Complications Related to Activity After Both Bone Fractures: Why do we restrict activity? (CRABB-Y)

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1.0 Background

Pediatric forearm fractures are extremely common, accounting for up to 40% of all pediatric factures and consequently, the financial healthcare burden is large. The rate of displacement following closed reduction with casting/splinting of such fractures is high, varying between 21-39% (Meta-analysis Sengab). Consequences of fracture displacement include multiple adverse complications such as repeat sedation and fracture manipulation causing pain and distress, urgent or unplanned surgical interventions, and potentially malunion of the fracture. In addition to the morbidity of suboptimal fracture healing, there are significant functional consequences that could result due to fracture malunion. Previous studies have evaluated risk factors for forearm fracture displacement following closed reduction including initial displacement, cast index, and BMI however, little work has been done to evaluate the influence activity plays on the displacement/malunion of these fractures. As a result, this leads to inconsistent and nebulous recommendations provided to families regarding activity restrictions after closed treatment of fractures (i.e. non-surgical treatment). One can find significant variability in activity recommendations based on practices and individual provider preferences. Several studies have been conducted in other pediatric patient population to assess activity levels of children with various comorbidities. The purpose of this study is to evaluate the effect of activity on fracture displacement using and actigraph activity monitoring device. This device is externally applied and is an FDA approved activity monitoring devices with an extensive research background.

2.0 Rationale and Specific Aims

Rate of displacement following cast/splint application has been studied and varies between 21-39% based on the meta-analysis by Sengab et al. This randomized pilot study will include roughly 50-100 patients and will be completed in approximately 1 year with preliminary results available at that time. Between the 8 physicians and 4 nurse practitioners on staff within the pediatric orthopaedics department, approximately 20 patients weekly are seen who would meet eligibility for study participation. Assuming a 10% successful recruitment rate, it would require 6 months to recruit the desired number of participants. Eligible patients will be offered study inclusion during the initial outpatient clinic visit. These patients typically present to the clinic 3-7 days following injury.

The primary aim of this study is to determine whether activity influences loss of reduction of forearm fractures. Secondary aims of this study may provide insight to many other related questions as seen below**:**

- Does increased activity lead to more complications.
- Do instructions given to families influence activity level and do patients/families accurately report activity levels?
- Does activity level affect recovery length time of forearm fractures based on x-ray findings?

3.0 Animal Studies and Previous Human Studies

Multiple previous studies have investigated risk factors for loss of reduction. Previous studies have identified increased displacement at the time of injury and a cast index >0.8 as risk factors for loss of reduction. No studies have been conducted regarding the influence of activity on pediatric forearm fractures. Thousands of previous studies have used actigraph activity trackers, the monitoring device to be used in this proposed study, in the area of pediatric obesity, cardiology, and oncology, but no known prior study has used the device in pediatric orthopedic patients.

4.0 Inclusion/Exclusion Criteria

Included in the study will be patients ages 8-18 years old with fractures of radius and/or ulnar shaft or distal radius fracture. Specifically the following fractures will be included:

- Isolated Distal Radius Metaphyseal Fx (with or without ulna styloid)
- Distal Third (<4 cm from physis) Radius and Ulna fracture (i.e. without obvious physeal involvement)
- Insolated Radial Shaft Fracture (diaphyseal)
- Radial and Ulna Shaft Fracture (diaphyseal)

Exclusion Criteria include:

- Initial presentation >7 days from the time of injury
- Pathologic fracture
- Any patient with metabolic bone disease (ex. Osteoporosis, skeletal dysplasias)
- Any patient with known bone fragility condition (ex. Osteogenesis imperfecta)
- If operative treatment is required at initial presentation

5.0 Enrollment/Randomization

General inclusion/exclusion criteria will be used to determine patient eligibility. All eligible patients will be identified when they present to Vanderbilt's pediatric orthopedic clinic based on the clinicians interpretation of their presenting x-rays.

Consent is obtained during the office visit on paper or by REDCap econsent. Patients and families will be given as much time as they need to review the documents and ask questions. The patient consent process will be conducted using a REDCap-based electronic consent form or a paper consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users.

If a patient decides to participate in the study, they will randomized to one of two groups: Group A and Group B. Patients will be randomly assigned to one of groups based on the date of enrollment. If the date of enrollment is an odd integer, they will be placed in Group A. If the date is an even integer, they will be placed in Group B.

6.0 Study Procedures

The procedure studies will be as followed:

- Once non-operative management is deemed appropriate based on review of imaging and shared decision making with the family, eligible patients will be offered study participation during initial presentation at outpatient clinic visit (about 3-7 days post-injury). At the initial visit:
    - Standard or care X-rays will be reviewed
    - As part of standard of care a cast will be applied (or overwrapped with fiberglass)
    - Some participants will be provided an activity monitoring, based on availability, to be worn on the uninjured wrist or ankle consistent with manufacturers recommendations for the duration of casting treatment.
    - Participants will be randomized into restricted activity vs full activity groups and be read a respective standardized script regarding activity limitations. The same guidance will also be provided in the after visit summary (AVS).
    - Basic data will be collected including patient age, sex, BMI, initial displacement measurements, and other pertinent fracture characteristics easily obtainable from review of present radiographs.
- Patients will follow up at standard of care 1-2 week intervals for alignment checks. At these visits:
    - If the participants was provided a tracker, data from the monitoring devices will be imported with only a study id and date of birth to identify the patient. All data on the device will be deleted when information is imported.
    - Repeat standard of care x-rays will be obtained to assess for loss of reduction (defined as any change in angulation >10 degrees compared to initial reduction).
    - Incidence of complications such as unplanned cast changes, excessive skin irritation, cast wedging, loss of reduction, and operative management will be recorded.
    - For all enrolled patients, regardless of use of activity monitoring device, a validated Pediatric Activity Survey will be provided at follow-up appointments.
- Following all data collection, patient, survey, and activity tracker data will be analyzed

