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Functional outcome after Mason II–III radial head and neck fractures: study protocol for a systematic review in accordance with the PRISMA statement

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ABSTRACT

Introduction: Fractures of the radial head and neck are the most common fractures of the elbow, and account for approximately one-third of all elbow fractures. Depending on the fracture type the treatment is either conservative or surgical. There is no absolute consensus regarding optimal treatment for different fracture types. The aim of this protocol is to present the method that will be used to collect, describe and analyse the current evidence regarding the treatment of Mason II–III radial head and neck fractures.

Method and analysis: We will conduct a systematic review in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) guidelines statement. We will search a number of databases with a predefined search strategy to collect both randomised and non-randomised studies. The articles will be summarised with descriptive statistics. If applicable a meta-analysis will be conducted.

Ethics and dissemination: Ethical approval is not required since this is a protocol for a systematic review and no primary data will be collected. The authors will publish findings from this review in a peer-reviewed scientific journal.

Trial registration number: CRD42016037627.

Strengths and limitations of this study

- A review on this subject has never, to the best of our knowledge, been performed before according to Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) standard.
- Very common injury with clinical significance for patients.
- No clear consensus regarding optimal treatment.
- There are few randomised controlled trials on the subject.
- Heterogenic outcomes and methods across the literature possibly making comparisons difficult.
- Only studies in the English language will be included, thereby introducing a possibility of language bias.

The Mason classification is used to describe radial head and neck fractures. The classification is commonly divided into four groups and has been modified several times. According to the iteration by Broberg and Morrey, Mason I is a non-displaced fracture, Mason II is a fracture with more than 2 mm displacement, involving at least 30% of the radial head, Mason III fractures are significantly comminute and Mason IV is a fracture of the radial head or neck with associated elbow dislocation. Mason IV usually indicates greater trauma and greater soft tissue damage but is a very heterogenic group. It is a heterogenic group since both a minimally displaced and severely comminute fracture could be classified as Mason IV as long as the patient also has an elbow dislocation. There are no significant differences in age or gender disposition between the different Mason groups.[3–6]

The treatment of Mason I fractures is conservative with aspiration of the haematoma in the joint, a pressure bandage and sling for support, and active mobilisation as early as

BACKGROUND
Rationale

Fractures of the radial head and neck are the most common fractures of the elbow, and account for approximately one-third of all elbow fractures. The estimated annual incidence of radial head and neck fractures are 2.8 per 10000. The fractures often occur after indirect axial trauma following a fall onto an outstretched arm. The mean age of a patient who fractures their radial head or neck are between 44 and 48 and the male-to-female ratio is 2/3.[1–4]

possible. There is currently no consensus on the treatment of patients with Mason type II fractures. Both conservative and surgical treatment is described with favourable outcome in the literature. Mason III–IV are treated in several ways, both open reduction internal fixation (ORIF) and arthroplasty are used as well as resection of the radial head.[7–15]

As described above, the treatment of radial head fractures is segmented. A few previous reviews have investigated the functional outcome after radial head fractures. However, the majority of these were conducted over 5 years ago and are only describing their results in descriptive ways.

To the best of our knowledge no standardised reviews according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) have been published.[16]

The goal of this study is to summarise the outcome and treatment of radial head and neck fractures with a systematic review. The results are important for healthcare policymaking and patient care.

Objectives

This study will provide an overview of the recent published data on the subject of radial head and neck fractures classified as Mason II–III. A comparison of the functional outcome after different interventions including ORIF, arthroplasty, radial head resection and conservative treatment will be done. We aim to report the findings of this study in a way that makes it easy to use for clinical decision-making.

METHODS AND ANALYSIS

The proposed systematic review and this protocol will conform to the PRISMA-P guidelines and this protocol will be made publicly available before we initiate the review process. This study is also registered at the International Prospective Register of Systematic Reviews (PROSPERO).[16]

Eligibility criteria
Population

Studies with a population of 20 or more patients that includes patients with an age of 15 years or older with a traumatic Broberg-Morrey Mason II–III radial head or neck fractures are eligible for inclusion. There will be no upper limit on the follow-up time but reports with a mean follow-up time of <1 year are ineligible.

