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Development and validation of the paediatric elbow trauma (PET) rules as a decision rule for radiography in traumatic elbow injuries: a study protocol

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ABSTRACT

Background Traumatic elbow injuries in children occur frequently and are among the most common traumatic injuries seen in the emergency department (ED) and in general practice. The use of a validated decision rule to enhance selective radiography in paediatric patients with possible elbow fractures may reduce unnecessary exposure to radiation in children.

Method and analysis This study is designed as a multicentre prospective cohort study. An expert panel of orthopaedic elbow surgeons, paediatric orthopaedic surgeons and trauma surgeons will initially determine clinical parameters that provide a possible predictive value for elbow fractures. Four hundred children between the ages of 2 and 17 years visiting the ED with pain following elbow trauma will then be included. The clinical parameters will be collected via patient history and physical examination. Elbow radiographs will be obtained in all patients to identify fractures. The data will be processed in a multivariable logistic regression analysis to determine which clinical parameters predict the presence of an elbow fracture. Only the clinical parameters that predict a fracture will be used to formulate the new decision rule: the paediatric elbow trauma (PET) rules. Internal validation of the prediction model will take place after inclusion is complete and by means of a bootstrap analysis on the acquired data. A calculation will be made to determine how many radiographs can potentially be reduced by applying the PET rules and a cost analysis will be performed.

Ethics and dissemination The study will be conducted according to the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act. The Medical Research Ethics Committees United stated on 16 May 2022 that The Medical Research Involving Human Act (WMO) does not apply to this study and an official approval by the committee is not required, reference number; project W22.086.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Paediatric elbow fractures are very common and only one diagnostic decision rule is available. Every child will have undergone a plain radiography to check for possible fractures.

WHAT THIS STUDY ADDS

⇒ To modernise the diagnostic decision rule for paediatric elbow fracture and increase its sensitivity, and to reduce the unnecessary radiation exposure to children in the emergency care when taking an overabundant radiography.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ To ensure not every child undergoes a radiography, but only those with a high chance of elbow fracture decided through our decision rule.

INTRODUCTION

Elbow fractures are defined as fracture of the distal part of the humerus and/or proximal part of the radius and/or proximal part of the ulna. Overall, 40%–60% of all boys and 25%–40% of all girls will visit the emergency care with a fracture during their childhood.[1] Paediatric elbow fractures are among the most common injuries seen in the emergency department (ED).[1] Incorrect diagnosis and treatment can lead to undesirable pain and decreased range of motion during adult life.

Plain radiography of the elbow is used to visualise the suspect diagnosis of a fracture. In the Netherlands, every child with a traumatic injury to the elbow visiting the ED must endure this very small but potentially harmful dosage of radiation, even though the majority of these patients have no fracture.[2] A decision rule may be useful to reduce the number of unnecessary radiographs.

More than a decade ago, the research group of Appelboam *et al*[3] developed the

elbow extension test, a decision rule to enhance selective radiography and decrease the risks of radiation by reducing the number of unnecessary X-rays. The use of this decision rule ultimately led to an absolute reduction in the number of unnecessary plain radiography taken from children. This trend is also seen in other decision rules designed for injuries to other joints, such as the ankle, knee, wrist and neck.[4–8]

Recently, a research group in Amsterdam developed the Amsterdam Pediatric Wrist Rules (APWR),[9 10] the first validated decision rule for paediatric acute wrist trauma. With the implementation of the APWR, an absolute reduction of 19% of the unnecessary radiographs was seen. These data highlight a knowledge gap and opportunity for the development of a decision rule for paediatric elbow fractures.

Our research objective is to develop and validate an extended decision rule for paediatric elbow fractures (the paediatric elbow trauma rules) to improve selective radiographic imaging. Furthermore, we aim to improve the quality of care for children who present themselves at the emergency care with an injury of the elbow by reducing the waiting times and healthcare costs.

METHODS AND ANALYSIS

Study design

This is a multicentre prospective observational study of paediatric patients who visit the ED with a traumatic elbow injury. The data will be collected in four different hospitals; one academic hospital, two large teaching hospitals and one general hospital.

