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Post-operative Pain Management in Children With Supracondylar Humerus Fractures

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Main Title

POST-OPERATIVE PAIN MANAGEMENT IN CHILDREN WITH SUPRACONDYLAR HUMERUS FRACTURES

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Purpose and Objectives

The null hypothesis for this study is: children with closed supracondylar humerus fractures, Gartland type 3, who are managed with closed reduction and percutaneous pinning with subsequent casting, will have similar post-discharge pain intensity and pain duration whether they are provided with Ibuprofen and as needed Acetaminophen or Ibuprofen and as needed Hydrocodone-Acetaminophen(Hycet).

The primary objective is to assess to what extent, if any, narcotic medication availability (in the form of a filled prescription of Hydrocodone-Acetaminophen) provides a benefit over non-narcotic analgesia for this population post-discharge.

Study Design

We propose a prospective randomized study to compare the post-discharge pain management efficacy for children who are treated with CRRP and casting for a closed supracondylar humerus (SCH) fracture. One group of patients will be discharged with weight-based oral ibuprofen and acetaminophen prescriptions. The other group will be discharged with a weight based oral ibuprofen prescription and 10 weight based doses of hydrocodone-acetaminophen (Hycet).

All patients guardians (including those receiving narcotics) will be counseled that using the narcotic medication is believed to be unnecessary and those who are receiving a prescription should only use it for breakthrough pain not controlled by ibuprofen.

Randomization will be 1:1 into the treatment arms and will be performed using a sealed envelope technique. 100 patient assignment papers will be printed ahead of time, 50 stating narcotic group and 50 stating non-narcotic group. The pain management designation will be placed in an opaque, sealed envelope. Envelopes will be labeled with a number on the outside and randomized. When marking the patients correct surgical site in the pre-operative area immediately before surgery, the surgeon will describe the study to

the patient family and if they agree to participate in the trial, the surgeon will open an envelope and inform the family what the postoperative prescription will be. Every patient will have equal probability to be assigned into either group. Since multiple surgeons will be able to consent patients and all envelopes will be randomized, it is improbable that an investigator could alter behavior or predict which group allocation is in the envelope prior to opening it with the patient.

There will be no blinding in this study. Patient families and clinicians will know the medication regimen that the patient is assigned to once they have opened the envelope.

Inclusion Criteria:

Patients presenting to Texas Children's Hospital (Main Campus, West Campus, and The Woodlands Campus) with an isolated closed supracondylar humerus fracture, Gartland 3 (a measure of amount of bone or periosteum providing stability) who are treated with closed reduction and percutaneous pinning with supplemental casting will be considered for inclusion. Patients must be age 3-12 years old at time of enrollment (day of surgery). Only patients who are expected to follow up with a TCH orthopedic surgeon will be included. Patients/guardians must speak English or Spanish.

Exclusion Criteria:

Complicated injuries such as open skin wounds, polytrauma, neurologic deficit, or vascular deficit. Patients who have a disability that interferes with reporting of pain such as intellectual delay. Patients who have a problem with bone healing such as osteogenesis imperfecta which would likely result in a significantly different injury and healing experience. Patients who are unable to take the standard dose of acetaminophen, ibuprofen, or hydrocodone for medical reasons (allergy, severe kidney disease, etc). Patients who are on chronic NSAID or opioid medication prior to injury. Patients with injury from suspected non-accidental trauma.

Procedure:

Patients with this injury present to either the emergency department or in clinic and are scheduled for surgery. On the day of surgery, eligibility will be determined by the treating orthopedic surgeon at the time of meeting the patient and family in the pre-operative setting (at the time of marking the patient and/or surgical consent). The surgeon will then play a video describing the study and obtain consent. If consent and assent is granted, the pain management group designation will be through a sealed envelope. After the guardian and patient is informed of their group designation (narcotic vs no-narcotic) , the patient's guardian will be given their group specific pain journal and counseled on how to fill it out appropriately. Patient's/guardians will also be shown another video with a more in depth

overview of how to fill out their pain journal. Research staff members will keep track of eligible and enrolled patients. The patient will then proceed with surgical fixation of their fracture. Patients will not receive local injection of anesthetic or any form of nerve block prior to incision. During the operation and post-operative period, all patients will receive standard of care used by the anesthesiologist for pain management. Upon discharge, those randomly assigned to the non-narcotic group will receive weight based oral Ibuprofen and Acetaminophen. This group will be counseled to take one dose of ibuprofen up to every 6 hours for pain. If they have breakthrough pain while taking ibuprofen, then they can take one dose of Acetaminophen as a rescue medication up to every 6 hours. Those randomly assigned to the narcotic group will receive weight based oral Ibuprofen and 10 weight based doses of Hydrocodone-Acetaminophen (Hycet). This group will be counseled to take one dose of ibuprofen up to every 6 hours for pain. If they have breakthrough pain while taking ibuprofen, then they can take one dose of Hycet as a rescue medication up to every 6 hours. All medications will be given at discharge using the Meds-to-Beds program. The following doses will be used: (1) Ibuprofen 10mg/kg every 6 hours, max daily dose 40mg/kg not to exceed 1200 mg (2) Acetaminophen 15 mg/kg, every 6 hours as needed, max daily dose 75mg/kg not to exceed 2600mg (3) Hydrocodone-Acetaminophen 7.5mg-325mg at 0.135mg Hydrocodone/kg every 6 hours as needed, max daily dose of 0.54 mg/kg not to exceed 40 mg. The additional requirement of the patients' guardian will be to complete the provided pain journal on post-operative day 0-7, 10, 14, and 21. The journal includes patient's reported pain severity based on the Wong-Baker Faces Scale (scaled 0-10), amount of each analgesic medications needed per day, and how many days any pain medication was needed. The journals will be returned to the surgeon either via MyChart or at their post-operative clinic visits. If patients have access to My Chart and a phone camera, they can choose to upload a photo of their pain journal and send it to their surgeon once they are through requiring any pain medication/having any pain or after day 21. Parents will be informed that uploading these forms to MyChart will allow any personnel with access to MyChart to have access to their uploaded pain journal. If parents or subjects do not want this information available to personnel with MyChart access or if they do not have the ability to upload, they can bring their pain journal to their first follow up appointment." In order to improve pain journal completion rates guardians will be contacted via text message or My Chart at 48 hours and 5 days after discharge. The message will remind guardians to fill out their pain journals and provide them with a number to call if they have any questions about completing the pain journal. The phone number will connect them with a research staff member. If patients have not uploaded their pain journal to my chart by the time of their first follow up appointment, patients will be called and reminded to bring their pain journal with them to their appointment. All children will be seen at an office visit at 3-4 weeks following surgery, as is the current

