Antibiotics usage in Pediatric Orthopaedic Percutaneous Surgery (APOPS)

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TABLE OF CONTENTS

1. Background Information & Significance

Supracondylar humerus fractures are some of the most common fractures in children accounting for 60% of all fractures around the elbow joint and approximately 3% of all fractures in children. Closed reduction and percutaneous pinning (CRPP) is a common treatment for displaced pediatric supracondylar humerus fractures (SHF). The incidence of infection following this procedure is estimated to be between 0-7% (Iobst et al.). Upon reviewing all available studies on infection after elbow pinning, Iobst et al. found an overall rate of infection of 2.34%. These data come from retrospective studies that either look at patient samples from a single or multi-center setting. These studies did not show significant difference in infection rates between patients that did or did not receive antibioitics. Usage of these preopertaive antibiotics continues to vary based on personal surgeon preference with no established standard of care. To our knowledge there have been no randomized, blinded prospective studies designed to assess the efficacy of preoperative antibiotics for preventing infections after CRPP of SCHFs.

2. Objectives, Contribution, & Hypothesis

Objectives: We propose to perform a prospective, randomized study to evaluate if antibiotics affect the outcome after percutaneous surgery for pediatric supracondylar humerus fractures.

Contribution: We hope that this study will result in a better understanding of the need for antibiotics prior to percutaneous surgery for pediatric supracondylar humerus fractures.

Hypothesis: The use of pre-operative antibiotics for percutaneous fixation of pediatric supracondylar humerus fractures does not affect the rate of infection.

3. Selection of Subjects

Inclusion Criteria: Age<14, open growth plates; Gartland type II and III extension type fracture, and flexion type fractures of the distal humerus

Exclusion Criteria: Need for open reduction; Need for antibiotics due to other injuries or conditions during the entire study period; immunosuppression, history of malignancy or

metabolic bone disease, open fractures, pre-existing infection, or intra-operative breech of sterile technique

Sample Size: We anticipate enrolling up to 200 patients to complete the study. Sample size was determined based on a non-inferiority study design, and a presumed infection rate of 2.34% from previous literature.

4. Study Procedure

Timeline: 24-36 months of data collection

Study Design: Prospective, randomized, double-blinded controlled study

Protocol: This patient population will be recruited from the cohort presenting to UMHS for percutaneous fixation of pediatric supracondylar humerus fractures. Participants will be asked to assent to take part in the study and their parents or guardian will be asked to sign an informed consent. Patients will be randomized to a treatment group that receives one dose of pre-operative antibiotics or one that does not. Randomization envelops will be created and stored in the operating room of the attending physicians. Prior to the time-out procedure, the resident assisting with the surgery will open the top envelope and display the randomization card to the CRNA/Anesthesiologist. Patients randomized to preoperative antibiotics will receive 25mg/kg cefazolin IV up to 1g or clindamycin 10mg/kg up to 600mg IV in cases of documented allergy to cefazolin. Patients randomized to the no-antibiotic group will receive a saline placebo. This placebo will consist of a 10 mL pre-filled syringe of normal saline, which is not charged individually to any patient, therefore, these research subjects will not be charged for this placebo. The resident, anesthesiologist, circulating nurse and other operating room staff will be instructed to not reveal the patient's randomization to the attending physician so as not to interfere with blinding. Special care will be taken to not mention preoperative antibiotic status as part of the normal "time-out" procedure, saying instead, "this is a study patient."

The patient will then undergo CRPP of SCHF. The entire affected extremity will be prepped with chlorhexidine sponge according to manufacturer's instructions. The entire affected extremity will then be draped in the usual sterile fashion. After manipulating the arm to achieve a closed reduction the fracture will be stabilized by Kirshner wires in a percutaneous fashion using fluoroscopy. A soft sterile dressing will then be applied to the elbow region followed by a long-arm cast. The cast may be bivalved in cases of excessive swelling. Final AP and lateral fluoroscopic images in the case will be taken and sent to PACS.

The patient will then be discharged from the hospital when pain is controlled with standard oral pain medications and all goals of inpatient management have been achieved. No patients will receive post-operative antibiotics regardless of randomization group as is the existing standard of care.

Patients will be scheduled to follow up in 3-6 weeks depending on age. At that time the cast will be removed and AP and lateral radiographs will be used to assess healing. The pins will be

removed in clinic and a soft dressing applied to the elbow region.

The primary outcome measure will be the presence of infection as judged by the blinded attending surgeon or nurse practitioner at the time of cast removal. A superficial infection is defined as a clinical diagnosis based on increased erythema, granulation tissue or purulence at the pin sites that resolves with a short course of oral antibiotics. A deep infection is defined as the presence of septic arthritis or osteomyelitis requiring return to the operating room for debridement or a prolonged course of IV antibiotics. In cases of a deep infection cultures will be taken at the time of debridement and the results recorded. Secondary outcome measures will be the patient's VAS pain score at 4 weeks, time to healing, need for repeat casting and loss of fixation.

In cases of excessive pain or cast loosening the patient may be seen in clinic earlier with radiographs and physical exam as indicated. If the attending physician or nurse practitioner determines that a deep or superficial infection is present at any time during the treatment period the patient will be categorized as infected. If no infection is detected at an earlier-scheduled appointment the patient will be recasted and instructed to follow up as previously scheduled.

5. Confidentiality of Data

Patient confidentiality during the course of this study will be protected in compliance with HIPAA requirements as well as the requirements of the University of Missouri Health-Sciences IRB.

All subjects will be assigned a study identification number that requires the use of a key in order to decipher a subject's personal identification information. The key will be kept in the Cerner Power Trials database, which is password protected. The study identification number will be used to label all paper data collection instruments.

All subject information in electronic format will be kept in password-protected storage. All subject information in paper format will be kept in locked cabinets in a secured suite at the Missouri Orthopedic Institute, and otherwise will be archived in a secure storage facility, or destroyed.

6. Assessment of Risks & Benefits

Risks: Risks for breach of confidentiality does exist but will be limited with tight control and limited access to the investigators. There are risks associated with taking medications. Cefazolin may result in loss of appetite, nausea, vomiting, diarrhea, or headache. Clindamycin may result in mild nausea, vomiting, or stomach pain; joint pain; vaginal itching or discharge; mild rash or itching; or. heartburn, irritation in your throat.

Benefits: We hope that this study will shed light on the necessity of antibiotics after percutaneous surgery for pediatric supracondylar humerus fractures, and decrease un-necessary medication use.

Data Safety Monitoring Plan: The primary (infection) and secondary (VAS pain score at 4 weeks, time to healing, need for repeat casting and loss of fixation) study endpoint data will be analyzed every 6 months to monitor the overall patient outcome data. The data from each outcome measure will be compared to those historically reported in peer-reviewed literature.

7. References

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