Intervention

Studies with patients that can be sorted into one or several of the following categories: conservatively treated patients, patients treated with ORIF, and arthroplasty or resection of the radial head are eligible for inclusion. If several treatments and/or Mason groups are represented in a study the patients will be subdivided and registered according to Mason classification and

treatment received. Patients described to have associated injuries such as elbow dislocation or Essex-Lopresti injury will be excluded.

Comparison

Quantitative studies with a longitudinal design will be included, such as randomised controlled trials, cohort studies, cross-over studies, retrospective studies and case–control studies. Data will be collected regardless of the intervention received. Cross-sectional studies and case reports will be excluded. To minimise bias due to high drop-out, reports with a drop-out rate higher than 30% will not be taken into account. Only studies that use a Mason classification will be included. We will adapt the studies to the Broberg-Morrey iteration of the Mason classification.

Outcome

The primary outcome will be the participants' mean functional level measured with elbow and arm scores. Secondary outcomes will be complication rates, pain and range of motion.

Search strategy

The search strategy will be constructed by and in discussion with a librarian with expertise in healthcare databases and systematic reviews. We will search EMBASE, PubMed and the Cochrane library and limit the search to studies published in the English language during the past 30 years. The search strategy contains both Medical Subject Heading (MeSH) and non-MeSH terms. A less extensive presearch without review of the result will be carried out to calibrate the search strategy. Depending on the time consumption of the review process an update search to include all the latest articles might be conducted at the end of the review process. The search strategy for PubMed is included in online supplementary appendix 1.

Study records

Search results are going to be saved and managed in Endnote V.X7 (Thomson Reuters, Philadelphia, Pennsylvania, USA). MH and AT will screen titles and abstracts of the found articles. Full text will be obtained of all articles that appear to meet, or if it is unclear if the article meets the predefined eligibility criteria. All exclusions and reasons for exclusion will be presented in a PRISMA flow chart together with the final review.[16] All study data are going to be collected and managed using Research Electronic Data Capture (REDCap), an electronic data capture tool hosted at Karolinska Institute.[17] REDCap is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

The data to be extracted is presented in table 1. Both reviewers will separately examine and extract data from the included studies, disagreement in the collected data will be resolved with discussion, if no consensus is reached a third reviewer (OS) will be consulted.

Outcomes and prioritisation

Several scores are anticipated to be used in the included studies.[18] If a study reports the outcome in more than one score, we will prioritise as follows: Disabilities of the Arm, Shoulder and Hand (DASH), quick-DASH, Mayo Elbow Performance Score (MEPS) and Broberg and Morrey index.[19] [20] The scores will be modified to make comparison possible, for example, all scales will be modified so that a lower score equals a worse outcome. Complication rate includes non-union, wound infection, radial nerve injuries and reoperations. The complication rate will be measured as a percentage of patients included in the studies. We will also, if available, extract rated pain and range of motion.

Risk of bias in individual studies

Randomised controlled trials will be independently assessed by AT and MH regarding bias with the Cochrane Collaboration's risk of bias tool. This tool includes assessment of random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), baseline imbalance bias and other bias.[21] To explore risk of bias in non-randomised studies the Newcastle-Ottawa scale will be used. The Newcastle-Ottawa scale has two different versions, one made to assess risk of bias in cohort studies and one made to assess case–control studies, the two versions differ slightly. The scale contains three categories: selection, comparability and exposure/outcome. These three categories are subdivided into 7–8 items.[22]

