# Analgesia after Total Knee Arthroplasty: Adductor Canal Block with Periarticular Injection and IPACK (ACB/PAI/IPACK) versus Periarticular Injection (PAI). A Double-Blinded Randomized Controlled Trial

FUNDER: Department of Anesthesiology

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# PROTOCOL SYNOPSIS

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| **Protocol Title:** | Analgesia after Total Knee Arthroplasty: Adductor Canal Block with Periarticular Injection and IPACK (ACB/PAI/IPACK) versus Periarticular Injection (PAI). A Double-Blinded Randomized Controlled Trial. |
| **Protocol Number:** | 2016-0168 |
| **Protocol Date:** | |
| **Sponsor:** | Department of Anesthesiology |
| **Principal Investigator:** | David Kim, MD |
| **Objective:** | A comparison of two pain control methods - the combination of Adductor Canal Block (ACB)/Periarticular Injection (PAI)/Infiltration of the interspace between the popliteal artery and the capsule of the posterior knee (IPACK) versus the Periarticular Injection (PAI) - in patients undergoing total knee arthroplasty. Primary outcome is NRS pain scores with ambulation on postoperative day one (24 hours post-block administration). |
| **Study Design:** | Prospective Cohort Study |
| **Enrollment:** | 86 |
| **Subject Criteria:** | 1. Patients with osteoarthritis scheduled for a primary total knee arthroplasty with a participating surgeon<br>2. Age 18 to 80 years<br>3. Planned use of regional anesthesia<br>4. Ability to follow study protocol<br>5. English speaking (secondary outcomes include questionnaires validated in English only)<br>6. Patients of participating surgeons: Drs. Alexiades, Mayman, Ranawat, Su, and Westrich |
| **Data Collection:** | **Sources:** EPIC, Medical Records, Anesthesiologist, Surgeon's office, and Patient Report<br>**Variables:** Name, DOB, Race, Gender, Ethnicity, BMI, ASA, Length of stay, Anesthesia, Surgery, Tourniquet start/end time, intra-op medication, NRS (at rest and with movement), opioid consumption, ORSDS, painOUT, time to reach DC Physical therapy, Nerve Block success, patient satisfaction with pain |

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| | control, Knee injury and osteoarthritis outcome score (KOOS) junior, blinding assessment, patient discharge plans |
| **Statistical Analysis:** | • Proposed analysis: Two-sample t-test<br>• Alpha level: 0.05<br>• Beta or power level: 80% |

## 1.0 INTRODUCTION

Total knee arthroplasties (TKA) are severely painful surgeries that require optimal pain control to ensure expeditious recovery and discharge. Nerve blocks, such as the femoral and sciatic nerves, are instrumental in effectively providing pain relief and improving patient satisfaction[1-2]. However, though pain scores notably decreased with the introduction of nerve blocks, motor blockade rendered these patients immobile and may pose a fall risk early in the postoperative period[3-6]. The advent of ultrasound introduces newer block techniques with adequate analgesia without the cost of motor blockade.

The adductor canal block serves as an alternative to the femoral nerve block in providing anterior knee analgesia without significantly compromising quadriceps strength[7-10]. However, patients' posterior knee compartment remains an issue for pain control. Sciatic and posterior tibial nerve blocks were implemented but again, results in motor blockade. A small percentage of sciatic nerve block cases also exhibit foot drop due to peroneal nerve injury[11]. Alternatively, as a sensory block, the periarticular injection (PAI) proves to hasten ambulation and recovery after TKA[12]. The PAI blind injection into the posterior capsule seems to aid in pain control of the posterior compartment and reduces the total number of physical therapy sessions[13].

Injection in the interspace between the Popliteal Artery and Capsule of the posterior Knee (IPACK) provides an alternative to the PAI blind technique for analgesia in the posterior compartment[14]. The IPACK block is not a nerve block, but rather infiltrates the area between the popliteal artery and femur[15]. This area is rich with sensory nerve fibers from the posterior capsule of the knee, which originates from the sciatic and posterior tibial nerve[16]. In this prospective study, we will compare pain scores between two groups: ACB/PAI/IPACK and PAI only. We will determine whether there is a difference between groups in NRS pain score with ambulation 24 hours post block administration.

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knee-extension strength is related to knee swelling after total knee arthroplasty. Arch Phys Med Rehabil . 2010;91:1770–1776.

