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Prognostic model for the determination of clinical outcome of shoulder fractures at 1 year after initial treatment

Submission date
13/03/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
22/03/2022

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Proximal humeral (shoulder) fractures are very common and account for 4% to 5% of all fractures seen in the average orthopedic clinic. Incidence increases with age and decreasing bone quality (i.e., osteoporosis). Stable proximal humeral fractures with minimal displacement are generally treated without surgery, whereas the majority of the unstable and displaced fractures require surgical treatment. The indications for selecting a specific treatment from the wide variety of available procedures remain controversial regardless of the fracture type. A great variety of options is available for the fixation of these fractures. However, all of them suffer from a persistently substantial rate of mechanical failure as well as a number of other complications, including decreased range of motion and poor functional outcomes. Patient age and sex, fracture type, other injuries and factors such as bone quality and blood supply to the fragments, influence the treatment chosen and its prognosis. The key may be to choose the most appropriate fixation method according to the exact patient and fracture characteristics based on clearly defined indications and contraindications. Currently there is not enough evidence to distinguish and measure the effect of a range of prognostic factors known to directly or indirectly influence the functional outcome of patients with proximal humeral fractures. The aim of this study is to develop a prognostic model for determining the functional outcome based on the minimum 1-year patient-reported outcome scores (quick-DASH and SPALDI) after conservative or surgical treatment.

Who can participate?
Patients aged 18 years and over with displaced two-, three-, and four-part fractures of the proximal humerus

What does the study involve?
The medical records of all patients with proximal humeral fractures who were admitted or followed up from 2000 to 2020 will be assessed and constitute the initial database. The patients will be re-examined at a minimum of 1-year follow-up clinically using quick-DASH and SPADI scores and by x-rays. Thirteen possible factors (age, gender, dominant side, other illnesses, fracture type, viability of the humeral head, presence of dislocation, type of intervention

[conservative or surgical], type of internal fixation (plate or sutures), physiotherapy, intraoperative complications, later complications, final radiological parameters and length of follow up) will be tested to determine their final prognostic value on the functional outcome.

What are the possible benefits and risks of participating?
These data will help the orthopaedic surgeon to better understand the complexity of the injury, suggest appropriate patient- and fracture-specific treatment options and improve operative techniques and interventions. There are no other risks for patients during their evaluation with the clinical scores at 1 year.

Where is the study run from?
Patras University Hospital (Greece)

When is the study starting and how long is expected to run for?
January 2020 to January 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Andreas Panagopoulos
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
ΕΗΔΕ 13298

Study information

Scientific Title
Prognostic value of different patient, injury or treatment-related factors at the 1-year functional outcome of proximal humerus fractures using the quick-DASH and SPALDI scores

Acronym
PRO.MO.FPH

Study objectives
In the present study, the technique of path analysis will be used to develop a prognostic model for determining the functional outcome, based on the 1-year Disabilities of Arm, Shoulder and Hand (Quick-DASH score) and Shoulder Pain and Disability Index (SPADI score) for displaced proximal humeral fractures in patients treated either conservative or with open reduction and internal fixation (plate or transosseous suturing) in a single University Hospital in order to analyze the complex inter-relationships between various patients-related, surgeon-related and injury-related factors and their effect on the final outcome.

The initial hypothesis is that all 14 factors would be related to the functional outcome at 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2020, ethics committee of Patras University (Rio 26504, Greece, +30 (0) 26130997841; ehde@upatras.gr), ref: ΕΔΗΕ 13298

Primary study design
Interventional

Study design
Single-center retrospective interventional outcome study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Fractures of the proximal humerus

Interventions
1. Surgical treatment of proximal humeral fractures with either a plate or transosseous sutures
2. Conservative treatment of proximal humerus fractures

The medical records of all patients with proximal humeral fractures admitted or followed up from 2000 to 2021 will be assessed and constitute the initial database. Only patients with full details of their medical record and pre- and post-operative radiographs will be included in the study. After informed consent the patients will be re-examined at a minimum of 1 year follow up clinically using quick-DASH and SPADI scores and radiographically. Thirteen hypothetic causal inter-relationship factors (age, gender, dominant side, comorbidities, fracture type, viability of humeral head, presence of dislocation, type of intervention [conservative or surgical], type of internal fixation [plate or sutures], physiotherapy protocol, intraoperative complications, later complications, final radiological parameters and length of follow up) will be tested to determine their final prognostic value on the functional outcome. The hypothetical causal path diagram will

represent the initial hypothesis based on current knowledge, whereas the final path diagram will be a refinement of the hypothesis using available observational data. These data will help the orthopaedic surgeon to better understand the complexity of the injury, suggest appropriate patient- and fracture-specific treatment options and improve operative techniques and interventions.

Observational databases can be used as a tool to analyze complex inter-relationships among patient, injury, and treatment factors and their relative effects on outcomes. Multivariable regression analyses are traditionally used to identify the most likely important prognostic factors and to quantify their strength of association with the outcome. In the context of a path analysis, this method presents a visual perspective of the associations among factors and the outcome. One of the strengths of this type of analysis is that prior knowledge of the most likely causal factors along with their temporal relationships is fundamental. The developed model must be clinically relevant and reflect the reality of the phenomena under study as much as possible.

Patient age and sex, fracture type, concomitant injuries, and biologic factors, influence the type of therapeutic intervention chosen and its prognosis. Yet the results are mostly derived from univariable analyses of low volume studies. To date, there are no current studies that clearly distinguish and measure the effect of a range of postulated prognostic factors known to directly or indirectly influence the functional outcome of patients with proximal humeral fractures.

The objective of this analysis is to test the hypothetic causal inter-relationships among 12 different factors potentially having a direct influence on the functional DASH and SPADI scores after proximal humeral fractures at minimum 1-year follow up.

The hypothetic causal path diagram will represent the initial hypothesis based on current knowledge, whereas the final path diagram will be a refinement of the hypothesis using available observational data. These data will help the orthopaedic surgeon to better understand the complexity of the injury, to suggest appropriate “patient- and fracture-specific” treatment options and to improve operative techniques and interventions.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical outcome measured with the Disabilities of Arm, Shoulder and Hand (Quick-DASH score) and the Shoulder Pain and Disability Index (SPANDI score) in 3, 6 and 12 months following the initial treatment

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
10/01/2024

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Displaced two-, three-, and four-part fractures of the proximal humerus according to Neer’s

classification (displacement >1 cm or angulation >45 degrees)
3. Complete medical records (including full series of pre- and post-operative x-rays)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Nonunion
2. Pathologic fractures
3. Re-fractures
4. Non-displaced fractures
5. Open fractures
6. Concomitant ipsilateral fractures of the upper limb requiring surgery
7. Multiple trauma patients
8. Major nerve or vascular injury
9. Severe dislocation or head splitting component
10. Rotator cuff tear arthropathy or severe rotator cuff insufficiency
11. Severe dementia and/or institutionalization
12. Inability to understand written and spoken guidance in Greek

Date of first enrolment
01/03/2021

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Greece

Study participating centre
Patras University Hospital
Orthopaedic Department

Papanikolaou 1, Rio
Patras
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26504

Sponsor information

Organisation
General University Hospital of Patras

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication