Original Article Clinics in Orthopedic Surgery 2024;16:397-404 • https://doi.org/10.4055/cios23287

Incidence and Risk Factors of Osteonecrosis of the Femoral Head after Cephalomedullary Nailing for Pertrochanteric Fractures: Observational Single-Center Study

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Background: The objective of this study was to investigate the incidence of osteonecrosis of the femoral head (ONFH) after cephalomedullary nailing in elderly patients with pertrochanteric fractures and to analyze the risk factors related to ONFH.

Methods: A total of 689 consecutive patients with cephalomedullary nailing for pertrochanteric fractures at our hospital were recruited. Of these, 368 patients who met the inclusion criteria were finally enrolled. ONFH after cephalomedullary nailing was identified by reviewing patients' electronic charts and serial radiographs. The ONFH group was then compared with the non-ONFH group.

Results: ONFH was identified in 9 of 368 patients (2.4%). The time to diagnosis of ONFH averaged 23.8 months (range, 5–54 months) after index surgery. The mean age, body mass index, and bone mineral density (T-score in femur neck) were 84.1 ± 7.1 years, 23.7 ± 3.6 kg/m^2, and –3.1 ± 0.7 kg/m^2, respectively. The times from injury to surgery, from admission to surgery, and operation time averaged 4.2 ± 2.7 days, 3.6 ± 2.6 days, and 87.2 ± 30.0 minutes, respectively. Among 9 patients, 3 underwent conversion arthroplasty. The ONFH group had advanced age (p = 0.029), more basicervical fracture components (p = 0.002), and inadequate reduction (p = 0.045) compared to the non-ONFH group. On multivariate analysis, advanced age (odds ratio [OR], 1.61;, p = 0.022), basicervical fracture components (OR, 24.58; p = 0.001), and inadequate reduction (OR, 4.11; p = 0.039) were identified as risk factors of ONFH.

Conclusions: Although ONFH is relatively rare after cephalomedullary nailing for pertrochanteric fractures in elderly patients, its risk may increase with advanced age, basicervical fracture components, and inadequate reduction. Therefore, in patients with these risk factors, meticulous and longer follow-up is needed even after bone union.

Keywords: *Pertrochanteric fracture, Cephalomedullary nailing, Osteonecrosis of femoral head, Risk factors*

Pertrochanteric fractures are gradually increasing with an aging population and rising incidence of osteoporosis.[1] Successful surgical treatment without complications is crucial for optimal functional recovery in debilitated elderly patients with pertrochanteric fractures.[2] Although the best fixation method remains controversial, cephalomedullary nailing has been widely performed for these fractures due to its biomechanical superiority and less invasive procedure.[2,3] Along with the continuous evolution in the design of the nail, cephalomedullary nailing for pertrochanteric fractures has shown favorable outcomes with

Received September 12, 2023; Revised January 18, 2024; Accepted January 18, 2024
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reduced complications. However, several complications such as fixation failure, nonunion, and osteonecrosis of the femoral head (ONFH) still occur in osteoporotic elderly patients.[4-6] According to recent studies, the complication rate in elderly patients treated with cephalomedullary nailing ranges from 2% to 8%.[4,7]

In femoral neck fractures, the blood supply to the femoral head can be disrupted and it is subsequently associated with the risk of ONFH. Meanwhile, pertrochanteric fractures, which occur mainly at the well-vascularized metaphyseal region, are known to have minimal effect on the blood supply to the femoral head and are not associated with the risk of ONFH.[8] Therefore, ONFH has been known as a relatively rare complication after osteosynthesis for pertrochanteric fractures. Yin et al.[9] reported a 0.87% incidence of ONFH while Mattan et al.[10] reported an ONFH incidence of 0.5% in pertrochanteric fractures. However, these studies included both extramedullary fixation and cephalomedullary nailing in the surgical treatment of pertrochanteric fractures.

The complications including ONFH after hip nailing have a significant effect on surgical outcomes including the morbidity and mortality in fragile elderly patients. Accordingly, the incidence and risk factors of these complications are of paramount importance for better surgical outcomes by reducing the morbidity and mortality in elderly patients. However, up to date, there has been limited information on the incidence and risk factors of ONFH after cephalomedullary nailing for pertrochanteric hip fractures, especially in elderly patients. Therefore, this retrospective study was conducted to investigate the incidence of ONFH after cephalomedullary nailing in elderly patients with pertrochanteric fractures and to analyze the risk factors related to its occurrence.

