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Outcomes of proximal humerus fractures in children: a study protocol for a retrospective cohort study

Samuel Richard Abbot ,[1,2] Susanna Proudman,[3,4] Kelly Hall,[4] Nicole Williams[2,5]

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[1]Orthopaedics and Trauma, Women's and Children's Hospital Adelaide, North Adelaide, South Australia, Australia
[2]Centre for Orthopaedic and Trauma Research, The University of Adelaide, Adelaide, South Australia, Australia
[3]Rheumatology Department, Royal Adelaide Hospital, Adelaide, South Australia, Australia
[4]Department of Medicine, The University of Adelaide, Adelaide, South Australia, Australia
[5]Department of Orthopaedic Surgery, Women's and Children's Hospital Adelaide, North Adelaide, South Australia, Australia

Correspondence to
Dr Samuel Richard Abbot; Samuel.Abbot@sa.gov.au

ABSTRACT

Introduction Proximal humerus fractures (PHFs) comprise <3% of all fractures in children and adolescents. While it is accepted that minimally displaced PHFs can be treated conservatively, the management of severely displaced PHFs remains controversial, especially in older children. This study will aim to analyse the functional and quality-of-life outcomes of children with PHFs, in order to inform their optimal management.

Methods and analysis We will conduct a retrospective cohort study to evaluate the outcomes of patients who were diagnosed with a paediatric PHF at the Women's and Children's Hospital (WCH) in South Australia. The primary outcome will be each participant's pain and quality-of-life outcome, determined by use of the Quick Disabilities of the Arm, Shoulder and Hand, Shoulder Pain and Disability Index and Paediatric Outcomes Data Collection Instrument. Secondary outcomes will include rates of non-union, persistent deformity and complications. The information for these variables will be acquired during a brief clinic appointment, and from the medical records and WCH radiology database. Multivariable logistic regression will be performed to determine the clinical variables associated with a worse clinical outcome.

Ethics and dissemination The study has been approved by the Women's and Children's Health Network Human Research Ethics Committee (protocol number: 2021/HRE00250). The study findings will be submitted to peer-reviewed scientific journals for publication and disseminated at conference presentations.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN12622000176763).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of this study is that it will evaluate the long-term functional and quality-of-life outcomes of paediatric proximal humerus fractures, whereas previous studies have only analysed radiological or short-term to medium-term outcomes.
⇒ A limitation is the use of patient-reported outcome measures that have only been validated for assessing upper limb pathology in adults, as no existing patient-reported outcome measure that has been validated for use in children.
⇒ Another limitation is the retrospective study design.

INTRODUCTION

Proximal humerus fractures (PHFs) comprise between 0.45% and 2% of all fractures in children and adolescents, and 3%–6.7% of all physeal fractures,[1–4] with an estimated incidence between 31.4 and 680 fractures per 100 000 children per year, and at least a 3:1 male preponderance.[1 3 5–8] There are two common responsible mechanisms, namely a backwards fall onto an out-stretched hand with the arm hyperextended and externally rotated, or direct trauma to the lateral aspect of the shoulder.[1 3 6 7 9] The usual cause of injury is age-dependent. In neonates, physeal separations can occur as a result of birth trauma.[3 7 9] PHFs in older children typically result from moderate-energy trauma during high-contact sports (such as football, horse-riding and gymnastics) or motor vehicle accidents.[1 3] A PHF occurring in an otherwise healthy infant should be considered suspicious for nonaccidental trauma.[7]

In 1965, Neer and Horowitz introduced a system to classify the severity of PHFs based on the degree of displacement.[10] Neer-Horowitz (NH) grade-I fractures are either non-displaced or displaced by less than 5 mm, grade-II are displaced between 5 mm and one-third of the width of the proximal humeral shaft, grade-III are displaced greater than one-third but no greater than two-thirds of the shaft width and grade-IV are displaced by more than two-thirds of the shaft width.[11] Eighty-five per cent of paediatric PHFs are either non-displaced or minimally displaced (NH grade-I or grade-II), with only 15% being severely displaced (NH grade-III or grade-IV).[4 11] PHFs that occur prior to skeletal maturity rarely lead to a functional or cosmetic deficit for a number of reasons.[7] First, they have a profound ability to remodel, due to the proximal humeral growth plate being responsible for 80% of overall humeral longitudinal growth.[6 12–15] Second, the periosteum in the immature humerus is metabolically active, which enhances its ability

to rapidly consolidate fractures and heal.[1 16] Third, the glenohumeral joint has the widest range of motion of any joint in the body, meaning it can accommodate a large degree of displacement and angulation without causing any significant functional impairment.[6 17 18] Because of these unique attributes, paediatric PHFs have historically been treated non-operatively, regardless of their severity.[2 19]

