STUDY PROTOCOL

Study protocol for a national retrospective review of femoral periprosthetic fracture management. Is there variation in practice?

Ahmed A. H. Nasser1,*, Govind Chauhan1, Khabab Osman1, Saroop Nandra2, Rajpal Nandra1 and Ansar Mahmood3

1Trauma and Orthopaedics, The Birmingham Orthopaedic Network, The Royal Orthopaedic Hospital, Birmingham B31 2AP, UK, 2College of Medical and Dental Sciences, Birmingham Medical School, University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK and 3Trauma and Orthopaedics Department, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Birmingham B15 2GW, UK

*Correspondence address. Trauma and Orthopaedic Specialty Registrar, The Birmingham Orthopaedic Network, The Royal Orthopaedic Hospital, Birmingham B31 2AP, UK. Tel: +447775989717; E-mail: Ahmed.Nasser@nhs.net

Abstract

Introduction: The incidence of femoral periprosthetic fractures (PPFs) in the UK is on the rise. This rising incidence presents a clinical and an economic burden on the national health care services. There is also uncertainty about the most effective treatment modality for femoral PPFs, as well as a lack of evidence for a standardized management approach. We aimed to identify the true incidence and any variation in the management of femoral PPFs nationally. Methods and analysis: This multicentre national collaborative study has been designed by a trainee led research network in collaboration with a well-established university research organization. Data will be collected from participating centres over a period of 10 years (2010–2019). All adults presenting with a femoral PPF will be identified, and the mode of treatment for each fracture subtype will be recorded. Other measures will evaluate patient and treatment variables, objective and subjective outcome measures. Univariate and multivariate regression analyses will be used, as well as the coefficient of determination (R) in an attempt to measure the degree to which the models could explain the variation in management. Ethics and dissemination: This multicentre national project was approved by the local clinical governance department at each participating hospital site. The results of this study will be submitted to international peer reviewed journals and appropriate national and international conferences.

INTRODUCTION

As our population is growing older, more arthroplasty procedures are being performed annually [1]. As a result, periprosthetic fractures (PPFs) are on the rise. Projection models estimate that the incidence of PPFs is expected to rise by 4.6% every decade over the next 30 years [2]. According to the National Joint Registry for England, Wales and Northern Ireland, >12,000 hip revision surgeries were performed since 2003 due to a hip PPF, whereas >3000 knee revision surgeries were performed due to a PPF [1]. The actual number of periprosthetic femoral fractures exceeds that, since the registry only reports cases that undergo revision arthroplasty and does not include fixation or non-operatively...
managed cases. The rising incidence of PPFs presents a clinical burden and a major economic impact on health care services [9]. The mean cost of treating a single patient with a PPF in a UK teaching hospital was estimated to be £23 469 [4]. Indirect health care costs have not been quantified.

There is evidence establishing the risk of PPFs by implant type. Several studies conclude that there is a significantly higher rate of femoral PPFs in uncemented stems when compared to cemented stems [5–10]. In addition, several studies suggest that polished tapered stems have a higher risk of PPF compared to other straight or anatomical cemented stems [11–14]. Authors also report an association between prosthesis and fracture type, specifically where a comminuted or spiral fracture type pattern is associated with cemented stems, whereas a clamshell or a simple oblique fracture type is associated with uncemented stems [15, 16]. Other studies report the risk factors associated with femoral PPFs such as age, bisphosphonate use, dementia, Parkinson, increasing trochanter-head distance in THA, increasing femoral head size, certain bearings and stem material, and anterior femoral overcut in total knee arthroplasty [17–20].

Less is known about PPFs of the knee joint. These fractures are complex heterogeneous injuries. A detailed evaluation of the prosthesis in place should be undertaken to aid in the decision to revise or to fix [21]. It is also established that periprosthetic distal femur fracture results are less favourable and more inconsistent than fractures around a hip prosthesis [22].

Although various studies describe management options for periprosthetic femoral fractures, there is uncertainty over the indications for fixation or revision [22]. There are many decisive factors when it comes to the management choice, including patient dependent and independent factors [23]. The site relative to the prosthesis and the implants stability classifies PPFs, whereas various surgical techniques exist for each type of these fractures. To demonstrate, a Vancouver A fracture may be managed conservatively or surgically with several options available such as cerclage wires/cables, cable plate devices, or claw plates and trochanteric bolts. In addition, Vancouver AL fractures (lesser trochanter involvement) that are mildly displaced may be managed conservatively or surgically because of possible loss of medial stem support [3]. Furthermore, unstable Vancouver B1 fractures may be treated with biplanar fixation using an anterior and a lateral plate or with stem revision, treating them as B2 fractures [3]. Although revision surgery can provide more predictable outcomes for unstable fractures and fractures around polished taper slip stems, consensus with regards to treating PPFs around well-fixed stems is still lacking [20]. Therefore, the standardization of management of PPFs should be implemented across the region, but the evidence for a standardized approach is currently lacking. This study aims to report the incidence and mode of fixation of femoral PPFs at a national level to reinforce and guide management techniques. The primary observation will be the mode of fixation for each fracture subtype. Secondary measures will evaluate patient variables, treatment variables, objective and subjective outcome measures.

