

**qIIS Protocol: Opioid-free Accelerated Recovery Total Knee Arthroplasty
Andrew Wickline, M.D.**

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Objectives:

- To prove that total knee arthroplasty can be performed with little, if any need for opioids using a combination of education, optimized pre-op and post-op pain protocols, and optimized recovery protocols.
- The secondary objective is to show that nearly all patients can be treated as outpatient joint replacements

Study Group:

All total knee arthroplasties

Comparison Group:

Cohort study: Start with 2- 3 months of patient enrollments (approximately 40 TKR/month). This could be baseline. In a years' time that would equal approximately 500 patients. We then collect data for 1 year. We can further examine other various outcome variables. The goal being opioid free total knee arthroplasty. To our knowledge there have been few studies using a multimodal approach that indicates the approximate number of opioid tablets physicians should order post-total knee replacement surgery that deals with patient's surgical pain. This is in part due to the unknown actual number of tablets taken post-op for surgical pain versus other comorbidities in these patients. Most studies are based on actual refills of opioids following total knee replacements. There has been other studies to examine post-operative opioid trends, predictors and use following total joint arthroplasty:

Dwyer, Maureen K, Trumpowsky, Catherine M, Hiltz, Nancy L, Lee, Joann, Healy, William L, Bedair, Hany S. et al. Characterization of Post-Operative Opioid Use Following Total Joint Arthroplasty

Goesling J. Moser SE, Zaidi B, Hassett AL, Hilliard P, Hallstrom B, et al. Trends and Predictors of Opioid Use After Total Knee and Hip Arthroplasty

Design:

Prospective, consecutive case series with historical matched control group

- All study patients will receive a standardized protocol
- All surgical procedures performed by a single surgeon using the same implants, same approach, same pre-op and post-op optimization, and same simplified pain protocol at a single hospital center and surgery center
- Researchers will attempt to minimize the number of anesthesiologists to further control variability in care

Research Team:

- Andrew Wickline, M.D., Principal Investigator, Surgeon – will review data weekly to ensure quality data collection
- PA's -Dennis Golis, Chuck Stefan, Anne Moore
- Full-time research associate Rph Mary Ann Stevenson – responsible for data collection

Methods

1. Data Collection

- EMR chart review (historical control)
- Pre-op assessment
- Post-op assessment – PACU, Phase II (prior to discharge)
- Phone calls after discharge
- Follow-up assessment in surgeon's office
- SwiftPath®
- KOOS, JR

2. Pre-op Optimization

- All patients enroll in SwiftPath® education program
- All patients have optimized BMI, hemoglobin, albumin, glucose control – A1C, and blood pressure control

3. Total Joint Procedure:

- Tourniquet-free cemented TKA performed with intra-articular block

4. Pain Management Regimen for TKA:

- Pre-op patient education regimen, which includes pre-op physical therapy teaching
- Post-op multimodal pain management regimen: Oxycodone 5mg every 4 to 6 hours or Tramadol 50mg every 4-6 hours, Acetaminophen 1000 mg three times a day, Celebrex 100mg twice a day, or Mobic 7.5mg twice a day, and cryotherapy (ice therapy)
- All patients have u/s guided adductor canal block with catheter
- Patients receive ON-Q adjustable pain ball in the recovery room starting at 4 ml/hr and are discharged when criteria the following criteria is met: ability to ambulate, can tolerate food/fluids, controlled nausea/vomiting, ability to empty bladder, vital signs within pre-op values, ability to pass physical therapy assessment for daily living skills
- Anesthesiologist regimen: adductor canal block with 20 ml ropivacaine 0.2% followed by catheter placement, a continuous infusion via pain ball containing ropivacaine 0.2% at starting rate of 4ml/hour in post- acute care unit (PACU). Patient given instructions on how to self- adjust infusion rate before discharge. Patient has the ability to titrate dose after discharge with duration lasting 3 to 5 days.

5. Inclusion Criteria:

- Partial and total knee arthroplasty
- Unilateral only
- Patient surgeries scheduled to be performed at the hospital and surgery center
- Patients must enroll in SwiftPath®
- Ability to read and understand English
- Primary care clearance for patients diagnosed with high/low blood pressures

6. Exclusion Criteria:

- Disease states, patient conditions to exclude-schizophrenia, bipolar disease, dementia
- Known allergies to local anesthetics
- Contraindications for regional analgesia
- Previous burn to affected extremity
- Previous fracture to affected extremity
- BMI >40
- Hemoglobin <12 female, <13 male
- Albumin less than 3.5
- A1C >8.0

Outcomes

1. Primary Outcomes:

- Post-op opioid consumption
- Pre-op opioid consumption
- Peri-op opioid consumption

2. Secondary Outcomes:

- Pain scores-NRS
- Sleep quality
- Adherence to prescribed post-op recovery protocol
- ROM
- Adverse events
- Serious side effects
- Length of stay in hospital (surgery to discharge)
- KOOS, JR and Swiftpath

- Discharge disposition
- Number of Physical Therapy visits – in-home vs outpatient

3. Data collection

- Intervals: PACU, DOS, POD 1, 2, 3, 10-14, 3week, 6week, 12weeks
- SwiftPath; A program that emphasizes patient/family engagement and education, using MIS techniques, reduction in narcotic use, utilization of modern pain management and early mobilization
- KOOS JR: This is a survey that is an assessment and questionnaire that rates a patient joint pain, stiffness and function in daily living.