Since the study by Neer *et al* in 1965, conservative management has remained the mainstay of treatment for minimally displaced (grade-I and grade-II) PHFs in children, whereas the management of grade-III and grade-IV fractures remains controversial, particularly in adolescents with limited remodelling potential.[4 10] There is now an apparent consensus in the contemporary literature that adolescents managed conservatively for severely displaced PHFs are at risk of a less than desirable clinical outcome.[8 13 20 21] In keeping with this, a recent trend towards operative treatment has been identified over the past decade.[1] Numerous algorithms for the treatment of paediatric PHFs based on patient age and grade of displacement have been proposed,[2 5 8] although there is considerable heterogeneity as to the proposed thresholds for surgery, and no generally accepted evidence-based guideline has been established.[4 8 21–23] Based on their retrospective analysis of 28 patients with NH grade-III and grade-IV PHFs, Dobbs *et al* recommended a protocol for patients following closed reduction. For patients <7 years old, postreduction angulation of up to 70° can be accepted; for patients aged 8–11 years, up to 60° can be accepted and for patients ≥12 years, up to 45° can be accepted. It was concluded that deformities greater than these thresholds for these groups of patients require open reduction and internal fixation.[8] The protocol suggested by Binder *et al* was more aggressive for patients over 10 years old. They recommended conservative management for children <10 years old with up to 20° angulation, and surgery for children >10 years with more than 20° angulation, citing an increased risk of soft tissue interposition in fractures with more than 20° of angulation.[13] The protocol proposed in the systematic review by Hohloch *et al* was considerably more conservative.[5] They recommended non-operative management for children <10 years old with a severely displaced PHF, and surgical treatment for those ≥13 years. As can be seen, there are considerable discrepancies in the various treatment algorithms that have been proposed to date. Furthermore, as PHFs represent less than 3% of fractures in children, studies that have investigated this subject tend to be retrospective analyses of small cohorts of patients, with only a short period of follow-up and low follow-up rates.[5 7] Consequently, there is a paucity of high-quality studies that have examined long-term functional and quality-of-life outcomes following paediatric PHFs from which to derive an evidence-based guideline regarding management options.[4 5] Our study will aim to analyse the functional and quality-of-life outcomes of a large cohort of children and adolescents with PHFs, in order to inform their optimal management. A secondary aim is to determine the clinical factors that predict a worse clinical outcome for paediatric PHFs, including patient demographics, fracture pattern and treatment methodology. The hypothesis is that adolescent patients treated non-operatively have a higher risk of a poor clinical outcome, especially when the initial displacement of their fracture is greater.

METHODS AND ANALYSIS

Study setting

This will be a retrospective cohort study. The study will be conducted at the Women's and Children's Hospital (WCH) in South Australia, the tertiary referral paediatric centre for orthopaedics for the state of South Australia and surrounding regions of south-western New South Wales and western Victoria.

Patient and public involvement

Patients were not involved in the design or proposed methodology of the study. The findings of the study will be disseminated to the study participants by mail, at the conclusion of the study.

Eligibility criteria

The principal investigator will identify potential participants from the medical records and radiology database of the WCH based on a diagnosis of a PHF when under the age of 18 years. The diagnosis will be confirmed on examination of the plain-film radiographs. The inclusion and exclusion criteria for the study are listed in table 1.

Case ascertainment

The study will begin with a retrospective analysis of the medical records at the WCH as well as the records at the private practices of WCH-coemployed orthopaedic surgeons. The records of consecutive patients diagnosed and managed with PHFs between 1 January 2010 and 1 June 2020 will be reviewed. Cases will be ascertained from the inpatient and outpatient records using International Classification of Diseases codes. Additionally, the WCH radiology database (Kestrel) will be reviewed using keyword search for "shoulder", "humerus" and "fracture" to identify fractures of the proximal humerus that have occurred between 1 January 2010 and 1 June 2020.

