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A study of patient records to assess a new classification system for intertrochanteric fractures

Submission date
22/04/2018

Recruitment status
No longer recruiting

Registration date
28/04/2018

Overall study status
Completed

Last Edited
27/04/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Intertrochanteric fracture refers to a hip fracture that occurs in the region between the main part of the femur and the ball that fits into the hip socket in the pelvis. This type of broken hip is the most common joint injury in the elderly. To improve guidance for doctors on how to best treat these fractures, we wanted to describe the different types of intertrochanteric fractures. Existing classification systems do not describe the shape of the fracture in enough detail. The purpose of this study was to classify intertrochanteric fractures and to assess how practical the new classification is when doctors are treating patients.

Who can participate?
Adults aged 18 years and older who have fallen indoors or outdoors and and had an intertrochanteric fracture.

What does the study involve?
This is a chart review study. The study involves investigating the patient notes and other records of people who had surgery for certain types of broken hip.Participants who underwent internal fixation using a intramedullary nail are reviewed. Their fractures are classified based on the new classification system. Their post-surgery scans and their final follow up data are used to calculate their mobility and complications.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
September 2009 to May 2017

Who is funding the study?
The capital health research and development of special (China)

Who is the main contact?
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Contact information

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Scientific

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Clinical Trials Information System (CTIS)
N/A

ClinicalTrials.gov (NCT)
N/A

Protocol serial number
N/A

Study information

Scientific Title
Radiological parameters, clinical functions and complications associated with different intertrochanteric fractures

Study objectives
Patients with different types had different clinical outcomes and complication rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Chinese PLA General Hospital, 10/05/2009

Study design
Retrospective chart review

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intertrochanteric fracture

Interventions
We retrospectively analyzed the data from medical records of patients who underwent closed reduction and intramedullary internal fixation (CRIF) to treat intertrochanteric fractures. All patients were treated using a general or spinal anesthetic and using indirect reduction and percutaneous surgical techniques. All surgeries were performed by senior orthopedic surgeons who were familiar with the surgical procedures. All the patients participated in similar rehabilitation protocols. Postoperative radiographs were also performed to evaluate the reduction and fixation positions of the patients. Time from fracture to surgery, duration of the surgical procedure (assessed by anesthesiology records), and intraoperative bleeding volume were recorded. Five radiographic parameters including femoral head height (FHH), femoral neck-shaft angle (FNSA), the length of medial cephalic nail (Lmcn), tip-cortex distance (TCD), and tip-apex distance (TAD) and four functional parameters including Functional Independence Measure (FIM), Parker-Palmer mobility score, the Timed Up and Go (TUG) test and the 2-minute walk test (2MWT) were used to evaluate the postoperative functional states and mobilization levels. In addition to this, postoperative complications were also recorded. All the parameters are used to evaluate the clinical outcome.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Radiographic parameters were measured on the radiographs obtained immediate postoperatively and the final follow-up using the measuring devices on the digital screen. All

results were calibrated according to the ratio of the known diameter of the cephalic nail to its diameter on the digital image. Complications like loss of reduction, cut-out, excessive sliding of the cephalic nail, implant breakage, nonunion, infection, periprosthetic fracture and loss of mobility were some of the complications recorded during the follow-up. We defined loss of reduction as the loss of NSA greater than 10°. Excessive sliding was defined as sliding distance ≥10 mm.
1. Femoral head height (FHH). The FHH relative to the nail was measured, allowing for the subsequent loss of reduction analysis. This measurement was done by drawing two lines, both perpendicular to the shaft nail. One was placed at the top edge of the nail and one was placed at the superior edge of the femoral head. The distance between these two lines was measured and designated as the FHH.
2. Femoral neck-shaft angle (FNSA). FNSA was measured by the angle between the femoral shaft and the femoral neck shaft.
3. The length of medial cephalic nail (Lmcn). Lmcn was the distance between the tip of the cephalic nail and medial edge of the shaft nail. The sliding distance of the cephalic nail was calculated by the Lmcn parameter in two periods.
4. Tip-cortex distance (TCD). TCD was the distance from the tip of cephalic nail to the femoral head cortex.
5. Tip-apex distance (TAD). We calculated TAD as described by Baumgaertner et al. using the anteroposterior and lateral radiographs to evaluate the implant position.

Key secondary outcome(s))
1. The Functional Independence Measure (FIM) assessment of degree of disability depends on the patient's score in 18 categories, focusing on motor and cognitive function at the final follow-up
2. Functional level was also measured using the Parker-Palmer mobility score at the final follow-up
3.Time taken to rise from a standard arm chair, walk 3 meters at a comfortable pace using their customary walking aid, turn, walk back to the chair, and sit down is measured using timed “Up & Go” (TUG) test at the final follow-up
4. 2-minute walk test (2MWT), which measures the distance walked in 2 minutes

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Computerised tomography (CT) scan data of the proximal femur obtained before surgical intervention
2. CT image thickness less than 3.0 mm
3. A minimum of 1 year of radiographic follow-up
4. Patients aged 18 years and older
5. Low-energy mechanism of injury
6. Participants underwent internal fixation using a intramedullary nail

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pathological fractures such as carcinomas, metastases of the bone, primary malignant or benign tumors, and metabolic disorders
2. Patient had mental disorder
3. Patient walked with assistive device before the fracture
4. Fractures with associated neurovascular injuries
5. Patient had pre-existing osteoarthritis or previous surgeries to the affected hip joints

Date of first enrolment
01/09/2009

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
China

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Chinese PLA General Hospital
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Sponsor information

Organisation
Chinese PLA General Hospital

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Not defined

Funder Name
The capital health research and development of special

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Li (lijiantao618@163.com).

IPD sharing plan summary
Available on request