METHODS

This retrospective cohort study was approved by the Institutional Review Board of Hallym University Sacred Heart Hospital (IRB No. 2018-07-014). Requirement for informed consent was waived owing to its retrospective nature. A prospectively compiled database was used to recruit patients who underwent cephalomedullary nailing for pertrochanteric hip fractures at our hospital between May 2010 and July 2019. Then, patients who met the following inclusion criteria were included: (1) age ≥ 65 years at the time of injury, (2) independently or dependently ambulatory prior to injury, (3) pertrochanteric fractures treated with cephalomedullary nailing, (4) bony union obtained without fixation failure, and (5) available postoperative follow-up records for at least 12 months. Patients with multiple trauma and pathologic fractures were excluded (Fig. 1).

Standard radiographs and 3-dimensional computed tomography (3D CT) scans of each patient were taken for a detailed assessment of the fracture pattern before surgery. All fractures were classified by 2 authors (DKK and SL) according to the AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification system.[11] In addition, the presences of a basicervical fracture component and comminution of the greater trochanter (GT) and anterior cortex of the proximal fragment were also analyzed. Basicervical pertrochanteric fracture was defined as a fracture in which the main fracture line of the proximal fragment crossed close to the base of the femoral neck and its junction with the trochanteric region.[12] In this study, we excluded 2-part basicervical neck fractures confirmed on 3D CT because these should be regarded as a variant of the femoral neck fracture.

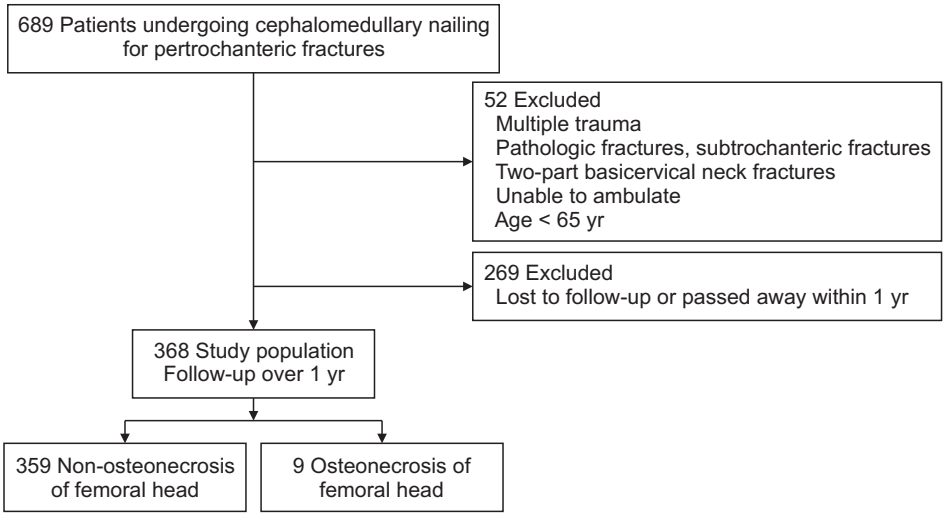

Fig. 1. Flowchart demonstrating patient selection.

During this period, 689 consecutive patients who underwent cephalomedullary nailing for pertrochanteric fractures were identified. Of these, 368 patients who met the inclusion criteria were finally enrolled with a mean follow-up of 28.6 ± 17.3 months. A total of 254 female and 114 male patients with a mean age of 77.8 ± 13.9 years were retrospectively analyzed. Age, sex, body mass index (BMI), bone mineral density (BMD), American Society of Anesthesiologists (ASA) grade, the time from injury to operation, the time from admission to operation, and the operation time were obtained from patients' electronic medical records (Table 1).

With the exception of specific patients with severe life-threating comorbidities, most patients underwent index surgery within 2 days and no longer than 3 days after admission, with a mean time from admission to operation of 3.7 ± 2.9 days. All operations were performed on the fracture table under fluoroscopic guidance by an experienced hip and trauma surgeon (JHY). Regarding the types of the nails used, a nail with a thread-type lag screw (Intertrochanteric/Subtrochanteric Fixation System, Zimmer) was used in 28 patients (7.6%), a nail with a helical blade (PFNA-II, Proximal Femoral Nail Antirotation; DePuy Synthes) in 24 patients (6.5%), a nail with a hybrid-type lag screw (Gamma3 U-blade, Stryker) in 267 patients (72.6%), and a nail with a lag screw and additional antirotation screw (Affixus, Biomet Trauma) in 49 patients (13.3%). We did not use bone cement or calcium phosphate intraoperatively in all patients.

