Effect of Perioperative Opioid Education on Outcomes After Total Knee Arthroplasty: A Randomized Study

FUNDER: Department of Anesthesiology

PROTOCOL NO.: 2022-1286

VERSION & DATE: 9/22/2022

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PROTOCOL SYNOPSIS

Protocol Title:	Effect of Perioperative Opioid Education on Outcomes After total knee arthroplasty: A Randomized Study
Protocol Number:	2022-1286
Protocol Date:	9/22/2022
Sponsor:	Department of Anesthesiology
Principal Investigator:	Bradley H. Lee, MD
Products:	N/A
Objective:	The aim of this study is to explore how a comprehensive educational pathway focusing on aspects of pain control and proper opioid use with repeated sessions will affect outcomes after total knee arthroplasty by comparing three groups – patients who 1) attend the virtual webinar, 2) an in-person session with PDF, and 3) a video session with PDF.
Study Design:	Randomized Study
Enrollment:	36
Subject Criteria:	Inclusion: • Age between age 18 and 80 years old • Undergoing primary total knee replacement surgery • English speaking Exclusion: • History of chronic opioid use (continuous opioid use for 3 or more months) • Opioid use within the past 3 months • Contraindication to NSAIDs or acetaminophen • Contraindication or allergy to opioids • Discharge to rehab or skilled nursing facility (opioids are not prescribed by HSS providers) • Contraindication or refusal to receive neuraxial anesthesia or peripheral nerve blocks (PNB) • Revision surgery • Ambulatory surgery • Patient is pregnant
Study Duration:	1 year
Data Collection:	**Sources:** EPIC, Medical Records, and Patient Reported. **Variables:** Name, MRN, DOB, Race, Ethnicity, Gender, Height, Weight, BMI, ASA class, email address, phone number, level of education, co-morbidities (diabetes, high blood pressure, cholesterol, rheumatological conditions, allergies), alcohol and tobacco use, Patient education class completion, Surgery details (surgeon, laterality, duration, tourniquet use), Anesthesia details (neuraxial, PNB, medications given), hospital length of stay (LOS), QoR15, Average

	NRS Pain Score, Opioid consumption (assess for cessation of opioids due to adverse effects), use of multimodal analgesia, opioid refill requests, opioid storage, opioid disposal, video on opioid and pain management viewed during hospitalization, reported sources of information on opioids and pain management, intervention assessment/feedback
Statistical Analysis:	1. **Proposed analysis (e.g., student's t-test, ANOVA, chi-square, regression, etc.):** Three Two-Sample T-tests: Video + PDF vs. Control and In-Person + PDF vs. Control , Video + PDF vs In-Person + PDF **2. Interim analysis planned?:** No 3. **Alpha level:** NA (Pilot Study) 4. **Beta or power level:** NA (Pilot Study) 5. **Primary outcome variable estimate (mean +/- s.d. for continuous outcome, frequency/percentage for categorical variable):** NA (Pilot Study) 6. **Number of groups being compared (use 1 for paired analysis within the same subjects):** 3 (2 Treatments vs. 1 Control) 7. **Effect size or change expected between groups:** NA (Pilot Study) 8. **Resulting number per group:** 12 9. **Total sample size required:** 12 x 3 = 36 patients

1.0 INTRODUCTION

Pain control after knee arthroplasty is challenging even with regional anesthesia, and patients often use opioids for prolonged periods and are at risk for developing chronic opioid use (Grosu, Hsia). Prior qualitative assessment revealed potential inconsistencies in pain expectations and the role of opioids (Lee). Specifically, patients acknowledge that opioids should be used to control pain enough to allow recovery, yet most feel that the goal with opioids is to experience minimal or virtually no pain (Lee). Therefore, patients may benefit from setting appropriate expectations of postoperative pain (Horn). Educational interventions have led to lower pain scores and may lead to earlier opioid cessation (Syed, Stepan, Egan, Nahhas). In addition, multimodal analgesia is an effective strategy for postoperative analgesia (Memtsoudis) and emphasizing the importance will hopefully improve compliance given less than half of patients seem to appreciate the purpose of multimodal analgesia (Lee).

Apart from pain control, patients should also understand details about opioid risks, storage, and disposal in order to promote proper handling (Syed, Lee). Prior studies show improved rates of handling and disposal with education (Nahhas). While prior studies of educational interventions have shown benefits, they often look at limited aspects of opioid use, such as opioid consumption (Syed, Nahhas). The aim of this study is to explore how a comprehensive educational pathway focusing on aspects of pain control and proper opioid use will affect outcomes after total knee arthroplasty that include pain, opioid refills, storage, and disposal.