Recruitment

Once potential participants have been identified, their vital status will be reviewed in the state-wide clinical information system to ensure that families of deceased patients are not contacted. Each potential participant will be mailed a copy of the Letter of Invitation to Participants, the Participant Information Sheet and the Informed Consent Form. If they do not opt out of the study by emailing or calling the principal investigator, they will then be contacted via telephone 2 weeks later and given verbal information about the research project. During this telephone call, the participant will be asked to sign

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Participants aged under 18 years at the time that they sustained a PHF. 2. All clinical subtypes of PHF, as outlined by the Neer-Horowitz and AO classifications. 3. Participants must have been diagnosed with their PHF at the WCH between 1 January 2010 and 1 June 2020, and had their definitive treatment either there, or at the private practice of WCH-coemployed orthopaedic surgeons.	1. Patients whose fracture was the result of reported or suspected domestic violence, or required mandatory reporting. 2. Patients less than 2 years of age. 3. Patients who are unwilling to give consent. 4. Patients who the researcher believes would be unable to participate in the study (eg, patients who are too young to provide answers in the structured questionnaire). 5. Patients with pathological fractures of the proximal humerus. 6. Patients who are under the guardianship of the minister.

PHF, proximal humerus fracture; WCH, Women's and Children's Hospital.

the informed consent form if they have not already done so.

Data collection and assessment tools

Participants who consent to participate in the study will complete a structured questionnaire over the telephone. This questionnaire will include the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), the Shoulder Pain and Disability Index (SPADI) and the Paediatric Outcomes Data Collection Instrument (PODCI).[24–26]

The original Disabilities of the Arm, Shoulder and Hand (DASH) score takes into account daily activities, symptoms and social function, and has been shown to have strong reliability and validity for assessing patients with PHFs.[27] From the original 30-item DASH questionnaire, the shorter 11-item QuickDASH was developed, which reduces the completion time and the administrative burden. The items in the QuickDASH were selected from the original instrument on the basis of them having the highest reliability, validity and responsiveness within each domain of the DASH.[28] The SPADI questionnaire was created in 1991 by Roach *et al* and consists of two components—one that assesses the participant's pain levels, and one that assesses the participant's ability to carry out various functional activities. The QuickDASH and SPADI have been validated for use via telephone.[29 30] The PODCI is a well-validated musculoskeletal health questionnaire that addresses a child's mobility, upper limb function, sports and physical function, pain and happiness.[31] While there is precedence for the PODCI being administered via telephone in previous studies,[32 33] the authors were not able to identify any study which has evaluated its validity for telephonic review. Additionally, participants will complete a questionnaire developed by the researchers that asks demographic and clinical questions related to the participant's current occupation, highest level of education, comorbidities and other musculoskeletal injuries that they have sustained.

At the conclusion of the telephone interview, participants will be invited to have either an in-person clinic appointment, or an online video meeting, to allow for a standardised clinical examination to assess their range of motion and strength. Participants who agree to an in-person clinic appointment will be asked to bring their signed consent form with them, so that a scanned copy can be made for our records. Those who undergo a video interview will be asked to scan and email their signed consent form to the principal investigator. The range-of-motion examination will involve three tests, namely the hand-to-neck, hand-to-scapula and hand-to-opposite-scapula tests.[34] Together, these tests assess movement of the shoulder joint in all dimensions, and they have been found to have strong intratester and intertester reliability.[34] Table 2 outlines the scoring system for these tests.

Participants who are examined in-person will also undergo an assessment of their shoulder's strength. Shoulder strength in forward-elevation, extension, abduction, adduction, internal rotation and external rotation will be scored out of 5, as according to the classification tool of the American Spinal Injury Association (see table 3).[35]

The strength of participants who undergo a video meeting will be assessed using the techniques introduced by Laskowski *et al*.[36] In these techniques, shoulder internal rotation and external rotation are assessed by the participant's ability to perform these movements against resistance, provided by either a doorframe or another person. Abduction strength is assessed by asking the participant to abduct their arm to 90° and apply self-resistance with the opposite arm. This technique could also be used to assess forward elevation, by asking the participant to maintain their arm 90° of forward elevation while applying a downward force with the opposite arm.