All patients were instructed to walk under tolerable weight-bearing with an assistive device (walker or cane) from the second postoperative day to 4–6 weeks later, as per our institutional protocol. Patients were followed up at 3, 6, and 12 months postoperatively and thereafter yearly. Anteroposterior and lateral radiographs were obtained at each follow-up visit.

On postoperative radiographs, reduction quality was assessed using a slight modification of Baumgartner et al.'s criteria[13] and the reduction status was categorized as ana-

Table 1. Demographic and Radiographic Data in All Patients (N = 368)

Variable	Value
Age (yr)	77.8 ± 13.9
Sex (female: male)	254 (69.0) : 114 (31.0)
Body mass index (kg/m^2)	22.9 ± 4.2
Bone mineral density (kg/m^2)	–3.1 ± 1.1
Time from injury to operation (day)	3.9 ± 3.2
Time from admission to operation (day)	3.7 ± 2.9
Duration of operation (min)	81.9 ± 32.0
Follow-up period (mo)	28.6 ± 17.3
ASA grade	
II	88 (24.0)
III	247 (67.1)
IV	33 (9.0)
AO/OTA classification	
1	119 (32.3)
2	218 (59.2)
3	31 (8.4)
Basicervical fracture component	147 (39.9)
Anterior cortex comminution	74 (20.1)
GT comminution	213 (57.9)

Value are presented as mean ± standard deviation or number (%).
ASA: American Society of Anesthesiologists, OTA: Orthopaedic Trauma Association, GT: greater trochanter.

Table 2. Postoperative Radiological Results (N = 368)

Variable	Value
Quality of reduction	
Good	283 (76.9)
Acceptable	78 (21.2)
Poor	7 (1.9)
Reduction status	
Anatomical	273 (74.2)
Extramedullary	63 (17.1)
Intramedullary	32 (8.7)
Time to union (mo)	4.5 ± 1.8
ONFH cases	9 (2.4)
Time to ONFH diagnosis (mo)	23.8 ± 16.0
Nail entry point	
Medial	7 (1.9)
GT tip	332 (90.2)
Lateral	29 (7.9)

Value are presented as number (%) or mean ± standard deviation.
ONFH: osteonecrosis of the femoral head, GT: greater trochanter.

tomical, extramedullary, and intramedullary.[14] In addition, the nail entry point was divided into 3 categories: medial, GT tip, and lateral (Table 2). ONFH was defined as the definite finding of ONFH on follow-up radiographs along with the limitation of motion, pain during weight-bearing, or resting pain. The patients who showed a subchondral

Table 3. Comparison between ONFH and Non-ONFH Groups

Variable	Non-ONFH group (n = 359)	ONFH group (n = 9)	*p*-value
Age (yr)	76.9 ± 10.3	84.1 ± 7.1	0.029*
Female	248 (69.1)	6 (66.7)	0.991†
Body mass index (kg/m^2)	22.9 ± 3.7	23.7 ± 3.6	0.691*
Bone mineral density (kg/m^2)	–3.1 ± 1.2	–3.1 ± 0.7	0.913*
ASA grade			0.122†
II	88 (24.5)	0	
III	239 (66.6)	8 (88.9)	
IV	32 (8.9)	1 (11.1)	
AO/OTA classification			0.875†
1	116 (32.3)	3 (33.3)	
2	212 (59.1)	6 (66.7)	
3	31 (8.6)	0	
Basicervical component	139 (38.7)	8 (88.9)	0.002†
Anterior cortex comminution	73 (20.3)	1 (11.1)	0.216†
GT comminution	208 (57.9)	5 (55.6)	0.991†
Time from injury to surgery (day)	3.8 ± 3.7	4.2 ± 2.7	0.428*
Time from admission to surgery (day)	3.7 ± 2.4	3.6 ± 2.6	0.710*
Duration of operation (min)	81.8 ± 36.5	87.2 ± 30.0	0.889*
Nail entry point			0.914†
Medial	7 (1.9)	0	
GT tip	324 (90.3)	8 (88.9)	
Lateral	28 (7.8)	1 (11.1)	
Quality of reduction			0.045†
Good	279 (77.7)	4 (44.4)	
Acceptable	73 (20.3)	5 (55.6)	
Poor	7 (2.0)	0	
Reduction status			0.781†
Anatomical	266 (74.1)	7 (77.8)	
Extramedullary	61 (17.0)	2 (22.2)	
Intramedullary	32 (8.9)	0	

