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Effect of Severe Bowing in Bisphosphonate-Related Atypical Femoral Fracture

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Background: Long-term use of bisphosphonate is a risk factor for atypical femoral fractures (AFFs). Femoral bowing is known to be associated with AFFs. However, whether femoral bowing quickens the occurrence of AFF is unknown. The purpose of this study was to determine whether AFF occurs earlier in patients with severe femoral bowing than in those without severe bowing.

Methods: One hundred and sixty-four patients (186 AFFs) from January 2006 to December 2022 were included in this study. According to severity of femoral bowing, patients were divided into 2 groups: severe bowing group (26 femurs) and minimal to moderate bowing group (160 femurs). Age, sex, and completeness and location of AFF were compared between the 2 groups. We compared the time of AFF occurrence after bisphosphonate therapy using cumulative percentage between the 2 groups.

Results: Age and sex were similar between the 2 groups, while body mass index (BMI) was lower (22.5 ± 3.0 kg/m^2 vs. 24.5 ± 3.5 kg/m^2, p = 0.003) in the severe bowing group. The duration of bisphosphonate use was shorter in the severe bowing group than in the minimal to moderate bowing group (3.3 ± 3.8 years vs. 5.0 ± 4.0 years, p = 0.048). In the severe bowing group, 85% of AFFs were diaphyseal in contrast to the 46% in the minimal to moderate bowing group (p < 0.001). Cumulative percentage plot of AFFs in the severe bowing group was left-shifted compared to the minimal to moderate bowing group.

Conclusions: At the time of AFF diagnosis, the severe bowing group exhibited shorter duration of bisphosphonate use, lower BMI, and a higher incidence of diaphyseal location. Shortening the duration of bisphosphonate therapy may be advisable in patients with severe femoral bowing.

Keywords: *Osteoporosis, Bisphosphonates, Atypical femoral fracture, Femoral bowing, Risk factor*

Bisphosphonate-related atypical femoral fracture (AFF) has appeared as a critical issue in the treatment of osteoporosis.[1-3] As prolonged use of bisphosphonate is a major risk factor for AFF,[4] international guidelines have recommended drug holiday in patients on long-term bisphosphonate treatment.[5-9] Those guidelines recommended considering drug holidays after 3 to 5 years, taking into account the risk of osteoporotic fractures, as well as the potency and administration route (oral vs. intravenous) of bisphosphonates.

Recent studies showed that severe femoral bowing and high body mass index (BMI) as well as the prolonged bisphosphonate use were associated with AFF.[10-12] The AFF is a kind of insufficiency stress fracture,[13] and the

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femoral bowing might accentuate AFF. Currently, however, there is a lack of evidence on whether femoral bowing accelerates the occurrence of AFF. Thus, we hypothesized that severe anterolateral femoral bowing quickens the occurrence of AFF. The purpose of the study was to compare the time of AFF occurrence between patients with and without severe femoral bowing.

METHODS

The design and protocol of this multicenter retrospective study were approved by the Institutional Review Boards of 4 institutions (IRB No. B-2301-806-106). Due to the retrospective nature of the study and the deidentification of the data, the requirement for patient consent was waived by the IRB.

We retrospectively reviewed 217 patients (239 AFFs) who were diagnosed with AFF between January 2006 and December 2022 at 4 hospitals. The diagnosis of AFF was made based on the definition by the American Society for Bone and Mineral Research in 2013.[2] Among them, we excluded patients for whom full-length anteroposterior radiograph of the femur was not obtained (n = 45), who had bony metastasis or metabolic bone disease (n = 5), and in whom the duration of bisphosphonates use was not described (n = 3). One hundred and sixty-four patients (186 AFFs) met inclusion/exclusion criteria.