Outcomes

Primary outcome measures

The primary outcome measure will be pain and quality-of-life outcomes, as determined by the QuickDASH, SPADI and PODCI questionnaires. Consistent with the methodology of two previous studies that have investigated paediatric PHFs, by Canavese *et al* and Khan *et al*,[16 37] a poor outcome for the QuickDASH will be defined as a score of 2 or more out of a possible 11 points. To the authors'

Table 2 Scoring system for the range-of-motion tests[34]

Hand to neck (shoulder flexion and external rotation)	
0	The fingers reach the posterior midline of the neck with the shoulder in full abduction and external rotation, without wrist extension
1	The fingers reach the midline of the neck, but do not have full abduction and/or external rotation
2	The fingers reach the midline of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation
3	The fingers touch the neck
4	The fingers do not touch the neck
Hand to scapula (shoulder extension and internal rotation)	
0	The hand reaches behind the trunk to the opposite scapula or 5 cm beneath it in full internal rotation
1	The hand almost reaches the opposite scapula, 6–15 cm beneath it
2	The hand reaches the opposite iliac crest
3	The hand reaches the buttock
4	Subject cannot move the hand behind the trunk
Hand to opposite scapula (shoulder adduction)	
0	The hand reaches to the spine of opposite scapula in full adduction without wrist flexion
1	The hand reaches to the spine of opposite scapula in full adduction
2	The hand passes the midline of the trunk
3	The hand cannot pass the midline of the trunk

knowledge, no previous study has used the SPADI to measure functional outcomes of PHFs in the paediatric population. A poor outcome will be defined as a SPADI score of greater than 3 out of a possible 10 points, based on the findings of the studies by Chester *et al*, Merolla *et al* and Kuhlmann *et al*,[38–40] who found that the mean SPADI scores for their cohorts of patients with shoulder pathology were between 3 and 4 out of a possible 10 points. Similarly, the authors were not able to identify any previous study that has measured the functional and quality-of-life outcomes of paediatric PHFs by use of the PODCI. However, multiple previous studies have used the PODCI to quantify outcomes following supracondylar humeral fractures in children, and have considered a score of less than 90 at final follow-up to be poor.[41 42] Based on the finding of these studies, a PODCI score of less than 90 will be defined as 'poor'.

Table 3 Scoring system for strength assessment[35]

0	Total paralysis
1	Palpable or visible contraction
2	Active movement, full range of motion with gravity eliminated
3	Active movement, full range of motion against gravity
4	Active movement, full range of motion against gravity and moderate resistance in a muscle-specific position
5	Normal active movement, full range of motion against gravity and full resistance in a muscle-specific position expected from an unimpaired person

Secondary outcome measures

Secondary outcome measures will include objective clinical and radiological assessments, including rates of union and non-union for fractures treated with the different treatment modalities, persistent deformity, degree of fracture angulation and NH grade of fracture displacement at final follow-up, complications of treatment (such as infection and need for reoperation), and shoulder strength and range of motion. The information for these variables will be acquired during the clinic/video appointment, and from the medical records and radiology database at the WCH and the private rooms of WCH-coemployed orthopaedic surgeons. The radiological assessment of each participant's fracture will be carried out by the principal investigator, who is an orthopaedic registrar at the WCH, on examination of the plain-film radiographs.

Baseline data

The following data will be obtained from the medical records and radiology database at WCH:

- Current age, gender, ethnicity.
- Age at fracture relative to expected age of skeletal maturity, as per the Menelaus rule-of-thumb.[43]
- Radiographic evidence of skeletal immaturity or maturity at the time of fracture, as evidenced by an open or closed proximal humeral physis on X-ray, respectively.
- Mechanism of injury.
- Fracture pattern.
- Treatment methodology.
- Duration of follow-up.
- Radiological outcome.
- Complications of treatment.

Table 4 Schedule of enrolment, data collection and assessments

Assessment/procedure	Screening of medical records and radiology database	Telephone interview	Clinic appointment	Review of medical records and radiology database
Identification of potential participants	X			
Send out letter of invitation to participants, participant information sheet and informed consent form	X			
Ensure informed consent form has been signed		X		
Structured questionnaire		X		
Range of motion and strength examination			X	
Demographic information				X
Fracture pattern				X
Treatment methodology				X
Complications of treatment				X

Data collected during interview and clinic appointment

The following data will be obtained during the telephone interview and subsequent clinic appointment:

- Comorbidities and medications.
- Pain and quality of life outcomes (QuickDASH, PODCI and SPADI questionnaires).
- Shoulder strength and range-of-motion.

Participant timeline

Table 4 outlines the process by which participants will be identified, consent will be obtained, and data will be collected from each participant.

