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Study protocol for the Nottingham Spinal Health (NoSH) Study: A cohort study of vertebral fragility fractures admitted to hospital

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ABSTRACT

Introduction

Patients presenting to hospital with acute vertebral fragility fractures (VFF) have varying levels of pain and disability for which a number of operative and non-operative interventions may be appropriate. Their complex care needs provide justification for the development of a specialised service for them. A cohort study to describe characteristics and health outcomes of these patients will be done to inform the development of such a service.

Methods

This is a single-centre prospective observational study of adult patients (≥50 years) admitted to hospital with an acute low trauma or atraumatic VFF. The sample size will be 100 participants. Patient characteristics and baseline measurement of health status will be collected on admission. Follow up at hospital discharge and at 6 months will assess for changes in pain, mobility, participation in activities of daily living, mood, cognition and quality of life. Inpatient and six month mortality, hospital related outcomes (length of stay, discharge destination and hospital related complications) and healthcare resource use after hospital discharge will also be measured. The treatment received in hospital will also be reported.

Discussion

In line with the initial phase of the Medical Research Council framework for developing and evaluating complex interventions, the findings from this study will add to the existing evidence base and theory to support the development of a specialised service for patients admitted to hospital with an acute VFF.

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INTRODUCTION

BACKGROUND

Vertebral fragility fractures (VFF), i.e. breaks in the bones of the spinal column, are the most prevalent osteoporotic fractures [1]. The fact that some patients require urgent admission to hospital points towards a group that potentially have either a more serious fracture or are more debilitated by it than those who are managed at home. This group of patients has been recognised to be older and frailer [2]. A recently concluded systematic review that we have submitted for publication, demonstrated that patients admitted to hospital with VFF have poor long term outcomes. One year mortality has been reported to be between 20–25% and 34-50% were discharged to a care facility. Patients were less able to participate in activities of daily living after their hospital admission. Older age and increasing number of comorbidities were associated with poorer outcomes.

In recent years, advances in operative and non-operative treatment for acute VFF have led to further options to manage this complex group of patients. Hence, there is possible justification for the development of a specialised hospital service bringing together expertise to manage these fractures, as has been done for patients with hip fractures [3]. Orthogeriatric care for hip fractures has been shown to deliver better outcomes in hip fracture management [4]. Therefore, such a model of care for patients admitted to hospital with an acute VFF could also potentially lead to improved health outcomes. Such a model has been advocated by clinical experts and one national guideline for hospital vertebral fracture care [5, 6, 7].

To identify if there is a role for an orthogeriatric model of care for VFF in hospital, a cohort study is planned to address the information gap identified in our recently conducted systematic review; and describe the characteristics and health outcomes of patients admitted to hospital with a VFF.

OBJECTIVES

The objective of this study is to describe the characteristics of patients admitted to hospital with a VFF and how this affects their health status in six months. This study will determine changes in pain, disability, mood, cognition and quality of life in this cohort. It will also examine the association between patient and fracture characteristics with mortality, length of stay, discharge destination and hospital complication. Alongside this, we plan to describe the care processes that occur in hospital for VFF management.

METHODS

Study design

This is a single centre prospective observational study of adult patients admitted to hospital with an acute VFF recruiting over a 12 month period. Follow-up measures will be collected on hospital discharge and at 6 months post-discharge from hospital.

Study setting

This study will be undertaken at the Queens Medical Centre, Nottingham University Hospitals NHS Trust, a 1800 bedded tertiary centre serving a population of 680,000. The regional spinal unit, the Centre for Spinal Studies and Surgery, located at the Queens Medical Centre has a further catchment area of up to 4 million people.

Eligibility criteria

Inclusion criteria:

- Adults ≥50 years of age admitted with either a low trauma or atraumatic VFF; or suspected VFF pending radiology investigation. A low trauma fracture is a fracture sustained after a fall from a standing height or less. A diagnosis of vertebral fracture is made radiologically (i.e. x-ray imaging, computerised tomography (CT), magnetic resonance imaging (MRI) or bone scintigraphy scan).

