Nonopioid Pain Control Regimen After Arthroscopic Hip Procedures

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IRB Minimal Risk Protocol Template

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points , save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Kelechi Okoroha

Study Title: Nonopioid Pain Control Regimen After Arthroscopic Hip Procedures

Protocol version number and date: v7 9/6/2024

Research Question and Aims

Hypothesis:

Aims, purpose, or objectives:

This project aims to compare postoperative pain control in patients in two treatment arms following Surgery: one treatment group given a nonopioid pain control regimen, and a control group given the standard post-operative opioid pain control regimen.

1) We aim to compare postoperative pain control following the use of traditional narcotic intervention and a novel nonopioid pain regimen.

2) We aim to review the operative time, blood loss, complications, and operative details of all patients undergoing Hip Arthroscopy at our hospital.

3) We aim to compare postoperative pain control interventions by looking at the amount of pain

medication required post-op, patient reported pain scores post operatively, and patient-reported side effects.

4) We hope to compare the type of pain regimen with amount of opiate use, patients pain score, speed of rehabilitation and overall cost difference to the health care system.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Narcotics are widely used for pain control following common orthopedic sport procedures. Traditionally, opioid analgesia has been the gold standard for postoperative pain control. However, given the harmful side effect profile and opioid epidemic in the United States, it is advantageous to use alternate forms of analgesia[3]. Multimodal pain control captures the effectiveness of different analgesic modalities and maximizes analgesia while minimizing side effects. The theory behind their use is that agents with different mechanisms of action work synergistically in preventing acute pain. Multimodal pain modalities have been used in orthopaedic trauma in the context of fracture care, as well as with knee and hip arthroplasty[2].

The purpose of the study is to investigate a potentially superior pain control modality in Hip Arthroscopy and its cost saving benefits[1]. Currently narcotic-based methods are effective, but have complications. This could potentially identify a pain control regimen that provides the same or better relief without the risk of complications and with decreased cost. This study has the potential to improve patient reported outcomes, patients' experience after common orthopedic procedures, and decrease overall hospital expenses.

Study Design and Methods

Methods: This is a 1:1 randomized-control standard of care clinical trial. All patients over sixteen desiring a Hip Arthroscopy will be eligible. The nonnarcotic postoperative pain control regimen described below was chosen based on previous studies in nonopioid postoperative management following common orthopedic procedures[4].

Patients will be consented and recruited according to the inclusion and exclusion criteria described below at their preoperative visit 1-2 weeks prior to their scheduled surgical date. Once participation has been determined and consent obtained, the names of participating patients and relevant procedure and contact information will be provided to the research assistant. Randomization will occur via block schedule; the schedule will utilize patient factors including BMI, age, and biological sex to allocate patients to a treatment arm. This block schedule will be designed in conjunction with biostatistician Stephanie Duong and colleagues and updated with new patients by the study coordinator and research assistants. Mayo Clinic research personnel and medical providers will be sole editors of the randomization matrix. All American Hip Institute (AHI) enrollment will occur using the approved Mayo Clinic consenting document and patient allocation will be completed by Mayo clinic personnel; no Mayo Clinic patient data or PHI will be transmitted to AHI.

Patients will be divided into one of the following 2 treatment arms: Non-narcotic and Narcotic based on your providers standard of care protocol the non-narcotic group will have two options.

Pre-operative pain protocol for all patients: Mobic 15mg PO, Gabapentin 300mg x1 dose pre-op, Epinephrine 1mg (1mL), 0.5% bupivacaine (58mL)

All patients will be given the following intraoperative pain injection: Acetaminophen 1000mg IV, Dexamethasone IV 8 mg x1 dose, Tramadol 30mg x 1

Non-narcotic Group Standard of Care Protocol Mayo Clinic:
Postoperative Weeks 1 and 2:
Motrin - also known as Ibuprofen (for 2 weeks)
800 mg TID; not to exceed 3200 mg/day
Gabapentin - 300mg TID for 5 days then wean off as described below
Days 6-7: 300mg BID
Days 8-9: 300mg Once daily
Days 10: No more Gabapentin
Tylenol (also known as acetaminophen) 1000 mg TID
Do not exceed a total of 4 grams of Acetaminophen per day.
Robaxin - 500 mg TID for 2 weeks
Weeks 3 – 4:
Tylenol (also known as acetaminophen) 1000 mg three times per day
Do Not exceed a total of 4 grams of Acetaminophen per day.

AHI Non Narcotic Standard of Care Protocol:

1. Naproxen (for 6 weeks)
   Directions: Take 500mg two times a day
2. Robaxin (for 2 weeks)
   Directions: Take 500 mg three times per day for two weeks
3. Gabapentin (for 9 days)
   Directions: Take three 100mg tablets OR one 300mg tablet three times daily for 5 days then wean off as described below

   Directions for weaning off Gabapentin:
   Days 6-7: Morning-300mg; Evening-300mg
   Days 8-9: Morning-300mg
   Day 10: No more Gabapentin

4. Tylenol (for 4 weeks)
   Directions: 1000mg three times per day; do not exceed a total of 4 grams per day
5. Aspirin (for 4 weeks)
   Directions: Take 325mg twice a day for four weeks

**If breakthrough pain occurs for any patient at any site, you may reach out to your provider and be prescribed Tramadol.

