CORTICES Study Group

STUDY PROTOCOL

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Expand the size of table cells as needed – TRY NOT TO EXCEED 2 PAGES)**

TODAY'S DATE:

7/31/2024

1. PROJECT TITLE:

Pediatric Traumatic Hip Dislocation

2. PRINCIPAL INVESTIGATOR and HOSPITAL:

Alexandre Arkader MD (CHOP) Keith D Baldwin MD (CHOP)

3. CO-INVESTIGATORS

Jonathan G. Schoenecker MD, PhD (Vanderbilt); Research Fellow: Akbar N. Syed, MD (CHOP)

4. METHODOLOGY *(RCT, Prospective, Retrospective, Quality-Safety-Value, Cross-sectional survey)*

Retrospective

5. STUDY SETTING *(check one)*

- ☐ *Study group (all sites)*
- ☐ *Study group (specific sites); name sites:*

6. BACKGROUND *(Research gap, study rationale, prior relevant work)*

Currently, the majority of evidence surrounding traumatic pediatric hip dislocation is concentrated in small retrospective case series. Existing evidence supports a positive relationship between time to reduction and AVN risk. However, there is no universal consensus on the management of pediatric hip dislocations and there is a paucity of literature comprehensively evaluating patients with this injury. With this study we seek to provide a comprehensive review of the presentation, management, and outcomes of pediatric patients treated for traumatic hip dislocation. In addition, characterizing patients who are at greatest risk for complications may help identify which patients will require more aggressive therapy and closer observation to avoid poor outcomes.

7. CLINICAL QUESTION & SPECIFIC AIMS

*Include PICOt components for aims: **P**opulation, **I**ntervention, **C**omparison, **O**utcome, time*

P	I	C	O
1. To determine the rate and risk factors for AVN and functional outcomes following post-dislocation AVN of the femoral head			
Pediatric Patients with Traumatic Hip Dislocations	Early vs Late reduction, Open versus closed reduction	AVN vs No AVN	AVN Rate, AVN Management, AVN resolution or progression, Upadhyay and Moulton grading of dislocation at final follow-up, Range of motion
2. To establish differences in reduction protocols/ incidence of femoral head fractures and other adverse events of reduction (OSH vs CORTICES hosp, and ED vs OR)			
Pediatric Patients with Traumatic Hip Dislocations	Reduction Location	OSH vs CORTICES hosp, and ED vs OR	Imaging modality, iatrogenic fractures, time taken for reduction, time to reduction, delay in care, other complications.
3. To establish post-reduction imaging protocols (MRI findings vs CT, what findings were present and addressed on MRI that would not have been found on CT)			
Pediatric Patients with Traumatic Hip Dislocations	Imaging Protocol	CT vs MRI vs Radiographs	Missed injuries, change in management, secondary procedures
4. To establish post-reduction rehabilitation protocols (bracing duration, immobilization strategy by age)			
Pediatric Patients with Traumatic Hip Dislocations	Rehabilitation Protocol	Immobilization type, length of immobilization, weight bearing restrictions	Time to return to activity, Time to fill weight bearing, Re-dislocation events, Time to development of recurrent instability

5. To determine factors influencing return to sport			
Pediatric Patients with Traumatic Hip Dislocations	Reduction and Rehabilitation Protocols	Re-dislocation events, Early radiographic arthritis, time for development of recurrent instability	Hip instability/re-dislocation/stiffness
6. To determine the risk factors for hip instability/re-dislocation/stiffness			
Pediatric Patients with Traumatic Hip Dislocations	Reduction and Rehabilitation Protocols	Re-dislocation events, Early radiographic arthritis, time for development of recurrent instability	Hip instability/re-dislocation/stiffness
7. Development of Classification system for Pediatric Hip Dislocations			

8. INCLUSION AND EXCLUSION CRITERIA

Inclusion:

- Presented with injuries between 1/1/2011 and 1/1/2023
- Age 0 to 18 years at date of injury
- Diagnosis of hip dislocation or fracture-dislocation (fractures of the proximal femur or acetabulum or pelvis)
- Minimum 3 months follow-up (for certain research questions)

Exclusion:

- Previous history of fracture without dislocation.
- Inadequate documentation or x-rays.

9. DATA POINTS AND TIME POINTS

- *Variables describing the study participants:* Demographic, injury, and treatment characteristics for all will be used as and when deemed appropriate.
- *Outcomes:*
  - To determine the rate and risk factors for AVN and functional outcomes following post-dislocation AVN of the femoral head
    - Time to reduction, Radiographic development of AVN, Resolution of the AVN, Upadhyay and Moulton grading of dislocation at final follow-up, Range of motion
  - To establish differences in reduction protocols
    - Imaging modality, Location of reduction. Iatrogenic fractures, time taken for reduction, time to reduction, delay in care.
  - To establish post-reduction imaging protocols
    - Missed injuries, change in primary management after advanced imaging, secondary procedures
  - To establish post-reduction rehabilitation protocols
    - Time to return to activity, Re-dislocation events, Time to development of recurrent instability
  - To determine factors influencing return to activity/sports
    - Time to return to activity, Full or partial return
  - To determine the risk factors for hip instability/re-dislocation/stiffness
    - Re-dislocation events, Early radiographic arthritis, time for development of recurrent instability

10. STATISTICAL ANALYSIS *(To be completed by a statistician)*

Describe statistical analysis plan & who will perform analysis.

Appropriate statistical testing will be performed – normality testing following by univariate/bivariate and multivariate analysis as needed.

11. SAMPLE SIZE ESTIMATION/POWER ANALYSIS *(To be completed by a statistician)*

Estimating the sample size a priori ensures the study is adequately powered to achieve its proposed aims.

NA