Exclusion criteria:

- Patients where subsequent investigation has excluded a recent VFF
- Patients admitted electively to hospital for management of their VFF
- Patients transferred from another hospital. This is because The University Hospital, Queens Medical Centre (QMC) is the tertiary spinal unit for the East Midlands. Patients with vertebral fragility fractures from other hospitals in the region, i.e. smaller district general hospitals, would refer patients to QMC primarily for surgical intervention as they have not responded to the non-operative management of their fracture. Hence, this group of patients represent a select group or patients, one where an operation is appropriate and they are fit enough for the demands of a general anaesthesia. After completion of their surgical assessment and intervention, these patients are transferred back to their local hospital to continue their recovery.
- A VFF sustained as a result of a high impact injury, e.g. road traffic accident, fall down a flight of stairs, etc.
- Patients presenting with a concomitant fracture elsewhere

- Patients admitted to hospital under a major trauma pathway
- Patients with known or suspected malignancy
- Patients with known primary bone disorder (e.g Paget's disease) other than osteoporosis
- Patients terminally ill or moribund

Recruitment and consent

All patients admitted to the medical assessment unit, care of the older person ward, general medical wards or referred to the spinal team with either a confirmed or suspected VFF will be invited to participate. The research team will be notified of the potential participant and will confirm details with the clinical care team. The process for obtaining participant informed consent will be in accordance with Good Clinical Practice and the provisions within the Mental Capacity Act 2005 relating to research. Relatives or carers of potential participants who are unable to provide consent independently will be approached as the participant's personal consultee. If there is no personal consultee, a senior member of the clinical team will act as the nominated consultee for the potential participant.

Study procedure

Baseline data collection:

Participants in the study will proceed to have data collected within 3 days of recruitment. Data will be collected from a combination of participant and/or carer questionnaire, performance measures, medical case notes and electronic hospital records. If an acute VFF is subsequently excluded, no further data will be collected and they will be excluded from the study.

Data collection on hospital discharge:

Data will be collected prior to discharge from speaking to the patient and/or their carer, medical case notes and electronic hospital records. At this stage, we will ensure consent is in place from the participant or personal consultee to collect follow up data at 6 months.

Data collection at 6 month follow up

Participants recruited into the study will be followed up at 6 months. Participants will have a face-to-face meeting to collect outcome measures. The local trust's lone working policy will provide guidance during home visits.

Study ends upon completion of the 6 month follow up visit and the appropriate data analysis.

Outcome measures

Primary outcomes:

- Change in pain measured using an 11 point numeric rating scale at baseline, on discharge from hospital and at 6 months
- Mood measured using the Geriatric Depression Scale at baseline and at 6 months
- Cognition measured using the Montreal Cognitive Assessment at baseline and at 6 months
- Participation in activities of daily living measured using the Barthel Index, Elderly Mobility Scale, Nottingham Extended Activities of Daily Living and Roland Morris Disability Questionnaire at baseline and at 6 months

Secondary outcomes:

- Hospital inpatient mortality and overall mortality at 6 months
- Hospital related outcomes on patients discharge - length of stay, discharge destination/changes in residency, hospital related complication (hospital acquired infection, pressure sore, venous thromboembolic event, delirium and neurological impairment)
- Quality of life post-hospitalisation for vertebral fractures using the EQ-5D measured at 6 months
- Healthcare resource utilisation after hospital discharge is measured through self or proxy reporting at 6 months
- Care processes delivered in hospital

Demographic data (age, gender, residential status, smoking and alcohol history), bone health history, presence of malnutrition, comorbidities (using the Charlson Comorbidity Index), medication use, frailty, admission and fracture details will also be collected.