Data synthesis

The collected data will be presented using appropriate descriptive statistics. If the available data permits, a meta-analysis will be conducted. We will subdivide and present the results according to the Mason group and intervention received. If a manageable amount of studies are found, we will also present the studies separately with all the extracted data. If this is not possible the data will be added as an appendix. A random-effects model will be applied as large heterogeneity regarding treatment conditions, participant characteristics and methodological factors are expected between included studies. A standardised mean difference with 95% CIs will be calculated to make comparison possible between studies that measure outcome with different rating scales. Dichotomous outcomes will be presented as risk ratios with 95% CIs. If important data are missing, efforts will be made to contact the corresponding author. The analysis will be performed using R V.3.2.3 (R Foundation for Statistical Computing, Vienna, Austria), with the meta and metaphor packages.[23]

Meta-biases

We plan to assess the possibility of bias (publication bias, language bias and methodological biases) by plotting the included studies in a funnel plot. Funnel plot asymmetry will be examined using Eggers test of the intercept.[24]

Confidence in cumulative evidence

The outcomes will be assessed regarding quality of evidence using the Grading of Recommendation Assessment, Development and Evaluation (GRADE).[25] Consideration will be given to each of the GRADE criteria for assessing the quality of evidence. This approach grades the cumulative evidence to one of four categories: high, moderate, low or very low evidence. The GRADE approach takes eight items into account: study quality, inconsistency of result, indirectness of evidence, imprecision, publication bias, large magnitude of effect, effect of plausible residual confounding.

DISCUSSION

We have not found any systematic review examining this area with a published protocol according to PRISMA-P. Previously published systematic reviews suggest that there will be low evidence in the published data with few randomised controlled trails (RCTs).[26–28] Owing to the lack of high-quality papers we will include both randomised and non-randomised studies. This approach enables a more comprehensive study of the available evidence regarding functional outcome after radial head and neck fractures.

As mentioned in the Methods and analysis section the Mason classification will be used in this review. This is a classification system with limitations since it has been revised several times. Some studies use the original three category classification while others use Broberg-Morreys or Hotchkiss four category iteration. The Hotchkiss and the Broberg-Morrey are quite similar and we will assume that a patient placed in a Hotchkiss group would be

Table 1	Data to be extracted
Publication data	Publication year, author
Study data	Design, size of population, type of intervention, mean duration of follow-up, complication rate (including pain and range of motion), drop-out rate, patient reported and/or functional outcome score(s), implant type
Patient data	Mean age, female percentage, type of fracture (classified according to Mason)

placed into the corresponding Broberg-Morrey group. This approach will in a few cases place the patients into wrong group introducing a limitation we will have to take into account when interpreting the results. A similar approach has previously been used by Kaas et al.[29]

The intraobservability and interobservability when diagnosing radial head and neck fractures is not as good as one could wish for. This is a problem that several other fracture classification systems have as well such as the Neer classification of proximal humeral fractures. However, the Mason classification is the most commonly used in clinical and research settings and even though it has several shortcomings; it is currently the only practical way of studying radial head and neck fractures.[30 31]

When studying radial head and neck fractures, associated injuries such as elbow dislocation and Essex-Lopresti injuries are of great concern. We will exclude patients who are described to have associated injuries. Since a fracture of the radial head or neck with an elbow dislocation should be classified as Mason IV these patients will if correctly diagnosed not alter the results of this review. Essex-Lopresti is a complicating factor that is sometimes overlooked but it is quite uncommon and should be of minor impact of this review; Grassman et al[32] found 12 patients with Essex-Lopresti injury out of 295 patients with radial head fractures.

Stiffness, range of motion, pain and mechanical blockage are important measures of complication but not always reported in an adequate way. To be able to get information covering these factors we will as mentioned use DASH as our main outcome. DASH is a 30-item questionnaire that includes three items covering pain and several questions covering stiffness and range of motion in an indirect manner.[19 29]

This is not the first review of this area but we believe that there is a need for an updated systematic review of this topic. A Cochrane study published 2013, only including RCTs, found three studies. With our review we will try to summarise more of the published studies available by also including other cohort studies. This will of course lower the possibility to draw firm conclusions but it will give a broader view of the available evidence. A study by Kaas et al was more thorough but is now 5 years old. We anticipate that by including recent publications we will be able to present the best available evidence regarding the best treatment of Mason II–III radial head and neck fractures.[29 33]

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