7.0 Risks

Given that there is not standardized or accepted activity recommendation for these patients, this study will not put these patients at increased risk of further injury. Further, the activity recommendations for the "unrestricted activity" group has common-sense exceptions on what the patient is allowed to do to prevent further injury such as avoidance of high risk situations such as contact sports. The devices are safe and usually well tolerated and have been validated for use in children. Minor possibility of skin irritation from the activity tracker due to chronic use however the device can easily be taken off if this is a problem. There are no other identifiable risks pertaining to the activity monitors or the activity restriction guidelines for providers, patients, or families.

Because patient data is being collected there is a slight risk of a breach of confidentiality. To reduce this risk, this study will utilize the REDCap platform for data collection and management. This project will utilize the REDCap platform for data collection and management. Project team

members listed as Key Study Personnel with existing electronic health record (EHR) system access rights may also be granted use of REDCap Clinical Data Interoperability Services (CDIS) tools. These tools are designed to enable transfer of relevant study-related data from the Vanderbilt Research Derivative and/or directly from the EHR into REDCap.

Only research personnel will have access to the patient's study information to ensure confidentiality. Any data sent to non-key study personnel for statistical analysis will be deidentified (dates will be shifted using a REDCap feature. The data obtained and stored in Redcap will only be accessible by research personnel. Any physical study forms (ex. Consent documents, surveys) will be kept in a locked cabinet in the principal investigator's office]. All study data will be maintained for 6 years following study completion. Following this 6 year period, the Redcap database will be archived, electronic files will be permanently deleted and all physical study forms will be disposed of in shred-it confidentiality bins provided by VUMC. This research may benefit patients in the future by allowing surgeons to provide more appropriate, evidence-based counseling to patients and families to prevent further injury/complication

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

All adverse events related to this study should be reported to the principal investigator immediately. The principal investigator will then ensure prompt reporting to the IRB based on policy number III.L.

9.0 Study Withdrawal/Discontinuation

Patients will be asked to contact study personnel if they decide they no longer want to participate in the study. Once a patient has withdrawn their consent, no further study data will be collected on them, and all data that has been collected up until the point their consent was rescinded will be destroyed.
If the patient refuses or withdraws from the study, they will continue receive routine care with normal follow up appointments consistent with standard practice.

Patients may be withdrawn from the study for lack of compliance wearing the activity monitor.

10.0 Statistical Considerations

Statistical analysis of data obtained from the patient charts, activity trackers, surveys, and investigator assessments will be conducted and analyzed by research personnel.

11.0 Privacy/Confidentiality Issues

During this study every attempt will be made to keep the patient's protected health information (PHI) private. Data obtained from this study will be stored in a Vanderbilt REDCap database or in a study folder on SharePoint. REDCap is a secure, web-based application for building and managing online databases. Only research personnel will have access to the patient's study information to ensure confidentiality. The data obtained and stored in Redcap will only be

accessible by research personnel. Any data sent to non-key study personnel for statistical analysis will be de-identified (dates will be shifted using a Redcap feature). Any physical study forms (ex. Consent documents, surveys) will be kept in a locked cabinet in the principal investigator's office]. All study data will be maintained for 6 years following study completion. Following this 6 year period, the Redcap database will be archived, electronic files will be permanently deleted and all physical study forms will be disposed of in shred-it confidentiality bins provided by VUMC.

12.0 Follow-up and Record Retention

The duration of this study will last until we have enrolled 100 patients and will continue 3-4 months after the last patient is enrolled to ensure fracture healing is complete and any potential complications are captured. No additional research related follow up visits are required as part of this proposed study. Patients will follow at routine intervals regardless of study participation. All study data will be maintained for 6 years following study completion. Following this 6 year period, the Redcap database will be archived, electronic files will be permanently deleted, and all physical study forms will be disposed of in shred-it confidentiality bins provided by VUMC.

Appendices:

Appendix A Standardized Scripts Regarding Activity

Actvity Restricted Group (GROUP A)

- "Your child has a forearm/wrist fracture. It is unknown if remaining active while in a cast affects the risk of complications after this type of fracture. Your child has been randomized to the "restricted activity" group. We ask that you limit sprinting, jumping, and organized sports during the time of cast immobilization. As a rule of thumb, we recommend "feet on the floor" activities while playing and avoiding playgrounds and gym class if possible. While it is not realistic to restrict a young child entirely, do your best to avoid strenuous or intense exercise until cleared by your physician or nurse practitioner"

Full Activity as Tolerated or Unrestricted Group (GROUP B)

- "Your child has a forearm/wrist fracture. It is unknown if remaining active while in a cast affects the risk of complications after this type of fracture. Your child has been randomized to the "activity as tolerated" group. Your child may participate in all desired activities except contact sports. Your child does not need to *increase* his/her activity level but should participate in activities as they feel comfortable doing so. Sprinting, jumping, and organized sports are acceptable as long as your child is not experiencing pain. Your child may use playgrounds and participate in gym class as desired. Do your best to avoid restricting your child from activities unless they are experiencing pain or you have concerns about their safety."