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## 2.0 OBJECTIVE(S) OF CLINICAL STUDY

The purpose of this study is to compare two anesthesia methods in reducing pain with movement 24 hours after surgery - the Periarticular Injection (PAI) vs. a combination of the Adductor Canal Block (ACB), Periarticular Injection (PAI) and Infiltration of the interspace between the Popliteal Artery and Capsule of the posterior Knee (IPACK).

Research questions/specific aims:

a) Is there a difference in NRS pain scores with ambulation 24 hours post block administration between patients that receive ACB/PAI/IPACK vs. PAI?

## 3.0 STUDY HYPOTHESES

We hypothesize that there will be a difference in NRS pain score with ambulation 24 hours post block administration between patients that receive ACB/PAI/IPACK vs. PAI.

# 4.0 STUDY DESIGN

## 4.1 Endpoints

### 4.1.1 Primary Endpoint

a) Our primary outcome will be NRS pain score with ambulation 24 hours post block administration.

### 4.1.2 Secondary Endpoints

a) Opioid consumption at 24 hours on POD 1, 48 hours on POD 2 and 72 hours on POD 3
b) NRS at rest at DOS (4 hours post-block), 24 hours on POD 1 and 48 hours on POD2
c) NRS with movement on DOS and 48 hours on POD 2
d) Physical Therapy milestones - time to reach discharge criteria
e) Patient satisfaction with pain control
f) PainOUT
g) Hospital length of stay
h) ORSDS
i) Knee Injury and Osteoarthritis Outcome score (KOOS) Junior
j) Patient discharge plans

Secondary outcomes will be measured on the day of surgery upon spinal resolution (4 hours post induction), once at 24 hours on POD 1 and at 48 hours on POD 2 post-block administration. ORSDS, and pain Outcomes Questionnaire (painOUT) will be administered at the same intervals. The KOOS-Jr will be administered by Research team on pre operatively on DOS and at 6 weeks postop by surgeon's office. Length of hospital stay, and narcotic consumption will be obtained from EPIC.

## 4.2 Study Sites

This study will take place at the main campus of the Hospital for Special Surgery (HSS).

# 5.0 STUDY POPULATION

## 5.1 Number of Subjects

86

## 5.2 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 80 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. Alexiades, Mayman, Ranawat, Su, & Westrich

### 5.1 Exclusion Criteria

Subjects will be excluded from the study if:

- Younger than 18 years old and older than 80
- Patients undergoing general anesthesia
- Allergy or intolerance to one of the study medications
- BMI > 40
- Hepatic or renal insufficiency
- Diabetes
- ASA of IV
- Chronic gabapentin/pregabalin use (regular use for longer than 3 months)
- 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 and flexion contracture
- Patients with preexisting mild dementia or cognitive decline

## 1.0 PROCEDURES

### 1.1 Pre-Operative Protocol

Both groups will receive preoperative meloxicam (7.5mg PO if age 75 or older; 15 mg otherwise) + extended release oxycontin (10mg PO).

Patients will be randomized into one of the two following groups: ACB/PAI/PACK or PAI. The randomization schedule will be created using SAS software by a member of the Healthcare Research Institute not otherwise involved in the trial.

### 1.2 Intra-Operative Protocol

Both groups will receive intraoperative intravenous sedation with midazolam and propofol. Patients will not be given intravenous ketamine during the operation. Patients will be given 4mg ondansetron (IV Push), 2mg famotidine (IV Push), and up to 100mcg fentanyl.

A combined spinal epidural anesthetic with 1.5% Mepivacaine (60mg) will be performed for both groups.

If the surgery is prolonged (>2 hours), the anesthesiologist will use an epidural bolus with 2% lidocaine (10cc) to maintain surgical anesthesia. The epidural will be removed prior to leaving the operating room.

<u>Group 1- Periarticular (PAI) only group</u>

The surgeon will perform the PAI; one deep injection prior to cementation and then a second more superficial injection prior to closure. The deep injection will consist of bupivacaine 0.5% with epinephrine, 30cc; methylprednisolone, 40 mg/ml, 1 ml;

cefazolin, 500 mg in 10 ml; normal saline, 22cc. The superficial injection will be 20cc 0.25% bupivacaine. Patients will also receive 2 mg IV dexamethasone.

Group 2- ACB with IPACK and PAI group

PAI administered as above. The local anesthetic used for the PAI technique will be altered to prevent local anesthetic systemic toxicity. 30 cc of 0.25% bupivacaine with epinephrine will be used for the deep injection and 20cc of 0.25% bupivacaine for the superficial injection. A previous study done by Dr. Goytizolo (ACB/PAI),used equivalent local anesthetic amount without any adverse events.