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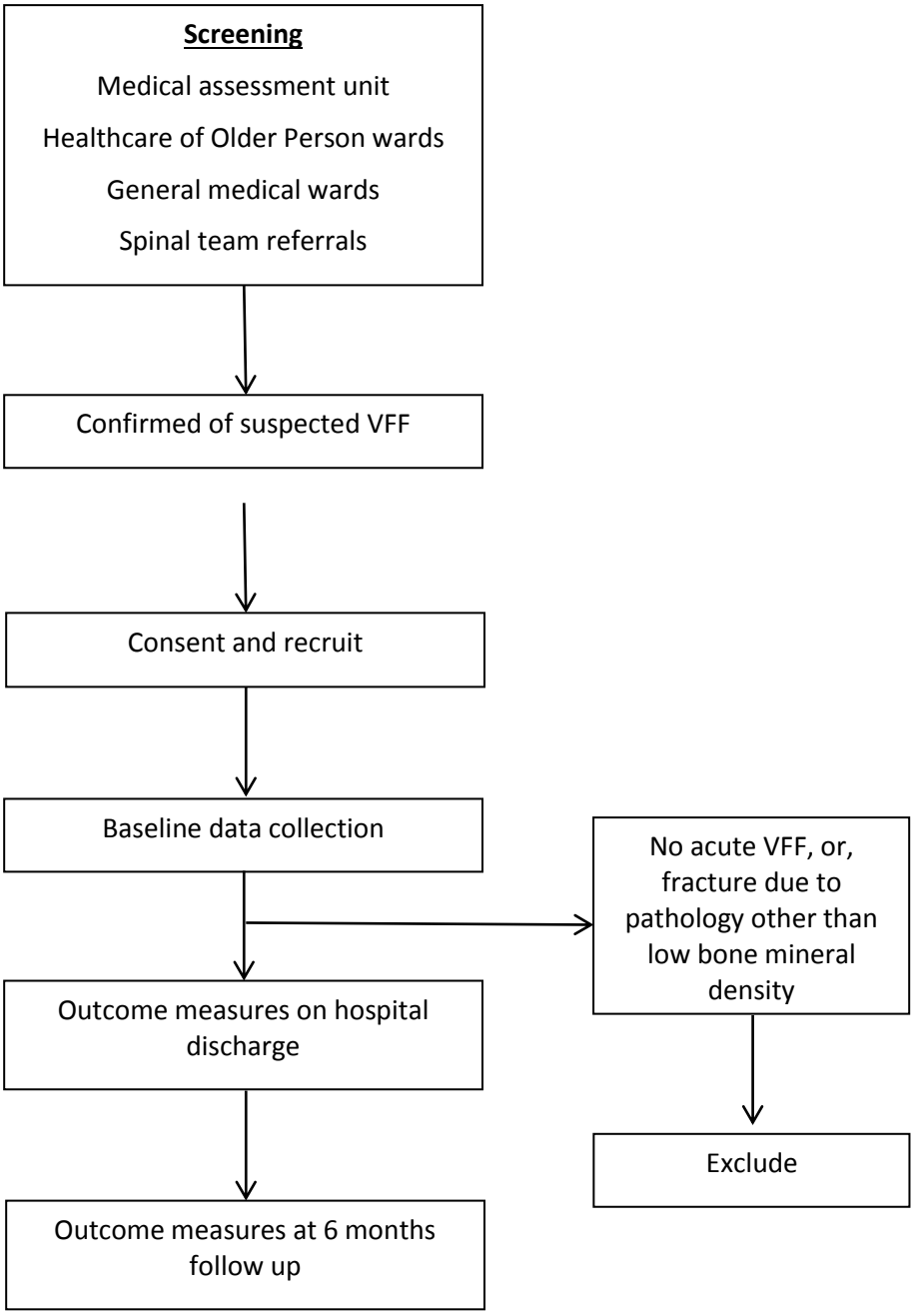
Figure 1 Study procedure for the Nottingham Spinal Health (NoSH) Study



Sample size calculation

This study was designed to be exploratory in nature with resources limiting the recruitment period. The true number of hospitalised patients due to acute VFF locally is uncertain. Local clinical service registry estimates 14 referrals per month to the spinal surgical team with acute vertebral fragility fractures. With an anticipated recruitment rate of 60%, a recruitment target is set for 100 participants over 12 months. Assuming a

potential loss to follow up of 20%, this represent a 95% confidence level with a margin of error of 8%.

