IPACK is also known as the SPANK block (sensory posterior articular nerves of the knee) and is shown to involve blocking the superior medial and lateral genicular nerves, providing analgesia to the capsule of the knee joint as well as the intraarticular and extra-articular ligaments. Typically, PAI's (peri-articular injections) are used for anterior and posterior pain control while the ACB/IPACK block also manages anterior/posterior pain, respectively. By incorporating these new techniques, it is possible to optimize pain relief without compromising motor strength. This has shown to facilitate ambulation and reduce opioid consumption (with its associated adverse effects), leading to earlier discharges. However, what happens when the blocks/infiltrations wear off when the patient is at home or rehab? A study done by the group in Virginia Mason, used an ambulatory continuous infusion at the rate of 8 ml/hr with a 400 ml reservoir. They placed adductor canal catheters as part of their TKR pathway and allowed continuation of the catheter at home, if the patient reaches discharge criteria prior to completion of the infusion.

With technological advancements in communication via hipaa-compliant text messaging services and video conferencing with smartphones and the exponential rise of telemedicine use in primary care services, we are able to expand the perioperative surgical home model by offering education forms, videos, and even video-visits to patients preoperatively via telemedicine. With this new form of communication, we will be able to inform and educate the patients not only the pain management plan but also set the expectations.

It has been shown that femoral nerve blocks accelerate the functional recovery of the patient and prolonging the optimization of pain control beyond the 24 hour period with femoral nerve catheters have reduced opioid consumption and pain scores. However, falls and quadriceps weakness from the femoral nerve catheters precludes the patients from early participation in physical therapy and being sent home. Recent studies examining the use of adductor canal catheters have not only demonstrated its motor sparing properties but also have shown analgesia that is equivalent to femoral nerve catheters.

The purpose of the study is to see if a continuous infusion of local anesthetics using an adductor canal catheter prevents rebound pain during the first 7 days after surgery and especially its impact on the development of chronic postsurgical pain.

By continuously infusing the catheter for 50 hours (up to POD 3), the patient should have better pain control, mobility, and have less rebound pain, often seen after POD 1. By infusing the catheter with a disposable single use ambIT system (Summit Medical Products), all patients enrolled in the ACC group will have the same amount running continuously and will lead to the possibility of discharging the patient with the catheter in place prior to the completion of the 50 hour infusion. The patients will be instructed prior to discharge on how to remove the catheter and also will download the Smartphone app "Diagnotes" in the hospital. The Diagnotes app (a HIPPA compliant text messaging service) will be the patients main form of communication with the anesthesiologist at home while the catheter is in place.

2.0 OBJECTIVE OF CLINICAL STUDY

The reason to do this study is to investigate whether the addition of a continuous ACB catheter will prolong analgesia beyond the 24-48 hour period and prevents the development of rebound pain and chronic postsurgical pain. Rebound pain is a known phenomenon where patients experience severe pain immediately after the resolution of the nerve block. It is also known that by prolonging the duration of analgesia, you diminish or prevent rebound pain from occurring. Motor sparing compartment blocks have revolutionized the ability of patients to participate in rehabilitation earlier than before, even ambulating on POD 0. Thus, by prolonging analgesia and promoting early ambulation, it is likely adductor canal catheters will not only lead to less opioid consumption but also allow earlier discharge. The two “hot” themes in recent TKR analgesia pathways are not only providing an effective ERAS (Enhanced recovery after surgery) protocol, but also using regional anesthesia and non-opioid multimodal pathways to combat against the opioid epidemic. This study will help answer which modality is better (single shot blocks with additive versus catheter) and introduce a novel method of following patients at home via a transitional pain service (telemedicine).

STUDY HYPOTHESES

Hypothesis 1: There will be at least a difference of 2 points on the Pain Numeric Rating Scale (NRS) 3 and 6 months post block administration.

STUDY DESIGN

2.1 Study Duration

1 year

2.2 Endpoints

2.2.1 Primary Endpoint

Our primary outcome will be pain perception in rest and with movement at 3 and 6 months post block administration. It will be measured in points on the Pain Numeric Rating Scale.

