Comparing Opioid Prescription Patterns in Total Joint Arthroplasty Patients: A Randomized Controlled Trial

Principal Investigator
Craig Della Valle, M.D.

Co-Investigators
Asokumar Buvanendran
Denis Nam, M.D.
Charles P. Hannon, M.D.
Brian Darrith, B.S.

Purpose

The primary purpose of this RCT is to determine whether prescribing fewer opioid pills per prescription reduces the total amount of opioids taken, even while allowing equal total opioid availability via increased frequency of prescription availability.

Hypothesis

We hypothesize that the experimental group—patients receiving fewer tablets per prescription yet more frequent prescription availability—will receive fewer opioids postoperatively within the first 90 days postoperatively. We also hypothesize that there will be no difference in patient reported outcomes, satisfaction, complication rates, or readmission rates during this same 90 days.

Background & Introduction

The United States constitutes <5% of the world's population but over 80% of the opioid supply and 99% of the hydrocodone supply.[3] In 2014, there were 18,893 deaths from prescription drug overdose, and orthopaedic surgeons are the third highest prescribing physicians for opioids.[2-3] Surgeons often prescribe opioids to minimize postoperative pain and to reduce the likelihood of readmission for pain. Available data suggests that orthopaedic surgeons are the most likely physicians to prescribe opioids to Medicare patients, whose opioid prescriptions are over 7 times more likely to come from an orthopaedic surgeon than another type of physician, but orthopaedic surgeons also had the highest readmission rate for post-operative pain.[1] Many studies have investigated the utilization of opioids after surgery to assess surgeon's tendencies to overprescribe, demographics of those likely to overuse, and adverse events of opioid abusers.[1-6]

A recent paper by Kim et al prospectively investigated opioid utilization after upper extremity surgery. This study (n=1,416) showed an opioid utilization rate of just 34%, taking an average 8.1 pills out of 24 prescribed.[1] Patients age 30-39, those having joint procedures, upper extremity/shoulder surgery, or self-pay/Medicaid insurance were all far more likely to overuse opioids.[1] The study concluded that their surgeons prescribed 3 times the required opioid following surgery and gave recommendations for opioid distribution based on location, procedure type, and patient risk factors. This study's identification of over prescription is congruent with a study completed by Bates et al that showed 67% of patients had a surplus of medications, with 92% not receiving proper medication disposal instructions.[5]

Comparing Opioid Prescription Patterns in Total Joint Arthroplasty Patients: A Randomized Controlled Trial

Other recent literature has attempted to risk stratify patients who are more likely to abuse prescription opioids. Morris et al identified various risk factors including: family history of substance abuse, nicotine dependency, age <45, psychiatric disorders, and lower level of education.[3] These risk factors are associated with aberrant behaviors (non-compliance, early refill request, "lost or stolen" medication), which should raise concerns for any provider prescribing opioids.[3]

Studies have shown that patients who are on chronic opioid therapy before surgery have worse outcomes. Nicholas Bedard et al compared chronic opioids users (n= 35,068) versus those who were opioid-naïve at the time of total knee arthroplasty (TKA) and found the opioid group had more opioid scripts filled per patient at discharge as well as at 3, 6, and 9 months (0.63 scripts/patient vs. 1.2 scripts/patient, $p<0.05$).[4] These patients also had a higher Charlson Comorbidity Index ($p<0.05$) and higher rates of respiratory failure, acute kidney failure, pneumonia, all post-operative infections, and infections requiring return to the OR.[4] The study concluded patients should have their opioid consumption controlled during the pre-operative and peri-operative period.

In addition to the complications of opioid medications experienced by orthopaedic patients, a recent nationwide retrospective analysis presents an unintended yet severe problem associated with opioid prescriptions. The incidence of pediatric hospitalizations for opioid toxicity nearly tripled from 1997 to 2012.[7] The over-prescription of opioids creates a readily available source for accidental ingestion by younger children and for intentional opioid overdose by older pediatric/adolescent patients. In fact, a family member's leftover pills have been described as the number one source for pediatric opioid overdose.[7-8] Moreover, the CDC reported that in 2015 the U.S. saw its highest incidence of opiod-related death.[9] Given the frequency and severity of opiod diversion and misuse, orthopaedic surgeons should consider the best methods for controlling patients postoperative pain and also avoid facilitating opiate misuse, whether by orthopaedic patients or other community members. With this goal in mind, our study will investigate regimens for effective postoperative pain control that also minimize the total amount of opioids prescribed.

Study Design
Prospective, single-institution, randomized controlled trial

Inclusion Criteria
Any patient > 18 years of age scheduled for a primary total hip arthroplasty or primary total knee arthroplasty who is not consuming opioids during the 4 weeks prior to surgery

Exclusion Criteria
1. Patients consuming opioids during the 4 weeks prior to surgery
2. Patients who are allergic to oxycodone or refuse to take oxycodone
3. Patients with a history of opioid dependence or illegal or "off-label" opioid use
4. Patients undergoing a revision total knee or total hip arthroplasty
5. Any patient less than 18

Comparing Opioid Prescription Patterns in Total Joint Arthroplasty Patients: A Randomized Controlled Trial

Sample Size Calculation
Based on the opiate consumption from a previous publication by Dr. Della Valle,[10] to detect a clinically significant 25% difference in opiate consumption between the two groups we would need 141 per group, or 282 total patients. We plan to do an interim analysis once half of this total is enrolled (71 per group). We will add 10% to account for patients lost to follow-up, for a total of 310 patients enrolled.

Treatment Groups
Group 1: 30 pills prescribed
Patients will receive one prescription at discharge for 30 tablets of Oxy IR 5 mg. Study Staff will call patients at 1 week after discharge to ask how many tablets they have remaining. If needed, patients will be sent two additional prescriptions for 30 tablets of Oxy IR 5 mg.