Statistical analysis

Data entered into the database will be validated before analysis of the findings to correct for any spurious and missing data. Excluding missing data from subsequent analysis will lead to a degree of bias. Therefore, missing data and its pattern will be analysed for evidence of missing at random and multiple imputation performed. Patient demographics, clinical characteristics, health status, fracture details, hospital details and outcome data will be described using appropriate descriptive statistics. Changes in pain and outcome measures from hospital admission and at 6 months will be measured as paired samples using statistical tests appropriate for either normally distributed or skewed data. Univariate and multivariate regression analysis adjusted for confounding baseline variables will be used to identify significant predictors of deterioration in participant health status and follow-up measures (length of stay, discharge destination, hospital complication). Subset analysis on outcomes will be done between those with single vertebral fracture and multiple vertebral fractures and those that managed operatively and non-operatively. In all cases, statistical significance will be accepted at a 5% level. Findings of the subset analysis will be interpreted in the context of potential sample size calculation using nQuery Advisor based on sample distribution. All analyses will be conducted using the latest statistical software SPSS version for Windows.

Discussion

This paper describes the protocol for the Nottingham Spinal Health (NoSH) Study. Its finding will help better define this particular cohort, understand the treatment currently delivered in hospital and what the short and medium term impact of an acute VFF that requires hospital admission. If there is a role for a specialised service for VFF, the results of this study will complement the findings of our earlier systematic review in shaping what this model of care would look like. This process falls under the initial phase of the Medical Research Council (MRC) framework for developing and evaluating complex interventions [8]. This ensures that further down the line the complex intervention is feasible, can be implemented and its findings robustly evaluated.

A limitation of this study is the limited time and resources allocated to participant recruitment. Therefore, the findings of this study have to be interpreted within its margin of error. Recruitment of older people into research can be challenging and there is a risk that only participants that are less frail and more physically robust would be willing to participate. Participants with cognitive impairment will be included in the study. A challenge when older people with cognitive impairment are recruited is that they may find it difficult to answer some of the questions asked. There is a possibility that there will be data missing which could affect findings. Family and carers will be approached to provide the relevant answers.

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Patient and public involvement

Our PPI group is made up of previous patients admitted to hospital with a VFF and also members of the Nottingham Osteoporosis Support Group, the local branch of the National Osteoporosis Society. Our PPI group will assist with identifying follow-up measures felt to be important to patients with VFF. This will be incorporated into the study's follow up measures. They will also assist in reviewing the patient information sheets. This will ensure that the information provided is easily read and understood by potential participants. Our PPI group will provide insight into how best to engage hospitalised older people and input ways to address any potential recruitment challenges. At the end of the study, they will help facilitate dissemination of findings through the osteoporosis support group, e.g. public meetings and newsletters. Members of the PPI will also provide suggestions on the basis of the study's findings as to what an appropriate model of care would look like, thus, informing the development of this particular complex intervention.

Ethical approval

A favourable opinion was granted by the East of England – Cambridge Central Research Ethics Committee on the 22nd July 2016 (reference 16/EE/0249). Health Research Authority approval was also granted on the 27th September 2016.

Trial status

Recruitment to the study began on the 30th September 2016. The expected time of recruitment completion will be 14th August 2017 with follow up to be completed in February 2018. ISRCTN reference number 32916.

Acknowledgement

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