2.2.2 Secondary Endpoints

1. Opioid consumption at PACU, 24 hours on POD 1, 72 hours on POD 3, 96 hours on POD 4, 1 week, 3 and 6 months after surgery
2. NRS at rest and with movement on DOS (PACU after spinal resolution, 3-4 hours post-block), POD 1, POD 2, POD 3, POD 4, and POD 7
3. Physical therapy milestones – time of ambulation (including distance traveled), stairs, time of ambulating > 30 m, reaching discharge criteria, POD 0-4
4. Patient satisfaction with pain control on POD 1,2, 4
5. Hospital length of stay (time of meeting discharge criteria of adequate analgesia (NRS <4 at rest), independence from IV PCA, PT discharge)
6. Opioid Related Symptom Distress Scale (PACU, POD 1,4)
7. Buckling/Falls/Quadricep weakness as determined by PT precluding ambulation (POD 0,1,2,3,4)
8. Intraoperative measurements (induction times) (time out to induction end), tourniquet time, blood loss)

9. Block resolution (patient will be asked beginning on am of POD 1, when they felt the block has worn off, and on pm of POD 3 after catheter been discontinued)
10. Distance of ambulation (POD 0, 1, 2, 3, 4), from PT notes in EPIC while inpatient
11. Catheter related complications (delayed weakness, unintentional dislodgment, leakage, catheter infection, dysesthesias, falls, LAST)
12. Readmission for pain control
13. Block complications (neuropraxia (saphenous), transient palsies: peroneal, tibial nerve)
14. Koos Jr at 6 weeks follow up
15. Orthopedic Outcome Flexion/ Knee Society Score (Surgeon's office)
16. SF-36 questionnaire (phone interview 12-16 weeks post-op)
17. Leeds Assessment of Neuropathic Symptoms and Signs (LANSS, if patient reports surgery-related pain greater than 3 on the NRS at the 3 months postoperative visit, patient will fill out the form)
18. Current opioid misuse measure (COMM, at the 3 months postoperative visit, if patients are still being prescribed opioids, patient will be asked to fill out the questionnaire)
19. Incidence of patient contact via text messaging/video calls
20. Number of unused opioids after 1 week.
21. Pain catastrophizing scale (PCS) (Preop, POD 4, 3 months, 6 months)
22. CPSP questionnaires: Pain Disability index Questionnaire (3 months and 6 months):
23. Blinding Assessment (POD 2): Patient, RA, TeleTPS MD
24. Block Complications- Quadriceps weakness and Foot Drops
25. Non Opioid Pain medications consumption (lyrica, robaxin, tyelnol, etc), which may be given at the discretion of the APS service. (PACU, 24 hours on POD 1, 72 hours on POD 3, 96 hours on POD 4, 1 week)
26. IV PCA Usage (Time in hospital)

2.3 Study Sites

Hospital for Special Surgery – Main Campus

3.0 STUDY POPULATION

3.1 Number of Subjects

A total of 60 subjects will be enrolled.

3.2 Inclusion Criteria

Subjects of either gender will be included if:

- Patients with osteoarthritis scheduled for a primary total knee arthroplasty with a participating surgeon
- Age 18 to 75 years
- Planned use of regional anesthesia
- Ability to follow study protocol
- English speaking (secondary outcomes include questionnaires validated in English only)
- Patients of participating surgeons: Drs. Mayman, Jerabek, Della Valle, Alexiades, Blevins, Chalmers, Ast, Carli, Ranawat
- Lives within two hours of the hospital
- Has a smartphone

3.3 Exclusion Criteria

Subjects will be excluded from the study if:

- Hepatic or renal insufficiency
- Younger than 18 years old and older than 75
- Patients undergoing general anesthesia
- Allergy or intolerance to one of the study medications
- BMI > 40
- Diabetes
- ASA of III,IV
- Chronic gabapentin/pregabalin use (regular use for longer than 3 months)
- Patients with chronic pain (from a referral to chronic pain service) or a pain catastrophizing scale (PCS) > 30
- Chronic opioid use (taking opioids for longer than 3 months, or daily oral morphine equivalent of >5mg/day for one month)
- Patients with severe valgus deformity or flexion contracture
- Patients unable to follow home catheter instructions and unwilling to go home with an infusing catheter
- Patients who have no home caregivers in the event if a catheter is to be sent home with the patient
- Patients with planned stay at rehab facility (to avoid medical device being tampered with at the rehab facility)
- Non English speakers (secondary outcomes include questionnaires validated in English only)

3.4 Randomization

Patients will be randomized into one of the two following groups: Adductor Canal Block + Sham Catheter and Adductor Canal Catheter. The randomization schedule will be created using SAS software by a member of the Healthcare Research Institute not otherwise involved in the trial.

4.0 PROCEDURES

4.1 Surgical Procedure

Total Knee Arthroplasty/Replacement

4.2 Medical Record Requirements

EPIC

4.3 Data Collection

The following data will be collected:

Day before surgery/Baseline

- KOOS Jr
- ACC
- Pain Questionnaires
- Pain Catastrophizing Scale
- Diagnoses App

Surgical procedure

- date of surgery
- type of surgery
- surgery details
- anesthesia details

Follow-up visits (PACU, POD1, POD2, POD3, POD4, POD7, 3 and 6 months post op)

- Diagnotes App
- Medication intake
- Numerical Rating Scale (NRS) Pain Score
- ORSDS
- Physical Therapy
- Blinding Assessment
- Patient Satisfaction
- KOOS Jr
- ACC
- OOFKSS
- COMM
- LANSS
- Pain Questionnaires
- Pain Catastrophizing Scale

4.4 Schedule of Assessments

Study-Specific Procedures	Who?/ (If RA, estimate overall hours)	Day before DOS	Pre-op (Holding Area)	POD 0 (4-6 hours post block)	POD 1	POD 2-4	3 months	6 months	Surgeon's Office Visit
Identify eligible patients on schedule day before surgery	RA	X							
NRS Pain	RA		X	X	X	X	X	X	
Diagnosys App	RA/MD	X	X	X	X	X			
ORSDS	RA			X	X	X	X	X	
Physical therapy	RA			X (SOC)	X SOC	X (SOC)			
Blinding Assessment	RA					X (POD2)			
Patient Satisfaction	RA			X	X	X			
Opioid consumption	RA/EPIC			X	X	X	X	X	
KOOS Jr	Surgeon	X							X (3 and 6 months)
ACC	Anes	X			X	X			
OOFKSS	Surgeon								X (3 and 6 months)
COMM	RA								3 and 6 months
LANSS	RA								3-4 months
Pain Questionnaires	RA	X							3 and 6 months
Pain catastrophizing Scale	RA	X				X (POD 4)	X	X	

5.0 STATISTICAL ANALYSIS

Proposed analysis:

Two-sample t-test or Wilcoxon rank-sum test

Interim analysis planned? No

Alpha level: .05

Beta or power level: .80

Number of groups being compared: 2

Resulting number per group: 30

Total sample size: 60

6.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report. Definitions for Adverse Event (AE) used in this study are listed below and are based on FDA and international guidelines:

6.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product.

6.2 Serious Adverse Events (SAE)

The event is serious and should be reported to FDA when the patient outcome is:

Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Congenital Anomaly/Birth Defect, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events).

6.3 Adverse Event Relationship

Relationship to study: definitely, probably, possibly, not related.

7.0 INVESTIGATOR RESPONSIBILITIES, RECORD AND REPORTS

7.1 Subject Consent and Information

Research assistants will screen the co-investigating surgeons' patients undergoing ambulatory total knee arthroplasty surgery. Screening will involve reviewing the patient's EPIC chart to ensure that they meet the inclusion criteria and are not excluded due to any of the exclusion criteria listed. Patients who meet the inclusion criteria will be identified as potential study participants. After the investigating anesthesiologists have confirmed the eligibility of all

potential participants, one of the investigating anesthesiologists will approach the potential patients in the pre-operative holding area, explain the rationale for the study, and ask if the patient is interested in participating.

7.2 Subject Data Protection

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the Research Director and accessible only to the principal investigator, in addition to other IRB-approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e., name, medical record number, date of birth, registry number) will be maintained in a different password-protected database maintained by Research Director, to which only the primary investigator will have access.

7.3 Staff Information

Primary Investigator: David Kim, MD

Research Coordinator: Lisa Reisinger, MD, 646-714-6315; Pa Thor, PhD, 646-797-8535,

7.4 Protocol Reviews

Study protocol reviewed and approved by:

- Anesthesiology CRP
- Hospital for Special Surgery Institutional Review Board

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