

Fracture Evaluation Management & Understanding Research (FEMUR):

A prospective cohort study

# Background

The femur is the largest bone in the body and femur fractures are common after injuries, globally. Femur fractures are psychologically traumatic for patients, causing severe pain and disability or death if not well managed. Multiple types of femur fracture exist, with some types being associated with high mortality rates and disability than others. However, evidence also suggest that for any given type of femur fracture, outcomes vary dramatically dependent on the geographical location of the patient. Patient age, sex, delays prior to receiving management, duration of surgery, preoperative physiological state, and management received also influence outcomes.

Evidence on outcomes after femur fracture and comparisons between management strategy and geographical regions is useful for raising awareness of disparities in quality of care and for health system planning. This evidence is currently lacking from the global literature.1-5 The aim of this study is to understand management provided for different types of femur fractures that are admitted to hospitals globally, and the outcomes for patients with these fractures.

# Objectives

1. To audit mortality, morbidity, and mobility outcomes 30 days after admission with femur fractures globally
2. To describe the management of femur fractures in hospitals globally

In comparing outcomes by management received, facility type, and global location, we will provide data to inform health system planning and utility for global advocacy.

# Study Design and Recruitment

This is a prospective, multicenter, cohort study conducted by the FEMUR Collaborative. The Collaborative consists of an international central team national leads, hospital leads, and data collection teams. National and hospital leads will be purposively recruited though personal invitations to colleagues, orthopedic professional associations and informal networks, the rural doctor’s association, and social media. The central team will provide support to national and hospital leads through monthly webinars and WhatsApp group chats. In each country, we aim to recruit as many hospitals as possible using a convenience sampling strategy.

Hospital eligibility criteria

* *Inclusion criteria*
* Hospitals that definitively treat a minimum of 5 femur fracture patients per month (operatively or non-operatively)
* Private and public sector hospitals that manage femur fractures from any province.
* *Exclusion criteria*
* Primary health care facilities, or community health centres, will not be eligible if they transfer all patients with femur fractures for management elsewhere.

# Participants eligibility criteria

* *Inclusion criteria*
* Adult (over 18 years of age) participants of any sex who are admitted to a facility for definitive management of a femur fracture
* Patients receiving emergency and elective procedures should be included.
* Patient management can include non-operative and/or operative treatment of the femur fracture.
* *Exclusion criteria*
  + Minors under 18 years of age will be excluded.
  + Patients with polytrauma (femur fracture and another injury) will be excluded. Repeat hospital admissions for the same femur fracture will be excluded

# Sample size

Through a literature review of mortality on different types of femur fractures globally was conducted, we ascertained an in hospital or 30-day mortality range of 1.6 to 13%. Correspondingly, to detect this range of mortality rates with a confidence interval of 50% of the proportion required was between 193 and 4023 participants. The minimal sample size, allowing for a 10% loss of data due to quality, is 4424 participants globally. We aim to recruit at least the minimum sample size but as many participants possible will be included.

# Data quality and validation

All hospital data collectors will undergo online training. REDCap data entry in real time is encouraged. Notes for clarity/images will be incorporated into the REDCap form to assist in grading pressure sores/defining fracture types. Data limits and data flow structures will be created to ensure erroneous data entry is minimised. Data missingness will be checked weekly. Data will be validated in a 10% randomly selected set of facilities. At each site, data will be checked for case missingness and accuracy on a random subset of participants. Only data sets with ≥ 90% data completeness will be accepted for pooled national analysis. To emphasise the importance of data completeness to collaborators, data collection periods with >10% missing data points will be excluded from the study and collaborators from those periods withdrawn from the published list of citable collaborators.

# Data anonymity, storage, and sharing

# Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application, ensuring safe anonymised data storage by collaborators worldwide. The service will be managed by the REDCap hosted at the University of Birmingham, UK. The security of the study database system will be governed by the policies of the University of Birmingham. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap database.

# Analysis plan

Study outcomes include 1) mortality, morbidity, and mobility outcomes at discharge, or 30 days after admission with femur fractures, and 2) types of femur fracture management at hospitals. Results will be described for the total sample and disaggregated by femur fracture types, age groups, sex, income country status, hospital types. Analyses to assess factors associated with the primary and secondary outcomes will be conducted on the whole sample and for each femur fracture type separately, using binary logistic, multi-level modelling (with levels including hospital level and country income status incorporated as random effects). Additional confounders will include management given, patient demographics, and delays to care.

# Ethical approval

* Necessary approvals in partner countries will be sought at the facility, institute, or other level, as appropriate for each country.
* Participant consent to supply data will be sought based on local regulations, noting that data will be collected from notes and no data will be collected directly from patients.

# Dissemination and authorship

Findings from the study will be written up as a scientific paper, aiming for publication in a high impact, open access, general medical journal. All data collectors will be be cited on the final manuscript. The manuscript will be published under a group name with authors and their contributions listed. All authors will be listed on PubMed.

# References

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1. Obey MR, Clever DC, Bechtold DA, et al. In-Hospital Morbidity and Mortality With Delays in Femoral Shaft Fracture Fixation. *J Orthop Trauma* 2022; **36**(5): 239-45.
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3. Reito A, Kuoppala M, Pajulammi H, Hokkinen L, Kyrola K, Paloneva J. Mortality and comorbidity after non-operatively managed, low-energy pelvic fracture in patients over age 70: a comparison with an age-matched femoral neck fracture cohort and general population. *BMC Geriatr* 2019; **19**(1): 315.
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