To address potential inconsistencies in femur rotation, we standardized the anteroposterior radiographs by positioning the patella facing forward. This method is straightforward and ensures consistency.[14] However, due to the limited size of the x-ray detector, the patella is not always visible in the radiographs. This limitation is inherent to the imaging process and does not significantly affect the assessment of femoral bowing.[14]

Femoral bowing was graded according to the grading system of femoral bowing by Park et al.[15] In that grading system, a reference line is drawn from the tip of the greater trochanter to the center of the intercondylar notch. Grade 0 (nearly straight) indicates that the reference line is located in the middle one-third of the medullary canal at the apex of the curve. Grade I (mild) indicates a reference line is located within the medial one-third of the medullary canal. Grade II (moderate) indicates a reference line starts outside the medullary canal on the medial side and passes through the medial cortex. Grade III (severe) indicates a reference line runs medial to the medial cortex. We categorized AFFs into a severe bowing group (grade III) and a minimal to moderate bowing group (Fig. 1). We categorized femoral bowing based on a standardized grading system and ensured that only the most severe cases were classified as severe bowing. This approach minimized the impact of any rotational discrepancies on the classification and analysis of femoral bowing. In patients with unilateral complete AFF, femoral bowing was measured on a radiograph of the contralateral femur.

The information on the specific name and duration of the previously prescribed bisphosphonates was obtained from the individual patients and their family or caregivers at the time of AFF diagnosis. If the patient could not remember the specific information of the bisphosphonate, the patient, the family, or the caregivers were asked to contact the hospital that prescribed the medication for further information. We compared the duration of bisphosphonate therapy and the cumulative percentage between AFF patients with severe femoral bowing and those without severe bowing.

Statistical Analysis

The Mann-Whitney *U*-test was used to compare continuous variables and Fisher's exact test for categorical variables. We plotted the cumulative proportion of AFF for each duration of bisphosphonate use. To examine the dose-dependent relationship between the severity of femoral bowing and the duration of bisphosphonate use, we conducted an exploratory analysis of variance (ANOVA) test to compare the mean duration of bisphosphonate treatment across different grades of femoral bowing (no,

Fig. 1. (A) A reference line is drawn from the tip of the greater trochanter to the center of the intercondylar notch. (B) When the reference line runs medial to the medial cortex of the femoral shaft, the femur is classified as severe bowing.

mild, moderate, and severe). If the ANOVA indicated significant differences, post-hoc pairwise comparisons were performed using Tukey's honest significant difference (HSD) test to identify specific group differences. Statistical analyses were carried out with SPSS version 16.0 (SPSS Inc.). A *p*-value less than 0.05 was considered to be statistically significant.

RESULTS

There were 160 women and 4 men, their mean age was 73.1 years (range, 46–91 years), and their mean BMI was 24.2 kg/m^2 (range, 13.5–33.2 kg/m^2) (Table 1). Twenty-two patients (13.4%) had bilateral AFFs. One hundred and thirty patients (79.3%) had a history of bisphosphonate use, and the mean duration of the bisphosphonate use was 4.7 years (range, 0–18 years). Twenty-six femurs (14.0%) were classified as severe bowing group, and the remaining 160 femurs (86.0%) as minimal to moderate bowing group. The number of femurs with complete/incomplete AFF in the severe bowing group and the minimal to moderate bowing group was 14 (54%)/12 (46%) and 108 (68%)/52 (32%), respectively ($p = 0.174$).

Age ($p = 0.612$) and sex ($p = 1.000$) were similar between the 2 groups while patients in the severe bowing group had lower BMI compared to the minimal to moderate bowing group ($p = 0.003$). The duration of bisphosphonate use was shorter in the severe bowing group than in the minimal to moderate bowing group (3.3 ± 3.8 years vs. 5.0 ± 4.0 years, $p = 0.048$) (Table 1). The location of AFF was subtrochanteric in 90 femurs and diaphyseal in 96 femurs in total. Eighty-five percent of AFFs were diaphyseal in the severe bowing group, while 46.2% were diaphyseal in the minimal to moderate bowing group ($p < 0.001$).

The cumulative percentage of AFF in the severe bowing group was left-shifted compared to the minimal to moderate bowing group, indicating that AFF occurred earlier during or after bisphosphonate use in the severe bowing group (Fig. 2). For further analysis, the ANOVA test indicated a trend towards significance (F = 2.41, $p = 0.069$), suggesting that there might be differences in bisphosphonate treatment duration between the groups. However, this did not reach statistical significance at the 5% level. Further post-hoc analysis using Tukey's HSD test revealed