Value are presented as mean ± standard deviation or number (%).
ONFH: osteonecrosis of the femoral head, ASA: American Society of Anesthesiologists, OTA: Orthopaedic Trauma Association, GT: greater trochanter.
*Student *t*-test. †Fisher's exact test.

fracture line on the superior aspect of the femoral head on follow-up radiographs were excluded under the diagnosis of subchondral insufficient fracture. This study has been reported in line with the STROCSS (strengthening the reporting of cohort studies in surgery) criteria.[15]

Statistical Analysis

Basic descriptive statistical analyses were used to describe the study population. For comparison between the 2 groups (ONFH group vs. non-ONFH group), Student t-test was used for continuous variables. For categorical variables, the chi-square test was used, whereas Fisher's exact test was used when the expected counts were < 5. Multivariate logistic regression was performed to identify the risk factors of ONFH. Odds ratios (ORs) were obtained with 95% confidence intervals. In all analyses, statistical significance was set at a value of $p < 0.05$. All statistical evaluations were performed using IBM SPSS version 24.0 (IBM Corp.).

RESULTS

Most patients obtained good or acceptable reduction quality (98.1%) and anatomical or extramedullary reduction status (91.3%). The nail entry point was located at the GT tip in most patients (90.2%) and the time to bone union averaged 4.5 ± 1.8 months (Table 2).

Of the total of 368 patients, 9 (2.4%) developed ONFH during the follow-up period after cephalomedullary nailing. Of the 9 patients, a nail with a lag screw combined with antirotation screw was used in 5 patients (55.6%), a nail with a hybrid-type lag screw in 3, and a nail with a helical blade in 1. The time to diagnosis of ONFH averaged 23.8 ± 16.0 months (5–54 months) after index surgery. These included 3 male and 6 female patients with a mean age of 84.1 ± 7.1 years. BMI and BMD (T-score in contralateral femur neck) were 23.7 ± 3.6 kg/m^2 and –3.1 ± 0.7 kg/m^2, respectively. The times from injury to surgery, from admission to surgery, and operation time averaged 4.2 ± 2.7 days, 3.6 ± 2.6 days, and 87.2 ± 30.0 minutes, respectively. Among the 9 patients with ONFH, 8 patients (88.9%) had a basicervical fracture component and 6 patients (66.7%) showed unstable comminuted fractures. In addition, anterior cortex comminution was observed in 1 patient and GT comminution in 5. The postoperative reduction quality was good in 4 patients (44.4%) and acceptable in 5, and anatomical or extramedullary reduction status was seen in all patients. The nail entry point was located at the GT tip in most patients (88.9%). Of these 9 patients, only 3 were converted to arthroplasty.

Table 4. Risk Factors Affecting Osteonecrosis of the Femoral Head after Cephalomedullary Nailing in Elderly Patients with Pertrochanteric Fractures (Multiple Logistic Regression)

Variable	Odds ratio (95% CI)	*p*-value
Age	1.61 (1.15–1.72)	0.022
Basicervical fracture type	24.58 (3.31–117.15)	0.001
Inadequate reduction	4.11 (2.07–49.31)	0.039

CI: confidence interval.

Despite the recommendation of conversion arthroplasty, the remaining 6 patients refused it due to their old age and comorbidities. All demographic and radiographic data are shown in Tables 2 and 3.

On comparative analysis, the ONFH group was relatively older ($p = 0.029$) than the non-ONFH group. However, other demographic data (sex, BMI, BMD, and ASA grade) and time-related factors (time from injury to surgery, time from admission to surgery, and operation time) showed no differences between the 2 groups (Table 3). On radiologic analysis, there were significant differences in the presence of basicervical fracture component and quality of reduction between the 2 groups ($p = 0.002$ and $p = 0.045$, respectively). Other radiologic data (AO/OTA classification, anterior cortex comminution, GT comminution, nail entry point, and reduction status) showed no difference between the groups. On multiple logistic regression, advanced age (OR, 1.61; $p = 0.022$), basicervical fracture component (OR, 24.58; $p = 0.001$), and inadequate reduction (OR, 4.11; $p = 0.039$) were identified as risk factors for ONFH (Table 4).

