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Original Article

Is It Possible to Increase the Clinical Effectiveness of the Fracture Risk Assessment Tool in Osteopenia Patients by Taking Into Account Bone Mineral Density Values?

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Abstract

The study aimed to investigate the effectiveness of the clinical use of the Fracture Risk Assessment Tool (FRAX®) developed by the World Health Organization identifying patients at risk of osteoporotic fracture and to evaluate changes in osteoporotic fracture risk prediction according to bone mineral density (BMD) values. We identified the occurrence of osteoporotic fracture among patients whose BMD was measured in our hospital between April 2003 and March 2013. We then analyzed FRAX® scores obtained with or without BMD on the day before the occurrence of an osteoporotic fracture in actual osteoporotic fracture patients. According to the National Osteoporosis Foundation high-risk criteria, we identified the percentage of high-risk patients before the actual fracture. Among 445 osteoporotic fracture patients, when FRAX®–BMD was used, 281 patients (63%) were identified as high-risk before an actual osteoporotic fracture, and when FRAX® without BMD was used, 258 patients (58%) were identified ($p = 0.115$). In the 84 osteopenia patients, 39 patients (46.4%) were identified as high-risk when FRAX® without BMD was used, and 19 patients (22.6%) were identified when FRAX®–BMD was used ($p = 0.001$). The use of BMD in FRAX® does not seem to increase the clinical effectiveness of predicting osteoporotic fracture in osteopenia patients.

Key Words: Bone mineral density; FRAX®; osteopenia; osteoporotic fracture.

Introduction

As the elderly population has increased worldwide, the number of patients with osteoporotic fractures has also increased, and the impact on healthcare costs has become a serious social and economic burden. In Korea, the proportion of the population over 65 yr old is expected to reach 14.3% in 2018 and 20.8% in 2026, beginning an era of the super-aged society *(1)*. Osteoporotic fracture often causes complications, which affect the patient, the patient's family, and even the entire society because of the disability of the patients. Therefore, it is important to prevent osteoporotic fractures by identifying and treating at-risk patients. Although bone mineral density (BMD) is an important risk factor in osteoporotic fracture, recent studies have reported that alone it has limited predictive value *(2,3)*.

Recently, the World Health Organization (WHO) developed the Fracture Risk Assessment Tool (FRAX®) that calculates the 10-yr risk of major osteoporotic fracture and hip fracture given an individual patient's clinical risk factors; the model provides a different fracture risk assessment depending on the country and has been recommended as a reference point in treatment guidelines. The 2008 osteoporosis treatment guidelines of the National Osteoporosis Foundation (NOF) state that patients are candidates for osteoporosis treatment if they had an existing femoral or spine fracture, a *T*-score below –2.5, or a *T*-score between –1.0 and –2.5 and a FRAX® score of 20% or higher for major osteoporotic fracture or 3% or higher for hip fracture *(4)*. In June 2010, the Korean FRAX® model was developed, and therefore more accurate fracture risk assessments can be expected in this country. However,

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research on the effectiveness of the clinical application of the Korean FRAX® model is limited.

The present study was conducted to calculate FRAX® score in actual osteoporotic patients the day before the occurrence of an osteoporotic fracture. According to the NOF high-risk criteria, we identified the percentage of patients classified as high-risk before the actual fracture. The purpose of our study was to determine the clinical effectiveness of the Korean FRAX® model by evaluating the percentage of patients classified as high-risk. In addition, we evaluated the difference in FRAX® scores according to application of the BMD value.

Materials and Methods

To define a population at high risk of osteoporotic fracture, we selected subjects among the database of patients whose BMD was measured in our hospital from April 2003 to March 2013. And we determined patients who have been hospitalized for suspected osteoporotic fracture. All patients included in the present study had a diagnosis of osteoporotic fracture by expert clinicians in osteoporosis management. A fracture was defined as osteoporotic based on its location and characteristics. Fractures of the proximal femur, spine, proximal humerus, distal radius, and pelvis that occurred without strong external force were considered osteoporotic fractures. Five hundred thirty-one patients had osteoporotic fracture and aged 50–89, while 67 were not diagnosed to have typical osteoporotic fracture.