**METHODS AND ANALYSIS**

**Study design and research questions**

This is a national retrospective service evaluation based in the UK. Data collected from participating hospital sites will be used to address the following objectives of the project:

1. to determine the incidence of periprosthetic femoral fractures across the UK,
2. to report on the variation in the management of femoral PPFs,
3. to assess the apparent impact of patient and surgical variables on patient-level outcomes,
4. to explore the association between prosthesis type and fracture type, and
5. to provide proof of concept data for larger experimental studies.

This study has been developed by the Birmingham Orthopaedic Network, a trainee led research collaborative based in the West Midlands, under guidance and support from the Birmingham Centre of Observational and Prospective Studies (BiCOPS), a university-based research organization. Collaborating with an academic institution allows researchers to utilize resources effectively, resulting in social and university benefits, and improves surgical trainees research skills.

**Study population**

All skeletally mature patients, 16 years or older, presenting with any of the following PPFs during the period from 1 January 2010 to 31 December 2020 will be included:

- Femoral PPF including fractures to any orthopaedic device (including, but not limited to, plates, screws, nails and arthroplasty);
- Knee arthroplasty PPFs including tibial tray and patella fractures.

Patients younger than 16 years old, intraoperative PPFs, isolated acetabular fractures and tumour or cancer suspected cases would be excluded.

**Participating sites**

All trauma and orthopaedic units in the UK are eligible to participate in this study including major trauma centres, tertiary units and smaller district general hospitals. An assigned team in each participating centre will consist of a site Lead (Consultant), and a trainee Lead and one other co-investigator. More co-investigators are permitted if deemed necessary. The participating team will be responsible for data collection and entry from their respective site. The role of the local study team is to facilitate delivery at site, liaise with the study management group as necessary and ensure appropriate local staff resources are maintained to deliver this project.

Each participating site will be asked to complete a single electronic registration form to take part in this study. Centres providing data will also be requested to register this project as a service evaluation through their local audit department to adhere to governance procedures and gain local trust site approval. Each participating site will decide on how to identify the eligible cases for inclusion from their electronic system or medical health care records department. Only the assigned participating team at the hospital site will access the identifiable data.

**Data collection**

Data collection will be performed through REDCap web application, a secure software platform that supports data capture for research studies [24, 25]. Sites need to indicate that they have approval in place before REDCap logins will be issued. A unique REDCap identifier will be allocated to each patient. This unique number will be used in all correspondence between the study office and the participating site.
Table 1. Description of patient variables

| Demographics                  | PPF characteristics                                      |
|-------------------------------|----------------------------------------------------------|
| Age                           | Date of first implant insertion                          |
| Gender                        | Site of periprosthetic femoral fracture                  |
| Ethnicity                     | Implant around which fracture has occurred**            |
| Postcode                      | Subtype of implant around which fracture occurred        |
| AMTS score                    | Femoral stem in situ (cemented versus uncemented)       |
| Clinical frailty score        | Type of cemented femoral stem (taper slip versus composite beam) |
| Mobility status               | Type of taper slip or composite beam stem                |
| Place of residence            | Collar                                                   |
| ASA grade                     | Type of uncemented femoral stem                          |
| BMI                           | Type of endoprosthesis                                   |
| Previous history of PPF and site | Type of TKR constraint                              |
| Comorbidities (as per CCI)    | Implant zone of fixation and type                        |
| Parkinsons disease            | Femoral head size                                        |
| Bisphosphonate use            | Type of femoral head                                     |
| Steroid use                   | Vancouver classification of PPF                         |
| Previous trauma, infection, AVN | UCS classification of PPF                  |
| Anticoagulant use             | Lewish and Rorabeck classification of distal femur PPF  |
| Smoking status                | Felix classification of tibial PPF                       |
| Alcohol use and amount        | Ortiguera and Berry classification of patella PPF       |
|                               | Mechanism of injury                                      |
|                               | Date of presentation                                     |
|                               | Open versus closed fracture                              |
|                               | Evidence of broken prosthesis radiologically            |
|                               | Evidence of infection around PPF site                    |
|                               | Evidence of loose prosthesis prior to PPF               |
|                               | Pain on history prior to PPF                             |
| Outcomes                      | Management of the PPF                                    |
| 30-day mortality              | Conservative versus surgical                            |
| Date of death                 | Time from presentation to surgery                        |
| Length of stay                | Type of surgery and mode of fixation                     |
| Postoperative SSI             | Implants used                                            |
| Postoperative dislocation     | Type of revision hip arthroplasty                        |
| Return to theatre and reason  | Type of revision knee arthroplasty                       |
| Re-admission within 30 days   |                                                          |
| Discharge destination         |                                                          |
| Other complications**         |                                                          |