Sample size calculation

Our sample size estimation, justification and power calculations were made by a University of Adelaide statistician, on the basis of the studies by Canavese *et al* and Khan *et al*, which suggest that between 26% and 37% of paediatric patients with a PHF will experience a poorer outcome, defined as a QuickDASH score of 2 or more out of a possible 11 points.[16 37]

Five items will be investigated as potential risk factors for a poorer clinical outcome: age at fracture, gender, fracture severity, comorbidities and treatment methodology. The data analysis will be with multivariable logistic regression, which requires a minimum of 10 events per variable to ensure adequate power and model stability. To allow for more complex relationships (eg, interactions or non-linear functions) in the data, this will be increased to 15 events per variable. The risk factors of interest translate into 10 predictors. As per the findings of previous studies, it is reasonable to expect that 30% of patients will have a QuickDASH score of at least 2.[16 37] If 10 predictors are used, this equates to a required sample size of 500 participants.

Since one of the key hypotheses of this study is that the adolescent group (aged 12–18 years) will have poorer outcomes than the younger group (2–11 years), power calculations were made to determine the level of power that the study would have to assess the difference in outcomes between these two groups, based on the number that will also be required to ensure a stable model when fitting a multivariable logistic regression model. With the assumed overall proportions being 30% and the hypothesis that the adolescent group will have worse outcomes than the younger group, the following calculations assume that 40% of the adolescent group (n_1) will have a poorer outcome, and 20% of the younger group (n_2) will have a poorer outcome. As shown in table 5, if 500 participants are recruited, this would confer 99.9% power.

Assuming 80% power to detect a proportion of 0.4 in the adolescent group and 0.2 in the non-adolescent group with a two-sided α of 0.05, with continuity correction applied this would require 91 patients per group, with an overall sample of n=182. As outlined above, however, we will attempt to recruit 500 participants so that the multivariable logistic regression model can be performed.

Data analysis

Multivariable logistic regression will be performed to determine the clinical variables that are associated with a worse clinical outcome. Subgroup analyses will also be performed on:

1. Participants aged 16–18 years old at the time they sustained the PHF.
2. Participants who sustained NH grade-III or grade-IV fractures.

Table 5 Power calculation for adolescent and younger group

Total sample ($n = n_1 + n_2$)	Power (%)
950	100
800	100
650	100
500	99.9

3. Participants who were skeletally mature at the time of diagnosis.

These subgroup analyses will allow us to assess the efficacy of treating adolescent patients conservatively rather than operatively, depending on the severity of their PHF.

ETHICS AND DISSEMINATION

Research ethics approval

The study has been approved by the Women's and Children's Health Network Human Research Ethics Committee (protocol number: 2021/HRE00250).

Safety considerations

As there is no intervention involved in this study, but rather simply a telephone interview with a structured questionnaire and a clinic appointment with a brief shoulder examination, the safety or well-being of the participants is unlikely to be compromised. The questionnaire is unlikely to cause any offence or distress. Participants will be allowed to have a family member present during the interview, to optimise their emotional security and support. Patients whose fracture was the result of reported or suspected child abuse, or required mandatory reporting, will be excluded from the recruitment process. Finally, any health concerns that are raised during the clinic interview will be addressed, and the participant will be offered a referral to the appropriate outpatient clinic or advised to consult their general practitioner about the health issue, if appropriate.

Consent

The principal investigator will obtain informed consent. The consent form will be completed by participants aged over 18 years, and by the guardian of participants who are under the age of 18 years.

Confidentiality

Clinical and radiological data will be collected using REDCap electronic data capture tools hosted at SA Health.[44 45] Participants will be listed by their WCH Unit Record Number with names removed. Data will be uploaded to Figshare, the University of Adelaide's data and digital object repository, where it will be stored until 30 years after the completion of the project, in accordance with the Government of South Australia General Disposal Schedule No. 28.[46] At this time, the data will be permanently deleted from Figshare and REDCap.

Access to data

Access to the raw data set will be limited to the statistician and the principal investigator.

Dissemination policy

The study findings will be submitted to peer-reviewed scientific journals for publication, and will also be disseminated at local, national and international conference presentations.

Contributors SRA, NW and SP developed the study. SRA is the principal investigator and drafted the protocol. NW and SP are the supervisors of the study, and have actively contributed in reviewing the protocol and methodology. KH is the statistician who is responsible for the statistical methodology and analysis. All authors have read and approved the final manuscript of the study protocol. All authors meet the ICMJE criteria for authorship.

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ORCID iD

Samuel Richard Abbot http://orcid.org/0000-0001-8829-862X

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