To calculate the FRAX® the day before the actual fracture, we did not consider the actual fracture as a previous fracture. And 12 patients were excluded based on the lack of BMD measurements within 2 wk after the occurrence of the fracture (under the assumption that there is no difference in the BMD scores within 2 wk of the fracture). Forty-six patients were excluded because of the lack of risk factor information needed to calculate the FRAX® score and 28 patients were excluded because they had been treated for osteoporosis previously. The FRAX® scores of the 445 patients who met the inclusion/exclusion criteria were calculated.

The South Korea-specific FRAX® scores were calculated using the WHO FRAX® website, version 3.8, available at http://shef.ac.uk/FRAX/. When determining the FRAX® scores on the day before the actual fracture, the osteoporotic fracture itself was not included as a risk factor. To calculate FRAX® scores, we reviewed medical records such as age, sex, body mass index, daily intake of 3 or more units of alcohol, smoking, hip fracture history of the patients' parents, osteoporotic fracture history during adulthood, intake of more than 5 mg of oral glucocorticoids for the last 3 mo, secondary osteoporosis, and presence of rheumatoid arthritis. Any information missing from the medical records, such as the hip fracture history of the patients' parents, was confirmed via telephone interviews in the form of a questionnaire.

The BMD of the hip and lumbar spine was measured with dual-energy X-ray absorptiometry (Hologic Discovery QDR® series; Hologic Inc., Bedford, MA) and values obtained within 2 wk of the fracture were incorporated in the model. For FRAX®–BMD, the BMD value (gram per square centimeter) of the femoral neck was used to obtain the FRAX® score. Moreover, because inclusion of BMD in the FRAX® model is optional, an additional FRAX® score was obtained without BMD (FRAX® without BMD). Patients were assigned to the osteoporosis group when their BMD, determined as the average of BMD values of 2 areas of lumbar segment L1–L4 or the lowest of the hip measurements excluding the area around the Ward's triangle, was lower than the *T*-score of −2.5. Patients were included in the osteopenia group when the *T*-score was between −1.0 and −2.5.

We evaluated the effectiveness of osteoporotic fracture prediction by determining how many of osteoporotic facture patients categorized as high-risk based on the NOF criteria were identified as such using FRAX® scores obtained on the day before the actual fracture. We also conducted a comparative analysis of predicted rates of osteoporotic fracture according to BMD values in 3 patient groups (normal group, osteopenia group, and osteoporosis group). Based on the NOF criteria, a patient was identified as high-risk if the FRAX® score was higher: ≥20% for major osteoporotic fracture or ≥3% for hip fracture.

All results are expressed as mean ± standard deviation (SD) or number (percent). Paired *t*-tests were used to determine differences in FRAX® scores according to BMD values. A chi-square test was used to compare the percentage of high-risk patients in FRAX® without BMD and in FRAX®–BMD. Statistical significance was defined as $p < 0.05$, and SPSS version 18.0 (IBM Corporation, Somers, NY) was used for all analyses.

Results

Among the 445 osteoporotic fracture patients who met the criteria of the study, 54 were men and 391 were women. The average age was 72.45 ± 6.96 (range, 50–89) yr, and the average body mass index was 23.14 ± 3.09 (Table 1). Osteoporotic fracture occurred in the proximal femur in 162 patients, in the spine in 138 patients, in the proximal humerus in 68 patients, in the distal radius in 68 patients, and in the pelvis in 9 patients. BMD measurements identified 10 patients (2.2%) with normal BMD, 84 patients (18.9%) with osteopenia, and 351 patients (78.9%) with osteoporosis (Table 1).

When BMD was used in the FRAX® model (FRAX®–BMD), 281 patients (63%) were identified as high-risk (10-yr major osteoporotic fracture probability ≥ 20% or 10-yr hip fracture probability ≥ 3%) on the day before an actual osteoporotic fracture, and when BMD was not used in the FRAX® model (FRAX® without BMD), 258 patients (58%) were identified as high-risk (Fig. 1). But the numbers of high-risk patients between FRAX®–BMD and FRAX® without BMD were not significantly different ($p = 0.115$).