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Effect of cement augmentation on early postoperative ADL score in patients treated with cephalomedullary nailing for trochanteric fractures

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ABSTRACT

Introduction

Femoral trochanteric fractures are among the most frequently encountered fractures in clinical practice, and the number of these fractures continues to increase owing to an aging society [1,2]. As the average patient age increases, many cases get complicated by severe osteoporosis [1,2]. The most common mechanical complication related to trochanteric fracture fixation with cephalomedullary nails (CMNs) is cut-out [3]. Screw cut-out and cut-through is reported to occur in up to 16.5% of cases and lead to fixation failure [4].

In several biomechanical studies, improvements in stability have been demonstrated with cement augmentation devices [5,6]. Therefore, fixation with CMNs and cement augmentation (CA) has been developed as a new treatment option for osteosynthesis of trochanteric fractures in osteoporotic bones. Procedures with CA reportedly have good short-term postoperative clinical results, including a lower implant failure rate [7-9]. Based on previous studies comparing hip fractures with and without CA, no significant differences were found in the results at 3 months after surgery in terms of mortality and intraoperative healing position [7]. However, postoperative pain and the activities of daily living (ADL) score in the CA group were better than that in the group without CA at 6 weeks after surgery [10]. Notwithstanding, the effect on ADL in the early postoperative period has not yet been investigated despite the importance of early ADL performance in reducing postoperative complications and regaining ambulation after surgery [11].

Therefore the purpose of this study is to clarify the effect of CA on early postoperative ADL scores in patients with trochanteric fractures. We hypothesize that the enhanced stability with CA will reduce loading pain, allowing patients to regain preoperative ADL in the early postoperative period and reduce perioperative complications.

Materials and Methods

Study design and setting

We will perform a prospective multicenter cohort study of patients with trochanteric fractures from February 2021, treated by 2 orthopedic surgeons from general hospitals in Japan. We designed the study in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria and will use the checklist for reporting purposes [12].

Details of the research design includes:

P (population of interest): Patients undergoing internal fixation with CMN for trochanteric fracture

I (intervention): Fixation with CMN plus CA

C (control): Fixation with CMN only

O (outcomes): Cumulated ambulation score (CAS) (representing ADL in the early postoperative period), pain scale, and adverse events.

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Patient selection

The inclusion criteria are patients with first-time trochanteric fractures (fracture type: AO Foundation/Orthopedic Trauma Association [AO/OTA] classification 31A [13]), age >60 years and ability to walk independently before the injury (walking without aid or with a cane or walker). The exclusion criteria are pathological fractures, open fractures, use of a wheelchair before the injury, history of allergy to cement, multiple lower extremity trauma, postoperative inability to bear weight, and postoperative medical complications making it difficult to leave the bed (pneumonia, heart failure, etc.).

Surgical procedures

First, we will perform a closed reduction on a traction table under fluoroscopic guidance. When we are not able to achieve adequate fracture reduction, we will add the procedures to achieve anteromedial cortical reduction via a lag screw incision or an additional mini-open anterolateral incision. [14]. We will then fix the fracture with a Trochanteric Femoral Nail Advanced (TFNA) perforated spiral blade (DePuy Synthes, Paoli, PA) following the manufacturer's recommendations. The indications for CA are surgeon-dependent.

Main exposure

In patients undergoing CA, Traumacem (DePuy Synthes, Paoli, PA), a polymethyl methacrylate (PMMA) cement, will be injected into the blade (3-6mL) under fluoroscopic control.

Preoperative variables

The preoperative variables will be compared between the CMN plus CA and CMN only groups: patient demographics (age, sex, height, weight and body mass index [BMI]), Charlson comorbidity index (CCI) [15] (including congestive heart failure, dementia, chronic lung disease, rheumatism, mild liver damage, diabetes with chronic complications, hemiplegia or paraplegia, renal disease, malignancy including leukemia and lymphoma, moderate to severe liver disease, metastatic solid tumors, and HIV/AIDS, American Society of Anaesthesiologists classification, preoperative blood samples results including hemoglobin (Hb) and albumin (Alb), pre-injury residence (single, co-residence, institutional, hospital), osteoporosis, bone mineral density measured at the total hip and forearm using dual-energy x-ray absorptiometry, fracture characteristics based on AO/OTA classification [13], and preoperative waiting period (day of hospital admission until day of surgery).

Postoperative variables

The postoperative variables include physical therapy intervention on postoperative day 1, reduction quality of fracture site, fixation quality, blade position, surgical time (min), and intraoperative blood loss (cc).
On the postoperative radiograph, the quality of reduction will be rated "good" (normal or slight valgus alignment on the anteroposterior radiograph, <20 degrees of angulation on the lateral radiograph, and maximum 4 mm of displacement of any fragment), "acceptable" (the reduction met the criterion for a "good" reduction with respect to either alignment or displacement but not both) or "poor" (the reduction met neither criteria) according to Baumgaertner (1995) [16]. On postoperative anteroposterior and lateral radiographs, we will assess quality of device placement with the tip–apex distance (TAD) [16], and the blade tip position by dividing the femoral head into nine zones according to Cleveland et al.(1959) [17].

Outcomes

The primary outcome of interest is the total CAS score on postoperative days 1, 2, and 3. The CAS is a valid and reliable assessment tool for evaluating a patient's mobility by observing the following three basic movements [18] : (1) getting in and out of bed, (2) sitting and rising from a chair (with armrests), and (3) indoor walking (with or without a walking aid).
The secondary outcomes are pain scores measured using the visual analog scale (VAS) at rest and VAS score during movement on postoperative days 1-3, and the Barthel index at 1-week postoperatively, walking ability (wheelchair, parallel bars, walker, cane or walking alone) and other complications within 1-week postoperatively (coronary artery disease, gastrointestinal bleeding, acute renal failure, delirium [diagnosed based on the confusion assessment method] [19], stroke, venous thrombosis, pneumonia, urinary tract infection, wound infection, pressure ulcer, death, or perioperative blood transfusion) [20]. Intraoperative adverse events related to the CA, such as cement allergy and cement leakage, are also included.

Sample size calculation

Based on previous studies using CAS as an outcome variable in acute hip fractures [21], a sample size of 42 patients (21 patients per treatment group) is needed for this study to have 80% power to detect a 2-point mean

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difference in CAS scores with a type I error of 5%. Therefore, we set a sample size of 50 patients (25 patients per treatment group) to accommodate for patient dropouts.

Statistical analyses

Continuous data with normal distribution will be presented as means ± standard deviations, and compared using t-test. Variables with non-normal distribution will be presented as medians and interquartile ranges and compared using the Mann–Whitney U test. Categorical data will be presented as a proportion of cases and compared using Fisher's exact test or $\chi 2$ test, as appropriate. Univariate and multivariate logistic regression analyses will be performed to clarify the effect of the CA. Significance will be defined as $P < .05$. All statistical analyses will be performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan).

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KEYWORDS

cement augmentation, CAS, cephalomedullary nail, trochanteric fracture

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