2.0 OBJECTIVE OF CLINICAL STUDY

The current education process at HSS involves patient referral to a virtual webinar which is optional. Pain topics are covered within a broader 50-minute presentation on numerous topics related to surgery. Information on pain topics may be difficult to process and retain because it is a single exposure that is combined with multiple unrelated topics, and there is no repetition or reference provided. The aim of this study is to explore how a comprehensive educational pathway focusing on aspects of pain control and proper opioid use with repeated sessions will affect outcomes after total knee arthroplasty by comparing three groups – patients who attend the virtual webinar, an in-person session with PDF, and a video session with PDF.

3.0 STUDY HYPOTHESES

Educational intervention delivered in repeated sessions either in-person or via video during perioperative period (prior to surgery then POD1) will reduce opioid refill requests within 30 days compared with opioid education delivered through webinar. Initial prescription is for 42 tabs of oxycodone 5 mg q4h prn pain, though alternate opioids may be used.

4.0 STUDY DESIGN

4.1 Study Duration

September 2022-September 2023

4.2 Endpoints

4.2.1 Primary Endpoint

- Opioid refill requests

4.2.2 Secondary Endpoints

- Hospital LOS
- QoR15 at baseline, POD1, POD7, POD14
- NRS Pain Score at POD0, POD1, POD7, POD14
- Opioid consumption (in Oral Morphine Equivalents) at POD0, POD1, POD7, POD14
- Rates of compliance with multimodal regimen
- Patients in this study will be prescribed acetaminophen, NSAIDs, and opioid (oxycodone, tramadol, etc.). Patients will keep “pain diary” to record use of each medication. Compliance will be defined as the percentage of prescribed medication (acetaminophen or NSAID) that is actually taken.
- Rates of proper opioid storage (opioids are reportedly stored “locked and hidden”)
- Rates of proper opioid disposal (opioids are reportedly disposed of by one of the accepted proper disposal methods)

4.3 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

36

5.2 Inclusion Criteria

Subjects of either gender will be included if they:

- Age between age 18 and 80 years old
- Undergoing primary total knee replacement surgery
- English speaking

5.3 Exclusion Criteria

Subjects will be excluded from the study if they:

- History of chronic opioid use (continuous opioid use for 3 or more months)
- Opioid use within the past 3 months
- Contraindication to NSAIDs or acetaminophen
- Contraindication or allergy to opioids
- Discharge to rehab or skilled nursing facility (opioids are not prescribed by HSS providers)
- Contraindication or refusal to receive neuraxial anesthesia or peripheral nerve blocks (PNB)
- Revision surgery
- Ambulatory surgery
- Patient is pregnant

5.4 Randomization

Participants will be assigned at random to one of 3 study groups:

- Group 1 (control): Patients should have been referred to and attended the Hospital's standard 1-hour virtual patient education webinar prior to surgery.
- Group 2 (in-person): Patients will receive two in-person education sessions (1st session before surgery and 2nd session after surgery). Patients will also receive pdf handouts about opioids and pain management.
- Group 3 (video): Patients will receive two video education sessions (1st session before surgery and 2nd session after surgery). Patients will also receive pdf handouts about opioids and pain management.

6.0 PROCEDURES

6.1 Surgical Procedure

Total knee arthroplasty (TKA)

6.2 Medical Record Requirements

Using EPIC, research staff will review the patient's medical history to determine eligibility to participate in the study.

PHI that will be reviewed:

Name, DOB, preferred language, medical history, allergies, current outpatient medication, weight & body mass index

6.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

Name, MRN, DOB, Race, Ethnicity, Gender, Height, Weight, BMI, ASA class, email address, phone number, level of education, co-morbidities, alcohol and tobacco use, patient education class completion,

Surgical procedure

- Surgery details (date of surgery, surgeon, laterality, duration, tourniquet use)
- Anesthesia details (neuraxial, PNB, medications given)

Follow-up visits (Post-operative day of surgery (POD) 1, 7, 14, 21, 30, 60,)

- QoR15
- Average NRS Pain Score
- Opioid consumption
- Use of multimodal analgesia
- Opioid refill requests
- Opioid storage
- Opioid disposal
- Video on opioid storage/disposal viewed during hospitalization?

- Video on pain management viewed during hospitalization?
- Reported sources of information on opioids and pain management
- Intervention assessment/feedback

7.0 STATISTICAL ANALYSIS

Proposed analysis (e.g., student's t-test, ANOVA, chi-square, regression, etc.): Three Two-Sample T-tests: Video + PDF vs. Control and In-Person + PDF vs. Control , Video + PDF vs In-Person + PDF
Interim analysis planned?: No
Alpha level: NA (Pilot Study)
Beta or power level: NA (Pilot Study)
Primary outcome variable estimate (mean +/- s.d. for continuous outcome, frequency/percentage for categorical variable): NA (Pilot Study)
Number of groups being compared (use 1 for paired analysis within the same subjects): 3 (2 Treatments vs. 1 Control)
Effect size or change expected between groups: NA (Pilot Study)
Resulting number per group: 12
Total sample size required: 12 x 3 = 36 **patients**

8.0 ADVERSE EVENT ASSESSMENT

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

9.0 REFERENCES

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