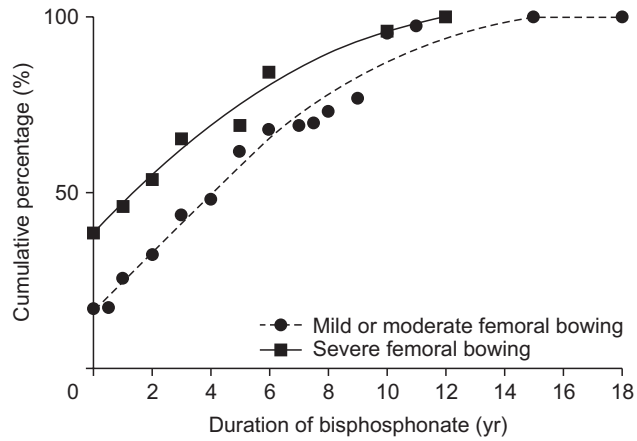

Fig. 2. Cumulative percentage of atypical femoral fractures by duration of bisphosphonate therapy in the severe bowing group and the minimal to moderate bowing group.

Table 1. Comparison of Severe Bowing Group and Minimal to Moderate Bowing Group

Variable	Severe bowing group (n = 26)	Minimal to moderate bowing group (n = 160)	*p*-value
Sex			1.000
Male	0	4 (3)	
Female	26 (100)	156 (97)	
Age (yr)	73.9 ± 7.9	73.0 ± 8.1	0.612
Body mass index (kg/m^2)	22.5 ± 3.0	24.5 ± 3.5	0.003
Complete AFF	14 (54)	108 (68)	0.174
Number of bisphosphonate users	17 (65)	132 (83)	0.061
Duration of bisphosphonate use (yr)	3.3 ± 3.8	5.0 ± 4.0	0.048
Location (subtrochanteric : diaphyseal)	4 (15) : 22 (85)	86 (54) : 74 (46)	< 0.001

Values are presented as number (%) or mean ± standard deviation.
AFF: atypical femoral fracture.

that there were no statistically significant differences in the mean duration of bisphosphonate treatment between any pairs of femoral bowing groups. The *p*-values for all pairwise comparisons were above 0.05, although the difference between the moderate and severe bowing groups approached significance ($p = 0.068$).

DISCUSSION

In our study, AFF patients with severe femoral bowing had a shorter duration of bisphosphonate use compared to those with minimal to moderate femoral bowing. Our findings may add a new dimension to the understanding of AFF pathogenesis by demonstrating that mechanical stress from severe femoral bowing can exacerbate the risk of AFFs even with shorter durations of bisphosphonate use. This suggests that severe femoral bowing may be a critical risk factor that may accelerate the occurrence of AFFs. Clinicians may need to include an evaluation of femoral bowing severity as part of the pre-treatment assessment, guiding the decision-making process regarding the initiation and duration of bisphosphonate therapy.

AFF is known to be a type of insufficiency fracture and pronged use of bisphosphonate has been linked to the occurrence of AFFs. Although the pathogenesis of AFFs is not completely understood, recent studies have noted that the suppression of bone turnover by bisphosphonates is responsible for AFFs.[2,16] Thus, several guidelines have recommended a "drug holiday" in patients who used bisphosphonate more than 3 or 5 years to reduce the risk of AFFs.[5-9] Moreover, shorter interval has been recommended especially in patients on treatment with high-potency bisphosphonates such as zoledronate.[5-9] Even though AFFs are often associated with anterolateral bowing of the femur,[15] no study has investigated whether the femoral bowing quickens the occurrence of AFFs. Actually, the mean duration of bisphosphonate use was lower in the severe bowing group (3.3 ± 3.8 vs. 5.0 ± 4.0, $p = 0.048$), and in Fig. 2, point reaching 100% cumulative (longest duration of bisphosphonate use) was earlier in the severe bowing group. Although it was not statistically significant, it is also notable that the starting point (proportion of non-user) was marginally higher in the severe bowing group (9 / 26 vs. 28 / 160, $p = 0.061$).