The first part of this research is the development of the decision rule with use of clinical parameters obtained from baseline patient characteristics, patient interview and physical examination. An expert panel of orthopaedic elbow surgeons, paediatric orthopaedic surgeons and trauma surgeons will determine which clinical parameters provide a possible predictive value for elbow fractures. We will collect all clinical parameters (originating from the expert panel) via the patient history and physical examination from all patients. All patients will get radiographs of the affected elbows and will be provided emergency care according to local hospital protocols. These patient data will be processed in a multivariable logistic regression analysis to determine the clinical parameters that predict the presence or absence of an elbow fracture. Only the clinical parameters which significantly predict a fracture, within this prediction model, will be used to formulate the new decision rule.

In the second part of this research, the newly developed decision rule will undergo internal validation using separate data identically gathered in a prospective fashion. At the same time, we will determine the primary outcome measurements: the potential absolute reduction in the number of X-ray examinations, a calculation detailing how much costs have been saved by taking more selective X-rays and a calculation on time saved during an ED visit.

Box 1 Inclusion and exclusion criteria used during the selection of paediatric patients in this study

Inclusion criteria

⇒ Patients aged between 2 and 17 years.
⇒ Traumatic injury of the elbow (maximum 72 hours prior to presentation on the emergency department).
⇒ Pain in the anatomical region of the elbow joint.

Exclusion criteria

⇒ Pre-existent neurological pathology, genetic disorders and/or bone disorders in the affected limb.
⇒ Current ipsilateral fracture of wrist or shoulder.
⇒ Previous fracture of the ipsilateral upper extremity (from clavicle to distal phalanges) <3 months.
⇒ Patients referred from another hospital where X-rays of the elbow were performed.
⇒ A multitrauma patient (Injury Severity Score >16).
⇒ Children with an intellectual disability.
⇒ Unable to communicate in Dutch or English.

The final study will include a completed version of the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) checklist. With this checklist, we hope to improve the transparency of our research by identifying the important factors in the prognostic prediction model, according to the TRIPOD statement.

Study population

The study population is defined as all consecutive children/adolescents aged 2–17 years who visit the ED of one of the participating hospitals with pain following elbow trauma. The anatomical region of the elbow is defined as the bony and articular surfaces of the distal humerus, the proximal ulna and the proximal radius.[11] A traumatic injury is defined as any direct or indirect low-energetic or high-energetic trauma involving the elbow. A full list describing the inclusion and exclusion criteria is given in box 1.

Sample size

A traditional sample size calculation is not recommended due to the multivariable character of this study. A sample size calculation through its ability to accurately estimate effect size is chosen, therefore, a modified convenience sample will be used. A logistic regression analysis is used to determine the potential variables for the final decision rule. The variance between outcomes per variable within a regression analysis dictates the sample size per variable. The variance between outcomes for the potential variables in the decision rule is estimated to be very small (predominantly yes/no answers). Jenkins and Quintana-Ascencio, Riley *et al* and Steyerberg[12–14] described a detailed calculation for an adequate sample size in clinical decision/prediction models. Based on their recommendations, we aim to include 400 patients for our study. To summarise: on average 8–12 participants are needed per variable to ensure a valid prediction can be made concerning the

variables' discriminative value. To increase the accuracy of the prediction model, we will focus on 10 predictive potential variables with a high a priori chance of underlying traumatic injury to the bone. Therefore, we will need to include a minimum of 100 patients (10 variables × 10 patients). To ensure an accurate internal validation for our updated clinical decision rule a minimum of 300 patients must be included.[14] Based on these estimates, we have chosen to include 400 patients for our research; 100 patients (25%) for the development of the decision rule and 300 patients (75%) for the internal validation of the decision rule.