Group 2: 90 pills prescribed
Patients will receive one prescription at discharge for 90 tablets of Oxy IR 5 mg. Study staff will call the patient 1 week after discharge to ask how many Oxy IR tablets he or she has remaining.

Demographics, Patient Specifics
Age, sex, ASA score, medical co-morbidities, weight, height, preoperative pain scores, hospitalization days, BMI, postoperative pain scores, postoperative inpatient opioid usage, Charlson comorbidity index, and postoperative outpatient opioid usage.

All pain scores are measured with the Defense & Veterans Pain Rating Scale. All opioid usage will be measured in mg oxycodone, allowing conversion for measurement in morphine equivalents.

Outcome Measurements
1. Number of Oxycodone 5 mg tablets taken by the patient
    a. Self-reported by patient
    b. Verified with patient bringing pill bottle in and counted by a study investigator
2. Number of tablets received from pharmacy
    a. Prescriptions verified with Illinois Prescription Monitoring Program
3. Postoperative Inpatient Pain Scores
    a. Defense & Veterans Pain Rating Scale
4. Postoperative Inpatient Opioid Utilization
    a. Converted and measured in morphine equivalents
5. Postoperative Outpatient Pain Scores
    a. Defense & Veterans Pain Rating Scale
6. Preoperative and Postoperative Patient Reported Outcomes
    a. Primary THA: Harris Hip Score & Hoos Jr
    b. Primary TKA: Knee Society Score & Koos Jr
    c. Veterans Rand-12 (VR-12)
    All PROMs are routinely collected as standard of care

Comparing Opioid Prescription Patterns in Total Joint Arthroplasty Patients: A Randomized Controlled Trial

7. Compliance
    a. The Illinois Prescription Monitoring Program will be utilized to be sure that patients do not receive any additional narcotic prescriptions beyond what is provided to them as part of this study.
8. Complications
    a. DVT or PE
    b. Return to the OR within 90 days
    c. Re-admission within 90 days
    d. Superficial infection
    e. Deep infection
    f. Periprosthetic fracture
    g. Cerebrovascular accident or Transient ischemic attack
    h. Dislocation
    i. Opioid Withdrawal

Outcome measurements will be assessed during postoperative clinic visits at 3 weeks, at 6 weeks, and at any clinic visits due to postoperative complications occurring within 90 days of surgery.

Risks, Benefits

All TJA patients are routinely prescribed opiates as standard of care in the postoperative time period, and therefore participation in this study does not involve any additional opiate-related risk. However, the ideal number of opiate pills to prescribe each patient is unknown, and therefore there is no true standard for this important aspect of patient care. There are known risks related to opioid use, but the benefits of pain control—both to patients and the health care system—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 in the research office of MOR.

References

1) Kim Nayoung, Matzon Jonas, Abboudi Jack, Jones Christopher, Kirkpatrick William, Leinberry Charles, Liss Frederic, Lutsky Kevin, Wang Mark, Maltenfort, Llyas Asif. A Prospective Evaluation of Opioid Utilization After Upper-Extremity Surgical Procedures: Identifying Consumption Patterns and Determining Prescribing Guidelines. *The Journal of Bone and Joint Surgery.* 2016; 98(89): 1-9.

Comparing Opioid Prescription Patterns in Total Joint Arthroplasty Patients: A Randomized Controlled Trial

2) Opioid Addiction 2016 Facts & Figures. *American Society of Addiction Medicine*. Retrieved from: http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf
3) Morris BJ, Mir HR. The opioid epidemic: impact on orthopaedic surgery. *Journal of the American Academy of Orthopaedic Surgery*. 2015 May; 23(5): 267-71. doi: 10.5435/JAAOS-D-14-00163
4) Bedard Nicholas, Callaghan John, Pugely Andrew, Martin Christopher, Duchman Kyle, Westermann Robert, Gao Yubo. Pre-Opioid Use: Is There an Association with Outcomes Following Total Knee Arthroplasty? In: American Academy of Orthopaedic Surgeons 2016 Annual Meeting; 2016 Mar 1-5; Orlando, FL. Presentation nr P161.
5) Bates C, Laciak R, Southwick A, Bishoff J. Overprescription of postoperative narcotics: a look at postoperative pain medication delivery, consumption and disposal in urological practice. Journal of Urology. 2011 Feb: 185(2): 551-5. doi: 10.1016/j.juro.2010.09.088
6) Opioid Use, Misuse, and Abuse in Orthopaedic Practice. American Academy of Orthopaedic Surgeons. October 2015. Retrieved from: http://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1045%20Opioid%20Use,%20Misuse,%20and%20Abuse%20in%20Practice.pdf
7) Gaither JR, Leventhal JM, Ryan SA, Camenga DR. National Trends in Hospitalizations for Opioid Poisonings Among Children and Adolescents, 1997 to 2012. *JAMA Pediatr.* 2016;170(12):1195-1201. doi:10.1001/jamapediatrics.2016.2154
8) Moreno MA. The Misuse of Prescription Pain Medicine Among Children and Teens. *JAMA Pediatr.*2015;169(5):512. doi:10.1001/jamapediatrics.2014.2128
9) Retrieved on 12/9/16 from: https://www.whitehouse.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment
10) Della Valle CJ, Dittle E, Moric M, Sporer SM, Buvanendran A. A Prospective Randomized Trial of Mini-incision Posterior and Two-incision Total Hip Arthroplasty. Clinical Orthopaedics and Related Research. 2010;468(12):3348-3354. doi:10.1007/s11999-010-1491-5.