The influence of femoral bowing on AFF has been investigated in previous studies.[12,17-26] Saita et al.[23] found that in patients with bilateral AFFs, the locations of fractures were similar in both sides. This finding led many physicians and surgeons to consider that proximal femoral anatomy could be playing an important role in the pathogenesis of AFFs. Varus deformity of proximal femur was found to be a predisposing factor for AFFs.[27] In 2016, Hyodo et al.[18] found a significant correlation between femoral bowing and middle location of AFF. The authors suggested the compressive force on the medial cortex and traction force on the lateral cortex could lead to incomplete lateral fracture at the apex of the femoral bowing.[18] Most of the clinical studies involving femoral bowing in the occurrence of AFF suggested that anterolateral femoral bowing is related to diaphyseal location of AFF rather than subtrochanteric location (Table 2). The mechanical stress on the lateral cortex caused by excessive bowing directly increases susceptibility of fracture on the diaphysis.[20,21] However, no previous studies have taken the duration of bisphosphonate into consideration according to the presence of femoral bowing. Only 1 study compared the location of AFF between a femoral bowing group and a non-bowing group, and provided the previous bisphosphonate use in 2 groups.[28] However, the number of AFFs were too small, and although the authors provided the previous duration of bisphosphonate use in all 13 patients, they did not analyze the difference of bisphosphonate duration that led to AFF in 2 groups.[28] In the current study, a total of 186 AFFs were presented with 84.6% diaphyseal location of AFF in the severe bowing group, and 46.2% in the minimal to moderate group, which is a consistent finding with previous studies.[12,17-26]

In our study, the severe bowing group demonstrated a lower BMI compared to the mild or moderate bowing group, which appears contrary to previous studies indicating higher BMI as a risk factor for AFFs.[10-12] This finding suggests that while higher BMI may contribute to mechanical stress on the femur in cases with minimal to moderate bowing, it may not be a necessary factor for the occurrence of AFF in patients with severe bowing. Severe anterolateral bowing could independently create enough mechanical stress on the lateral cortex to predispose the femur to fracture, even in individuals with lower BMI. Thus, our findings emphasize the importance of evaluating femoral bowing as a critical factor, particularly in patients with lower BMI, who may still be at substantial risk for AFFs despite lacking the traditional risk factor of higher body mass. Further research is required to explore the interplay between BMI and femoral bowing in the pathogenesis of AFFs, but our results highlight the need to consider multiple risk factors concurrently when assessing fracture risk.

In this study, we focused on the role of bisphosphonate duration as well as femoral bowing as in clinical setting, where both femoral bowing and bisphosphonate

Table 2. Studies on the Relationship between Femoral Bowing and Atypical Femoral Fracture

Study	AFF (n)	Definition of bowing	Previous BP use	Previous BP duration	AFF location	Consideration of BP duration
Chen et al. (2014)[28]	17	Degree (lateral bowing angle 7° as cutoff value)	Bowing group, 60%; non-bowing group, 87.5%	Bowing group, 4.5 yr; non-bowing group, 5.7 yr	100% Diaphyseal in severe bowing group	NA
Soh et al. (2015)[12]	21	Degree	100%	NA	Diaphyseal fractures occurred with more severe anterolateral femoral bowing	NA
Hyodo et al. (2017)[18]	38	Grade	Proximal location group, 100%; middle location group, 16%	NA	Significant relationship between bowing and middle fracture location ($p < 0.001$)	NA
Kim et al. (2017)[19]	147	Degree	Diaphyseal group, 77%; subtrochanteric group, 73%	Diaphyseal group, 54.7 ± 45.4 mo; subtrochanteric group, 50.1 ± 45.1 mo	Diaphyseal AFF → more severe bowing (lateral: 7.8° ± 4.8° vs. 1.6° ± 1.8°; anterior: 8.2° ± 2.9° vs. 11.1° ± 4.5°)	NA
Shin et al. (2017)[24]	49	Anterior (°), lateral (mm)	NA	NA	Femoral bowing: AFF group > intertrochanteric fracture group (7.88° ± 5.4°, 909.7 ± 351.7 mm vs. 4.6° ± 3.8°, 1,050.1 ± 2 71.9 mm; $p < 0.001$, $p = 0.008$)	NA
Oh et al. (2017)[20]	22	Anterior (mm), lateral (°)	Mid-shaft group, 50%; subtrochanteric group, 70%	Diaphyseal group, 4.25 yr; subtrochanteric group, 6.78 yr	Mid-shaft AFF → more severe bowing (6.0° ± 2.4°, 664.6 ± 115.1 mm vs. 0.5° ± 1.5°, 845.5 ± 108.1 mm)	NA
Yoo et al. (2017)[26]	56	Degree	Diaphyseal group, 67%; subtrochanteric group, 60%	Diaphyseal group, 53.60 ± 53.20 mo; subtrochanteric group, 56.33 ± 44.14 mo	Greater femoral bowing in diaphyseal group (10.10° ± 3.79° vs. 3.33° ± 2.45°)	NA
Cho et al. (2018)[17]	51	Degree	Diaphyseal group, 94.3%; subtrochanteric group, 93.7%	Diaphyseal group, 93.4 mo; subtrochanteric group, 98.2 mo	FNSBA was greater in subtrochanteric group: 113.9° ± 6.8° vs. 128.5° ± 3.8°	NA
Park et al. (2019)[22]	43	Grade	Straight group, 91.1%; bowing group, 90.7%	Straight group, 7.9 yr; bowing group, 8.2 yr	Bowing group → diaphysis (100%)	NA
Oh et al. (2020)[21]	37	Anterior (mm), lateral (°)	Mid-shaft group, 61%; subtrochanteric group, 84.2%	Long-term user (over 3 yr): mid-shaft group, 50%; subtrochanteric group, 73.7%	Mid-shaft AFF → more severe bowing (683.8 ± 93.1 mm vs. 954.7 ± 195.3 mm, 6.0° ± 2.5° vs. 0.4° ± 1.1°)	NA
Takakubo et al. (2021)[25]	98	Degree	Diaphyseal group, 74%; subtrochanteric group, 86%	Long-term user (over 3 yr): diaphyseal group, 27%; subtrochanteric group, 56%	Lateral bowing angle was larger in diaphyseal group (1.7° vs. 11.8°)	NA
This study	186	Grade	Severe bowing group, 63%; minimal to moderate bowing group, 82%	Severe bowing group, 3.3 ± 3.8 yr; minimal to moderate bowing group, 5.0 ± 4.0 yr	Severe bowing group, 85% diaphyseal; minimal to moderate group, 46% diaphyseal	Severe bowing was related to shorter duration of BP use of developing AFF.