Tramadol 50 mg 1 or 2 tablets ever 8 hours as needed

Narcotic Group:
Postoperative Weeks 1 and 2:
Will be given 40 pills of Oxycodone 5 q4 hours PRN and Acetaminophen 1000mg TID for 2 weeks.
Patients in both groups will be instructed to take pain medications only as needed (PRN), but not more often than the scheduled dose. The usage of pain medication will be reported by the patients via Mosio Software. Mosio is a text-message delivery system which will message patients three times daily to ask their pain.

Both Groups:
Primary endpoints are reduction in pain as measured by VAS and PROMIS Pain interference questionnaire. VAS score will be collected pre-operatively and for the first 14 days post-operatively. PROMIS Pain interference will be collected once pre-operatively and at the first post-operative visit. Following the procedure, pain will be assessed subjectively through thrice daily VAS (as recorded through Mosio), PROMIS Pain interference questions (at post-operative appointment), nurse recorded pain scores while in-hospital, and objectively through narcotic pain requirement.

If pain is uncontrolled, patients can call the resident on call, available 24-hours per day, if additional pain control is needed.

Incisions will be closed in typical fashion and the wound dressed. The tourniquet will be deflated. Following the procedure pain will be accessed subjectively through patient pain journals, nurse recorded pain scores and objectively through narcotic pain requirement..

Patients will be presented with consent for the clinical trial at the time of surgical consent, always performed during the final preoperative office visit 1-2 weeks prior to the surgical date. The subject will have the duration of the office visit to decide on participation. Understanding will be ascertained using the teach-back method of informed surgical consent. Language used in the surgical consent will mimic a sixth-grade reading level. The patient must be able to verbally state their diagnosis and planned intervention. The risks and benefits of the proposed treatment will be detailed and the patient must repeat these back to the person obtaining consent. Voluntary withdrawal at any point will be stressed. The alternative to study inclusion (no randomized treatment) will be presented as a perfectly reasonable course of action. Patients will be allowed unlimited time to ask and have their questions answered by an M.D. involved in the study. Non-English speaking persons will not be eligible for study participation.

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Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 198

Subject population (children, adults, groups): Patients age 16 and older

Inclusion Criteria: All patients age 16 and over scheduled for a primary Hip Arthroscopy at Mayo Clinic (Rochester, MN), Mayo Clinic Orthopedics and Sports Medicine (Minneapolis, MN), and American Hip Institute & Orthopedic Specialists (Des Plaines, IL) will be eligible for inclusion in this study

Exclusion Criteria: Exclusion criteria will include patients with a medical history of allergies or intolerance to Motrin, Gabapentin, Tylenol, dexamethasone, tramadol, Robaxin, substantial alcohol or drug abuse, and pregnancy, history of narcotics within 6 months of surgery, renal impairment, peptic ulcer disease, GI bleeding.

Biospecimens

Biospecimens will not be collected for this study.

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☐ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.

- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Randomization:
As detailed above in the Methods section, randomization will occur via block schedule by 4 patient-specific stratification factors—biological sex, BMI, age range, and activity level. This will be designed by biostatistician Stephanie Duong and her colleagues, and maintained by study personnel, including study coordinator and research assistants.

Power Statement:

4/15/2022 Sample size estimate using a new standard deviation assumption and less power:

From the Huang et al. (2022) publication the standard deviation of the postoperative pain VAS score at the postoperative appointment (which occurred minimum at 5 years after surgery) was 1.89 points[1]. Assuming that similar variability in VAS scores will be observed in the proposed study, a sample of 35 subjects in each group (n=70 total) will provide 80% power to detect a difference of at least 1.3 points in VAS score measured at post-operative Day 14. In order to protect against a potential drop-out rate of 20%, a total of 84 subjects will be enrolled. Calculations were based on a two-sample t-test, with alpha=0.05, two-sided equal variance test.

Data Analysis Plan:

All outcomes will be reported descriptively using appropriate summary statistics, including 95% confidence intervals, where appropriate. Because this is a prospective, randomized trial, no formal between-group comparisons of baseline covariates will be performed. The primary study outcome will be change in VAS pain at post-operative Day 14. Secondarily, we will assess a variety of both continuous and categorical outcomes between groups including VAS pain scores at available time points, pain interference scores, operative details (i.e. operative time, blood loss, complications), and opioid medication use. Outcomes measured on a continuous scale, including pain interference and opioid medication use, will be compared between the 2 study groups using two-sample t-tests if the data are sufficiently normally distributed; otherwise non-parametric Wilcoxon rank sum tests will be used. Ordinal variables such as VAS pain scores will be analyzed using non-parametric Wilcoxon rank sum tests. Binary and nominal categorical outcomes, including complications will be compared between the study groups using chi-square tests, logistic regression, or Fisher's exact tests, if low expected cell counts are observed if follow-up data are complete; if follow-up data are incomplete, complications will be analyzed as a time-to-event outcome using the Kaplan-Meier method with Cox regression used to compare the two groups. All statistical tests will be two-sided and the threshold of statistical significance will be set at $\alpha = 0.05$.

Endpoints
Primary:
Reduction in pain as measured by VAS throughout multiple time points will be summarized and compared between the two treatment arms.
Secondary:

- Patient-Reported Outcomes Measurement Information System (PROMIS) Pain interference score at first postoperative visit. PROMIS Adult Short Form v1.0 Pain Interference 6b questionnaire will be collected at baseline and at the first post-operative visit which typically occurs at 14 days.
- Operative time, blood loss, complications, and operative details of all patients undergoing Hip Arthroscopy.
- Amount of pain medication taken post-operatively estimated by oral morphine equivalents
- Speed of rehabilitation
- Cost difference to the healthcare system