Statistical analysis

The data from standardised electronic case report forms (CRFs) will be used to develop the prediction model, by using a multistep logistic multivariable analysis in a shrinkage model. The shrinkage model used will be a ridge regression, because of its ability to analyse data suffering from multicollinearity (multiple independent variables are correlated). During the first step, a univariate logistic regression analysis will be used to estimate the regression coefficients and analyse the correlation between a variable and the presence or absence of a fracture. The regression coefficients will be processed, in the second step, through a multivariate shrinkage model to establish significant regression coefficients and generate a relative risk score per variable. Sensitivity, specificity, positive predictive value and negative predictive values will be gathered. The accuracy of the model will be estimated by a goodness-of-fit test with a graphical calibration curve and a receiver operating characteristics curve with a discriminative curve. Overfitting will be controlled by calculating the optimism estimation of the C-statistic. Internal validation will be performed through bootstrapping to estimate overfitting and adjust the model accordingly. The final decision rule will be presented as a simplified risk score for easy use by emergency care physicians.

Missing data

We will use three strategies to avoid or adequately substitute potential missing data: (1) optimising the study design and implementation methods to avoid missing data, such as; training doctors, creating simplified CRFs and adhering to normal treatment protocol, (2) sending regular updates to all participating hospitals and (3) investigating patterns of missing data to allow analyses to explore potential reasons for missing data and impute missing values by chained equations to avoid bias.

Study procedures

Data collection will take place starting May 2023 and will be completed after including 400 patients, preferably within a 2-year period. All paediatric patients presenting to the ED following a traumatic injury of the elbow will receive care as usual according to hospital protocol. To develop the decision rule, we will collect patient characteristics in a standardised fashion during the interview and physical examination. A standardised electronic CRF will be generated to collect the data during the participant's visit. The CRF will contain basis information on patient characteristics such as age, gender, injured arm, it will also include a physical examination, the results of the X-ray and the possible predictive clinical parameters. The attending (orthopaedic/surgical) physicians collecting the data will receive instructions and training before recruiting participants to the study. Possible predictive clinical parameters are patient age and gender, point tenderness at lateral or medial distal humerus, radial head, olecranon, limited range of motion for supination/pronation/flexion and extension, hypoesthesia of the lower arm, increased capillary refill test, visible haematoma and trauma injury mechanism. All participants will receive plain elbow radiographs, according to Dutch guidelines; anterior–posterior view with the hand in anatomical position and a lateral view with the thumb in upwards position.[15] Additional imaging for associated injuries or to confirm suspected diagnosis will be performed at the discretion of the treating orthopaedic or trauma physician.

Primary outcome parameters

Our primary outcome measurement is the existence of a fracture on the conventional X-ray diagnosed by a musculoskeletal radiologist. A fracture is defined as a partial or complete disruption of one or more of the cortices in the ulna, radius or humerus within the elbow region and all epiphysial growth plate injuries visible on AP or lateral view. Avulsions or displacement of apophyseal growth plates are also defined as a fracture. All additional imaging (radiography, MRI or CT) performed by the on-call physician and radiologist will be taken into account when diagnosing the fracture.

Our primary outcome, a fracture of the elbow, will be measured after inclusion of all 400 patients. All participants will receive a conventional radiography. After inclusion has ended all conventional radiographs will be gathered for final inspection. This will be done by two musculoskeletal radiologist in consensual agreement and blinded to the clinical parameters and medical history of the patient. The two musculoskeletal radiologist will provide a detailed diagnostic report, after reaching consensus, for every radiography performed on our patients. This final report will dictate the presence or absence of a fracture of the elbow after traumatic injury to the elbow in the paediatric patient.

Withdrawal of individual subjects

Participants can leave the study at any time for any reason if they wish to do so without any consequences. The principal investigator or treating physician can decide to withdraw a subject from the study for urgent medical reasons.

Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (64th World Medical

Association General Assembly, Fortaleza, Brazil 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO, valid since 1 July 2021).

Recruitment and consent

Potential participants and/or the parents or legal guardians of the participants will be asked to join our study by the physician on call in the ED prior to regular diagnosis and treatment. Verbal informed consent will be given. Participants have no obligation to participate and will receive diagnosis and treatment as normal. Participants who are willing to join will receive similar treatment, the only difference is that clinical parameters recorded during patient interview and physical examination will be more extensive and will be recorded in a CRF.

Patient and public involvement

No patients were involved during the creation of this study protocol.