DISCUSSION

The incidence of ONFH (2.4%) in our study including only elderly patients with a relatively long follow-up is thought to be substantially higher than known (0.3% to 1.16%) in previous studies with a relatively short-term follow-up and young patients.[9,10,16,17] Shih et al.[16] reported an incidence of ONFH of 0.3% (6 patients). Their ages ranged from 19 to 67 years with an average age of 46 years. Of these 6 patients, 3 suffered pertrochanteric fractures due to high-energy trauma. Similarly, Yin et al.[9] reported an incidence of ONFH of 0.87% with a median age of 51 years. Furthermore, the authors investigated the incidence of ONFH after pertrochanteric fractures treated with intramedullary and extramedullary fixation. Mattan et al.[10] documented an incidence of ONFH of 0.5% in per-

trochanteric fractures. All of the ONFH patients in their study were fixed with DHS. Contrary to previous studies, only elderly patients who underwent cephalomedullary nailing for pertrochanteric fractures were enrolled in this study, excluding extramedullary fixation such as DHS, high-energy trauma, and younger patients < 65 years, which have been reported as risk factors of ONFH in pertrochanteric fractures. Pertrochanteric hip fracture is one of common osteoporotic fractures due to low-energy trauma in elderly patients and the surgical outcomes including complications have a significant effect on the morbidity and mortality in these fragile patients. Accordingly, we believe that the incidence of ONFH after hip nailing in our study is of paramount significance given that the current study aimed at only elderly patients ≥ 65 years with pertrochanteric fracture resulting from low-energy trauma.

As mentioned above, one of the reasons for the high incidence of ONFH in this study is thought to be advanced age of the enrolled patients. Advanced age is a well-known and extensively debated risk factor for ONFH after fixation in pertrochanteric fractures.[18,19] Elderly patients' vessels are inevitably less flexible than those of younger patients due to aging degeneration. Consequently, they are more likely to be injured during fracture and reduction maneuver, which may jeopardize the precarious blood supply to the femoral head.[18] Another reason for higher incidence of ONFH in our study may be that only patients treated with cephalomedullary nailing were included although previous studies enrolled all patients treated with cephalomedullary nailing and extramedullary fixation. The proximal reaming for nail entry with the thick reamer of 15.5-mm diameter during hip nailing is performed at the area (GT tip or just medial to GT tip) close to vessels to the femoral head. This proximal reaming may injure the vessels to the femoral head, increasing the risk of ONFH after cephalomedullary nailing along with the fracture itself. Meanwhile, during extramedullary fixation, the reaming is performed only for lag screw insertion within the femoral head from the lateral cortex. This reaming is unlikely to cause the injury to the blood vessels to the femoral head and subsequently to have the effect on the occurrence of ONFH after extramedullary fixation such as DHS. Therefore, we believe that cephalomedullary nailing can increase the incidence of ONFH compared to extramedullary fixation such as DHS.

Up to date, unstable fracture pattern, less accurate reduction, and a nail entry point located in the trochanteric fossa have been mentioned as risk factors injuring this blood supply in proximal femur fractures.[20,21] Our finding that inaccurate reduction is a risk factor of ONFH is consistent with Mussbichler's study[20] demonstrating that blood circulation improves when reduction and internal fixation are performed effectively. However, there were no significant differences in the nail entry point and fracture type (AO/OTA classification) between the ONFH and non-ONFH groups in the current study. Additionally, we revealed that the basicervical fracture component is a risk factor of ONFH along with advanced age and inaccurate reduction. This finding is similar to Yin's study reporting that ONFH occurs more frequently in more proximal fracture lines.[9] Similarly, Bartonicek et al.[19] reported that the fracture line passing higher than its usual course in pertrochanteric fractures was a risk factor of ONFH. Therefore, the basicervical fracture type is considered to affect the disruption of the blood supply to the femoral head because the main fracture line is more proximal than in conventional pertrochanteric fracture with no basicervical fracture component. Accordingly, thorough evaluation on standard radiographs and 3D CT should be implemented to confirm this risk type preoperatively and to pay more attention to patients with this fracture type after surgery.