Adductor canal block technique; supine position, after IV sedation. Ultrasound guided with c60 sonosite probe (5-2 Hz). Chiba needle, 22 G / 4 inches. Identify the femoral artery in the adductor canal deep to the Sartorius muscle. Mid-thigh injection of 15 cc of bupivacaine 0.25% with 2 mg of Preservative free Dexamethasone. The local anesthetic will be delivered periarterial with spread anterior to the femoral artery, encompassing 9 o'clock to 3 o'clock position of the artery.

*The block function will be assessed and recorded by the Anesthesiologist postoperatively. The assessment of the adductor canal block will be done in the Recovery room after the resolution of the spinal anesthesia. We will use an alcohol swab to test the cold sensation first on the non-operated leg and then on the operated one. The test will be performed at the level of the medial malleoli of the tibia. If the patient has sensation or no sensation will be recorded as block working or NOT working, respectively. The same procedures will be followed for the periarticular injection only group, so as to not unblind participating patients.

IPACK technique: prone or supine, frog-leg position. Ultrasound guided with linear transducer 10 MHz or curvilinear 8 MHz. 22G 4 inch Chiba needle. Identify the popliteal artery at popliteal crease; move cephalad, just beyond the femoral condyles. Identify space between the femur and popliteal artery. From medial to lateral, place needle in between the popliteal artery and femur with the tip ending 2-3 cm lateral to the artery. Inject 25 cc of 0.25% bupivacaine infiltrating the area between the artery and femur.

### 1.3 Post-Operative Protocol

Analgesia:
Postoperative analgesia will consist of:

- Acetaminophen (1 g IV q 6 hr x 3 doses; then 1g PO q 8hr)
- Ketorolac (30 mg IV q 6 hr X 4 doses, 15 mg for 75 or older)
- Dexamethasone (4mg IV push PRN)
- Oxycodone (5 - 10 mg q 3 hr PRN)
- Meloxicam daily (7.5mg PO if age 75 or older; 15 mg otherwise, to start after ketorolac is finished).
- Ondansetron (4mg IV q 8 hr PRN nausea)
- Metoclopramide (10mg IV q 6 hr PRN nausea)

In cases of severe pain (NRS scores greater than 6 for >2 hours), salvage therapy will be available using intravenous hydromorphone PCA.

### 1.4 Physical Therapy

Standard of Care - one session DOS, two sessions on POD1 and POD 2.

### 1.5 Data Collection

The following data will be collected:

**Questionnaires administered by Research staff:**

1. DOS, pre-op – NRS pain scores, KOOS Jr
2. DOS, upon spinal resolution - NRS pain scores, painOUT, ORSDS
3. POD 1 – NRS pain scores, painOUT, ORSDS,
4. POD 2 – NRS pain scores, painOUT, ORSDS, blinding assessment
5. 6 weeks post-op – KOOS Jr (if not administered by surgeon's office)

**Pre-operative/Baseline**

- Name
- DOB
- Race
- Gender
- Ethnicity
- BMI
- ASA
- NRS (at rest and with movement)
- Knee Injury and Osteoarthritis Outcome Score (KOOS) Junior

**Surgical procedure (Intra-operative)**

- Anesthesia, Surgery, Tourniquet Start/End Time
- Intra-op medication

**Day of Surgery**

- NRS (at rest and with movement)
- Opioid consumption
- OSRDS
- painOUT
- Time to reach DC Physical Therapy

**Post-Operative Day 1 (POD 1)**

- NRS (at rest and with movement)
- Opioid consumption
- OSRDS
- painOUT
- Time to reach DC Physical Therapy

**Post-Operative Day 2 (POD 2)**

- NRS (at rest and with movement)

- Opioid consumption
- OSRDS
- painOUT
- Time to reach DC Physical Therapy
- Patient satisfaction with pain control
- Blinding assessment

**Post-Operative 6-weeks**

- Knee injury and osteoarthritis outcome

## 2.0 STATISTICAL ANALYSIS

- Proposed analysis: two-sample t-test
- Interim analysis planned: No
- Alpha level: 0.05 (one-sided)
- Beta or power level: 80%
- Primary outcome variable estimate: NRS pain score with ambulation 24 hours post block administration in PAI group: 4.9 (Sawhney 2016) ± 3.0 (rounded up from 2.7; Sawhney, 2016; YaDeau, 2013).
- Number of groups being compared: 2
- Effect size or change expected between groups: 2 points (Farrar, 2001)
- Resulting number per group: 39
- Total sample size required: 78 + additional 10% to account for attrition = 86

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## 3.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report.