standard practice, for pin removal and cast exchange or removal. The visit will be conducted per standard clinical care. The additional requirement outside the standard care will be for patients to return their completed pain journal if they have not already done so. There will be no additional clinic visits outside of the standard of care. The expected total follow-up time for each patient will typically be about 2 months, the longest expected time for essentially complete resolution of this injury. Surgeons recommended follow up time will only be based on standard clinical care and not participation in this study. After collecting the pain journals from patients/guardians, the information from these journals will be collected by research staff and put into an excel file. The data will be coded by giving each patient a unique study identifier. The codebook for connecting patient's identities will only be accessible by investigators/co-investigators listed on this IRB reviewed protocol. This file will be password protected and stored on secured servers or always using secure Texas Children's Hospital or Baylor College of Medicine cloud-based services. The following data will be reviewed and collected from the patient's chart or returned pain journal and analyzed: guardian contact information (for contacting about reminders) , patient demographics (age, gender, race/ethnicity), mechanism of injury, radiographs of injury and subsequent follow up radiographs, radiographic diagnoses and features, surgery date/time, time from injury to surgical stabilization, number of pins used for stabilization, lateral-only or medial-and-lateral pin entry, narcotic vs non-narcotic assignment, frequency of pain medication requested by patient, patient's reported pain intensity, medication administered for patient's pain from initial evaluation for fracture to last follow up appointment, clinical notes and radiographs for all follow up appointments, pain journals and information sent through My Chart, and any complications and subsequent treatment that developed. All information in post-operative clinic visit notes will be reviewed for outcomes, and any potential complications that may arise.

Recruitment

The population will be identified by all participating orthopedic surgeons within the department of TCH orthopedics. When a surgeon is assigned a closed reduction and percutaneous pinning for a supracondylar humerus fracture, they will determine if the patient meets inclusion criteria. On the day of surgery, during the pre-operative period the surgeon will meet with the patient prior to surgery per usual stand of care. During this meeting, the surgeon will ask the patient/family if they are interested in hearing about a study being conducted in this patient population. The surgeon will then play a video that explains the purpose, objectives, potential risks/benefits, and brief overview of additional requirements necessary for participation in the study. After watching this video, the surgeon will emphasize the potential risks/benefits of the study with patient/family and answer questions they have. The surgeon will give them adequate time to consider all

options and decide whether they want to consent to be enrolled into the study. If they want to participate in the study, a parent/guardian will be asked to consent for their child. Many of the subjects in this study cannot cognitively understand the purpose and procedures of this study; however, the study will always be discussed with the child to the best of his or her ability to understand depending on cognition level and assent will be obtained. If the parent/guardian refuses permission for their child to participate, then all clinical care will be provided to the child in accordance with usual institutional practice. If the child refuses to participate, then they will not be enrolled. A single parent/guardian will sign the consent form. Parent/guardian will also sign stating that their child gives their assent.

Statistical Analysis

Sample size was based on the Wong-Baker FACES pain scale which ranges from 0-10. This study consists of 2 independent groups with a 1:1 allocation ratio and has a continuous primary endpoint. We will use alpha level of 0.05 and a power of 80%. We assumed a standard deviation of 1.7 based on previous literature. In order for the study to find a difference of 1 point or larger between pain severity scores, a total of 90 patients would need to be enrolled (45 in each treatment group). 1 point was found to indicate a clinically significant change in severity rating.

Since this trial does not deviate from typical treatment practices, it is anticipated that nearly all patient families will follow the treatment guidelines and thus not request additional pain medication. However, it is possible that not all families remember to fill out their Recovery Journal forms each day. If approximately 10% of patient's guardians do not complete their recovery journal, then approximately 100 total patients would need to be enrolled.

Power analysis cannot be performed as there is not reliable estimation of the portion of patients that will request narcotic analgesia after this procedure. The sample size was chosen partially out of convenience: this number of patients likely can be recruited within approximately half a year and also will likely allow adequate insight into the baseline needs of this Population. It can be used for future Power Analysis, if further study of this situation is desired.

Descriptive statistics will provide mean and standard deviation. The sample sizes were inadequate for meaningful analysis. The mean and standard deviation reported on ClinicalTrials.gov are based on the limited data available based on mean/standard deviation pain score over the study period.