Data collected from each participating site will include patient demographics, PPF characteristics, management of the fracture and outcomes (Table 1). The type of femoral stem implant will be classified according to cementation, type of cemented femoral stem if applicable, collar and implant name (Table 2). Further sub classification will be performed for PPFs involving a femoral nail, dynamic hip screw (DHS), endoprosthesis and total knee arthroplasty.

Missing data

The online database allows participating sites to securely access patients data throughout the study period. Any missing or erroneous data can be amended by the local investigators, whereas the data collection period is ongoing. A minimum of 80% of the data must be completed by the participating sites for data to be accepted for analysis.

Analysis

Categorical variables will be presented as totals and percentages. Continuous variables will be presented as means and medians. A chi-squared test will be used for discrete variables, and the Student’s t-test or Wilcoxon rank-sum test (Mann–Whitney) will be used for continuous variables depending on the distribution of the data. Missing data will be identified and coded. Where possible, statistical methods including imputation will be used to account for missing data.

Regression models will be developed to identify factors that are significantly associated with a specific management option. Statistical significance will be defined as \( P < 0.05 \). SPSS will be used to perform the statistical analyses for this study.

A univariate analysis will initially be performed. Variables that are potentially associated with revision arthroplasty in the univariate analyses will be included in a multivariable regression model to identify the significant factors that are associated with
Table 2. Types of femoral stem

| Cemented taper slip | Cemented composite beam | Uncemented |
|---------------------|-------------------------|------------|
| Exeter              | Charnley cemented stem  | SPS HA Accolade |
| CPT                 | Lubinus SPII cemented stem | Synergy |
| C-Stem              | Stanmore modular stem  | Anthology |
| MS-30               | Muller-Biomet           | Corail |
| CPS                 | Muller - straight stem  | VerSys |
| CPS Plus            | Elite Plus cemented stem | Wagner Cone |
| Furlong             | Omnifit cemented stem   | Modulus |
| Taperfit            | CCA cemented stem       | Excia |
| Taperloc            | Charnley modular        | Bimetric |
| Olympia             | P10 Muller              | Mallory Head stem |
| Ultima TPS system   | Spectrum                | Taper loc Hip system |
| Aeon                | Centrament              | Furlong HAC coated |
| Profemur            | VerSys cemented stem    | Alloclassic Zweymuller SL |
| Corail              | CMK cemented stem       | CLS Spotorno |
| Edinburgh           | Excia cemented stem     | M/L Taper |
| other               | Ultima Straight stem    | Aria |
|                     | other                   | Origin |

that management option. In addition, an attempt at measuring the degree to which the models could explain the variation in management will be performed using the coefficient of determination (R).

Patient and public involvement

Patients and the public were not involved in the development of this study.

ETHICS AND DISSEMINATION

Data protection and confidentiality

The security of the study database system is governed by the policies of the University of Birmingham. The study database will be hosted on the University’s REDCap system managed and maintained by the BiCOPS team.

Data management and data security within the BiCOPS will abide by the requirements of the General Data Protection Regulations. Data will be acquired and stored on the REDCap platform. Access to data will be restricted; each individual collaborator entering data for the study will have their own username and password. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All patient identifiable data will be anonymised on the REDCap database. All data collected about patients will be identified using only a unique study number (REDCap ID). Any correspondence between the study management group and the participating centres will only use this unique study number. The linkage between the database study ID and the actual patients will be confidentially maintained at the participating site. This data will not be submitted to the study office and will not be sent outside of the participating site. The patients identified for this study will not be identifiable in any future publication that results from this project. Patients identified for this study will not undergo additional investigations or follow-up after this study has been conducted.

Dissemination of results

The results of this study will be submitted to a peer reviewed scientific journal. The results will also be presented at national and international conferences. Participating centres will receive results on their own units’ performance and the region as a whole. If a hospital submits up to 10 patients (with a minimum 80% completion of the data fields), then one collaborator and the supervisor will be included in the authorship. Authorship at the head of the primary results paper will be cited as a collaborative group.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

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