In the current study, the mean period from index surgery to diagnosis of ONFH was 23.8 months with a range of 5–54 months. Baixauli et al.[21] reported 3 cases of ONFH more than 4 years after surgery (55, 56, and 120 months, respectively). Similarly in our study, 2 cases were

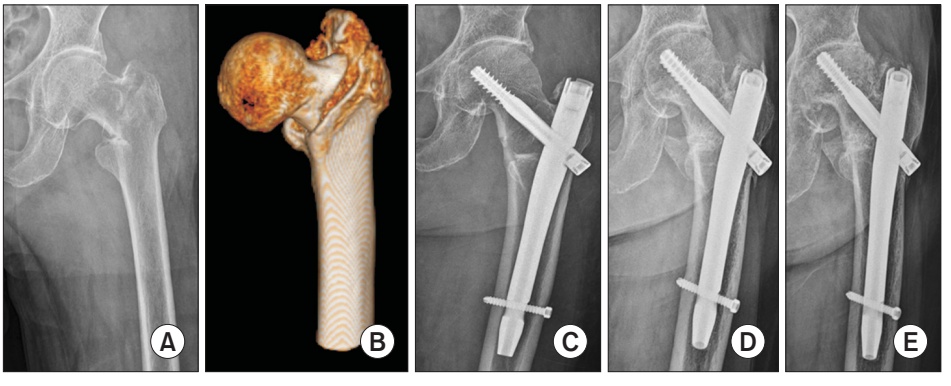

Fig. 2. Initial radiograph (A) and 3-dimensional computed tomography (B) of a 91-year-old woman showing a pertrochanteric fracture. Postoperative radiograph (C) and anteroposterior radiograph (D) at 36 months after surgery, showing good reduction status and bone union. (E) Anteroposterior radiograph showing osteonecrosis of the femoral head at 41 months after surgery.

observed 41 and 54 months after index surgery, respectively (Fig. 2). These cases would have been undetected or overlooked if the follow-up period had not been long enough. These results suggest that ONFH after hip nailing in pertrochanteric fractures is a rare but relatively late complication and a relatively long follow-up is required to evaluate more accurate incidence because the longer the follow-up period, the incidence may increase. Therefore, we tried to follow up many patients as long as possible while concurrently treating osteoporosis so that we could enroll many patients with sufficiently long follow-up as a single-center study.

This study has some limitations. First, this was a retrospective study design. Second, patient-related factors such as metabolic disorders and alcoholism affecting ONFH were not considered. However, there were no underlying diseases in all patients who developed ONFH after hip nailing in this study. Third, a statistically significant difference may not be clinically significant because of the relatively small number of patients with ONFH considering the low incidence of ONFH in pertrochanteric fractures. Finally, it is difficult to determine the exact incidence and time to diagnosis of ONFH after cephalomedullary nailing for pertrochanteric fractures. Elderly patients with asymptomatic early ONFH or mild pain are likely not to visit an outpatient clinic and to be undiagnosed subsequently. Moreover, since we could not perform magnetic resonance imaging on all patients, ONFH was diagnosed only in patients with symptoms and ONFH findings on follow-up radiographs. Accordingly, the incidence of ONFH would have been higher if patients with asymptomatic early ONFH or mild pain due to ONFH had been included. Besides, had it been diagnosed earlier in these patients, the time to the diagnosis of ONFH would have been shorter.

Despite these limitations, to the best of our knowledge, this is the first study to report the incidence and risk factors of ONFH after cephalomedullary nailing and subsequent bony union in elderly patients with pertrochanteric fractures. Another strength of this study is to enroll the large number of elderly patients with a relatively long follow-up as a single-center study, considering the difficulty of a long-term follow-up in these patients. We could maintain a relatively long-term follow-up for a large number of elderly patients because we continued osteoporosis medication via the outpatient clinic even after bone union. Accordingly, most patients enrolled in our study were able to ambulate independently or dependently.

In conclusion, although ONFH after cephalomedullary nailing for pertrochanteric fractures in elderly patients was relatively rare (2.4%), the risk of ONFH increased in elderly patients with advanced age, basicervical fracture components, and less accurate reduction. Therefore, meticulous monitoring is required along with longer follow-up for patients with these risk factors even after bone union, and these patients and their families should be informed of this risk.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

ACKNOWLEDGEMENTS

This work was support by the Hallym University Research Fund 2022 (HURF-2022-32).

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