Administrative aspects

Handling and storage of data and documents

All acquired patient-related data will be anonymously coded with a referencing legend for safe used by members of the research team. Research data will be stored in a database (SPSS V.25 and Castor EDC and SMS) and can be traced to individual persons only by authorised personnel. The personnel authorised to view the database include the members of the research team, members of the healthcare inspection and members of the medical ethics committee. Review of the data may be necessary to ensure the reliability and quality of the research. The handling of personal data is in compliance with the Dutch act on Implementation of the General Data protection Regulation (in Dutch: 'Wet Algemene Verordening Gegevensbescherming persoonsgegevens'), the EU General Data Protection Regulation and the privacy regulation of all involved hospitals.

Contributors In the process of creating the manuscript, the seven authors fulfilled the following roles and tasks: TFFS main author; set up the design of the study, recruiting an expert panel, conception and writing of the manuscript; CJAvB study designer; conception and design of the study, provided orthopaedic and scientific expertise and critical revisions to the study protocol. BT expert panel; providing critical revisions and help with interpretation of data. PBvH expert panel; providing critical revisions and help with interpretation of data. NWLS expert panel; providing critical revisions and help with interpretation of data. LCvB legal counsel and statistical help; aided in legal issues, assisted with administration and data management, provided statistical help. DE final author; conception and design of the study, provided orthopaedic and scientific expertise and critical revisions to the study protocol. Final author of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This Medical Research Ethics Committees United stated on 16 May 2022 that The Medical Research Involving Human Act (WMO) does not apply to this study and that an official approval by the committee is not required, reference number; project W22.086.

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Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information.

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REFERENCES

1 Naranje SM, Erali RA, Warner WC, *et al*. Epidemiology of pediatric fractures presenting to emergency departments in the United States. *J Pediatr Orthop* 2016;36:e45–8.
2 Sintenie J, Allema J, Ivanyi B, *et al*. Diagnostiek distale humerusfractuur kind. 2019.
3 Appelboam A, Reuben AD, Benger JR, *et al*. Elbow extension test to rule out elbow fracture: multicentre, prospective validation and observational study of diagnostic accuracy in adults and children. *BMJ* 2008;337:a2428.
4 Stiell IG, Wells GA, Hoag RH, *et al*. Implementation of the Ottawa knee rule for the use of radiography in acute knee injuries. *JAMA* 1997;278:2075–9.
5 Stiell IG, Clement CM, Grimshaw J, *et al*. Implementation of the Canadian C-spine rule: prospective 12 centre cluster randomised trial. *BMJ* 2009;339:b4146.
6 Walenkamp MMJ, Bentohami A, Slaar A, *et al*. The Amsterdam wrist rules: the multicenter prospective derivation and external validation of a clinical decision rule for the use of radiography in acute wrist trauma. *BMC Musculoskelet Disord* 2015;16:389.
7 Bachmann LM, Kolb E, Koller MT, *et al*. Accuracy of Ottawa ankle rules to exclude fractures of the ankle and mid-foot: systematic review. *BMJ* 2003;326:417.
8 Stiell IG, Greenberg GH, McKnight RD, *et al*. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. *Ann Emerg Med* 1992;21:384–90.
9 Mulders MAM, Walenkamp MMJ, Slaar A, *et al*. Implementation of the Amsterdam pediatric wrist rules. *Pediatr Radiol* 2018;48:1612–20.
10 Slaar A, Walenkamp MMJ, Bentohami A, *et al*. A clinical decision rule for the use of plain radiography in children after acute wrist injury: development and external validation of the Amsterdam pediatric wrist rules. *Pediatr Radiol* 2016;46:50–60.
11 Bryce CD, Armstrong AD. Anatomy and biomechanics of the elbow. Orthop Clin North Am 2008;39:141–54.
12 Jenkins DG, Quintana-Ascencio PF. A solution to minimum sample size for regressions. *PLoS One* 2020;15:e0229345.
13 Riley RD, Ensor J, Snell KIE, *et al*. Calculating the sample size required for developing a clinical prediction model. *BMJ* 2020;368:m441.
14 Steyerberg EW. *Clinical prediction models, a practical approach to development, validation, and updating*. New York, NY: Springer, 2009: 50–1.
15 Lampignano J, Kendrick L. *Bontrager's textbook of radiographic positioning and related anatomy*. 2020.