A Single Center Prospective Controlled Study of Direct Anterior Approach and Posterior Lateral Approach in the Treatment of Femoral Neck Fractures in Elderly Patients

Team leader unit: Fujian Provincial Hospital

Project leader: Xu Wei

Responsible department: emergency surgery department

Contact number: 13959116868

Participants: Fujian Provincial Hospital

Study years: February 2023 - August 2024

scenario summary

project name	A single-center prospective controlled study of a direct anterior versus posterolateral approach for femoral neck fractures in very elderly patients
purpose of research	To evaluate the clinical efficacy of a direct anterior approach (DAA) versus posterolateral approach (PLA) hemiarthroplasty for femoral neck fractures in advanced elderly patients.
research design	A prospective controlled study including the patients treated for femoral neck fracture between February 2023 and 20 August 2024 were randomly ized into DAA and PLA groups according to different surgical methods for a 3-month follow-up to compare the outcomes of the two groups. Main observations include Harris hip function score (preoperative, 1 week, January, march), VAS pain score (preoperative, 1 week, January, march), secondary observations include operation time, intraoperative bleeding, blood transfusion rate, HB difference before and after surgery, CK before and after surgery, perioperative complications, postoperative lower limb length difference, postoperative discharge, postoperative ICU occupancy rate, ICU stay and total hospital stay.
Total number of cases	43 Cases
Case	① Age over 80 years old; ② confirmed unilateral femoral neck fracture by imaging examination; ③ tolerated surgery and consent to

selection	surgery; ④ initial HA; independent walking and complete cognitive function before ⑤ injury.
	① Bilateral femoral neck fracture; ② patients with pathological fracture; ③ with hip dysplasia and rheumatoid osteoarthritis; ④ with systemic or surgical site local infection or inflammatory reaction; ⑤ with other lower limb fractures or severe injuries to other parts of the body; ⑥ with previous history of hip surgery.
statistical method	In this study, the statistical analysis was performed using the SPSS 27.0 statistical software.
The study period	February 2023
	August, 2024

1. research background

Femoral neck fracture is a common fracture type in the elderly, and its high disability and mortality make it a fatal killer to the life and health of the elderly. Surgery is the main treatment of femoral neck fracture in the elderly patients. Traditional femoral neck fracture in elderly patients mostly adopts the posterolateral approach (PLA) hemihip arthroplasty under spinal anesthesia, and the direct anterior approach (DAA) emerging in recent years can also be used as an option for the treatment of femoral neck fracture in elderly patients. However, due to the long learning curve of DAA, the operation is difficult, and whether this operation can be used as an effective way of femoral neck fracture in elderly patients still needs further study.

2. purpose of research

1. Primary objective: To evaluate the clinical efficacy of direct anterior approach (DAA) and posterolateral approach (PLA) hemiarthroplasty in the treatment of femoral neck fractures in elderly patients.

2. Secondary purpose: To provide some reference for the clinical treatment of femoral neck fracture in the elderly.

3. Type and principle of the study design

1. Study design

In a prospective controlled study, patients who underwent femoral neck replacement for femoral neck fracture between February 2023 and 20 August 2024 were randomly divided into DAA and PLA groups according to different surgical methods for a 3-month follow-up to compare the outcomes of the two groups.

4. Case selection

1. Inclusion criteria

① Age over 80 years old; ② confirmed unilateral femoral neck fracture by imaging examination; ③ tolerated surgery and consent to surgery; ④ initial HA; independent walking and complete cognitive function before ⑤ injury.

2. Exclusion criteria

① Bilateral femoral neck fracture; ② patients with pathological fracture; ③ with hip dysplasia and rheumatoid osteoarthritis; ④ with systemic or surgical site local infection or inflammatory reaction; ⑤ with other lower limb fractures or severe injuries to other parts of the body; ⑥ with previous history of hip surgery.

5. observation item

General information: gender, age (age), height (cm), weight (kg), comorbidity, American Association of Anesthesiologists (American Society of Anesthesiologists, ASA) classification.

Fracture related data: fracture side division, fracture Garden classification and anatomical site classification, Pauwels angle (°).

Main indicators: Harris hip function score and VAS pain score before, 1 week, 1 month and 3 months after surgery.

Laboratory indicators: hemoglobin value (hemoglobin, HB) (g / L), creatine kinase value (creatine kinase, CK) (U / L) before and after surgery, and the difference was recorded and calculated.

Surgical index: operation time (min), intraoperative blood loss (ml), and intraoperative blood transfusion rate (%).

Perioperative complications: Surgery-related complications include periprosthetic fracture, dislocation, surgical site infection and LFCN injury, while systemic complications include lower limb venous thrombosis, pulmonary infection, death, etc.

Other indicators: postoperative length difference of both lower limbs,

postoperative discharge, postoperative transfer to ICU, ICU length of stay (days), total length of stay (days), mortality rate (%).

Six, data security monitoring

The clinical study will develop a corresponding data safety monitoring plan according to the risk size. All adverse events are detailed documented, Properhandled and tracked until properly resolved or stable, Report serious adverse events and unexpected events to the Ethics committee, competent authorities, sponsor and drug regulatory department in time; A cumulative review of all adverse events was performed periodically by the principal investigator, Hold investigator meetings when necessary to assess the risks and benefits of the study; Double-blind tests may be performed for emergency unblinding when necessary, To ensure the subjects safety and rights and interests; Studies greater than the minimum risk will schedule an independent data monitor to monitor the study data, The high-risk study will establish an independent data safety monitoring board to monitor the accumulated safety data and efficacy data, To make recommendations on whether the study continues.

VII. Statistical treatment

Statistical analysis of the data was performed using the IBM SPSS Statistics 27 software. Measurement data are expressed as $x \pm s$, compared by t-test or Mann-Whitney U test according to whether the data conform to the normal distribution; count data are compared by x^2 test or Fisher exact probability method according to the conditions. A $P < 0.05$ was considered as a statistically significant difference.

VIII. Ethics of clinical research

Clinical research will follow the provisions of the Declaration of Helsinki.

The clinical study was performed before EC approval of the study protocol. Before each subject is included in the study, the investigator has the responsibility to present the subject or his agent about the purpose and procedures and possible risks to the study and sign a written informed consent to inform the subject that they have the right to withdraw from the study at any time, and the informed consent shall be retained as a clinical study document for future reference. Personal privacy and data confidentiality will be protected during the study.

Ix. Research progress

2023.02-2023.10 Preliminary data collection

2023.11-2024.08 Completed data collection, data collation and statistical analysis

2024.09-2025.06 Papers writing and submission

X. Participants

surname and personal name	**Professional title / major**	**assignment**
Chen Jian	Graduate student in emergency medicine	Data collection and data analysis
Hong-ru CAI	associate chief physician	Data collection and data analysis
Xu Wei	botanic physician	Arc ata collection and data analysis