AFF: atypical femoral fracture, BP: bisphosphonate, NA: not available, FNSBA: femoral neck shaft bowing angle.

use are commonly and concurrently encountered. The interplay between mechanical factors (severe femoral bowing), pharmacological factors (bisphosphonate use), and patient characteristics (lower BMI) highlights the need for a comprehensive risk assessment approach. Severe femoral bowing exacerbates the risk of AFFs, even with shorter bisphosphonate exposure, suggesting an additive effect of these risk factors. Clinicians should adopt a holistic management strategy that considers all potential risk factors to prevent AFFs and other complications.

Our further exploratory analysis showed a trend towards a dose-dependent relationship between the severity of femoral bowing and the duration of bisphosphonate use, although this did not reach statistical significance. The post-hoc analysis confirmed that there were no significant differences in bisphosphonate treatment duration between any specific bowing groups. These findings suggest that while there may be a potential influence of femoral bowing severity on bisphosphonate treatment duration, further research with larger sample sizes is needed to confirm this relationship.

Our study has some limitations. First, even though we conducted a multicenter study, the number of AFF with severe femoral bowing (26 femurs) was small, and we could not perform a multivariable analysis with confounders such as completeness of fracture. In fact, the ideal study design would be investigating the proportion of AFF in population with and without severe bowing. However, this would require very large dataset with radiographic data to diagnose AFF and measure and categorize the femoral bowing. Considering AFF is a rare condition and the prevalence of severe femoral bowing is quite low, the design of the current study was not ideal but the number of our subjects was enough to analyze an effect of severity of femoral bowing on AFF. Second, it was conducted in East Asian AFF patients and there might be an ethnic difference in the femoral bowing or lower limb alignment,[29] which might have affected the occurrence of AFF. Third, we could not evaluate the effect of type (oral vs. intravenous) or potency of bisphosphonate because the sample size was too small to analyze. Fourth, the asymptomatic patients with incomplete AFF were not identified. Despite these limitations, our study conceptualized the severity of femoral bowing in the development of AFFs.

At the time of AFF diagnosed, the duration of bisphosphonate was shorter, BMI was lower, and diaphyseal location was more common in the severe bowing group. Our study highlights the need to re-evaluate the initiation of drug holiday as well as optimal duration and dose of bisphosphonate therapy, especially in osteoporosis patients with severe femoral bowing. In these patients, shortening the duration of bisphosphonate use needs to be considered.

CONFLICT OF INTEREST

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

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