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Validation of FRAX without BMD: An age-related analysis of the Fifth Korean National Health and Nutrition Examination Survey (KNHANES V-1, 2010)

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ABSTRACT

Although the Fracture Risk Assessment Tool (FRAX) is widely used to evaluate probabilities of fractures, there is no consensus regarding whether it is accurate when bone mineral density (BMD) is not included. This cross-sectional study aimed to compare the 10-year predicted fracture probabilities calculated using FRAX with and without BMD. Data were collected from the 2010 Fifth Korean National Health and Nutrition Examination Survey, and 2706 participants (1260 men and 1446 women) aged 50–90 years were analyzed. Ten-year predicted probabilities for major osteoporotic and hip fractures were calculated using the FRAX model. In men, the 10-year probabilities without BMD were 3.9 ± 1.8% and 1.3 ± 1.4% for major osteoporotic and hip fractures, respectively. In women, the 10-year probabilities without BMD were 7.7 ± 4.4% and 2.6 ± 2.9% for major osteoporotic and hip fractures, respectively. These probabilities were significantly correlated with the probabilities calculated using FRAX with BMD (all, $p < 0.001$). When participants were divided into 10-year age groups and compared with the 10-year predicted fracture probability with BMD, the 10-year predicted fracture probability without BMD was lower in men 50–59 years old, similar to men 60–69 years old, and higher in men ≥70 years old. The FRAX scores without BMD were generally lower for all women. The FRAX model without BMD appears to be a slightly lower fracture probability compared to that calculated with BMD, especially in younger participants. Although these results have important clinical implications for areas with limited ability to evaluate BMD, they must be confirmed by a large prospective study.

Introduction

The prevalence of osteoporosis and osteoporotic fractures has considerably increased due to the rapidly aging population in most developing and developed countries [1,2]. These conditions have become an important health care issue, as osteoporotic fractures reduce patient's quality of life and increase medical and health care costs [2,3]. To prevent osteoporotic fractures in a cost-effective manner, patients at high risk of osteoporotic fracture must be detected and proactively treated [4].

The FRAX model is an internet-based fracture risk calculator that is used worldwide as a tool to assess risk of fracture [5], and has also been used to identify individuals suitable for pharmacological intervention [6]. The FRAX probability of fracture is based on the assessment of readily accessible data regarding 10 clinical risk factors for fracture: age, individual and family history of fracture, tobacco use, excessive alcohol consumption, glucocorticoid use, low bone mineral density (BMD), body weight, secondary osteoporosis, and rheumatoid arthritis [7]. Although low BMD is a strong predictor of osteoporotic fracture, BMD data can be omitted from the FRAX model in areas with limited access to BMD data [5]. However, there is no consensus regarding whether FRAX is accurate with or without femoral neck BMD, and the use of FRAX without BMD must be validated by additional research. We conducted this study to test the hypothesis that 10-year predicted fracture probabilities calculated by FRAX with and without BMD are different, using a large national database and subanalysis by age and sex. The aim of this study was to compare the 10-year-fracture probabilities calculated by FRAX with and without BMD data using a Korean national database, with additional subanalyses according to sex and age distribution.

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Material and methods

Study population

The Korean National Health and Nutrition Examination Survey (KNHANES) Osteoporosis Survey was a large-scale component of the 2010 KNHANES V-1. KNHANES V-1 was a nationally funded, cross-sectional, nationwide survey that used a multistage sampling design to collect data regarding the health status, health behaviors, nutrition, and socio-demographics of the general Korean population. As the data collection was performed by highly skilled surveyors and controlled for quality, the data are considered highly accurate and reliable [8].

Between January 2010 and December 2010, trained KNHANES V-1 interviewers conducted face-to-face interviews with 8958 individuals in their homes. Among these individuals, 3054 individuals were identified as men or women aged ≥50 years. Exclusion criteria for our analysis were as follows: 1) >90 years old (small sample size); 2) lack of health interview survey; 3) refusal or inability to undergo dual-energy X-ray absorptiometry (DXA) due to femur surgery, fracture, or deformity; 4) inability to assume the supine position for examination (e.g., due to restricted mobility); 5) radiologic testing with a contrast agent within the past week or nuclear medicine scanning within the past 3 days; or 6) participants who received osteoporosis interventions. Based on these criteria, 223 individuals were excluded, yielding a final sample of 2706 study participants (Fig. 1).

Each participant provided informed consent prior to inclusion in the study. KNHANES V-1 was performed by the Korea Centers for Disease Control and Prevention (KCDC), and was approved by the institutional review board of the KCDC (2010-02CON-21-C).

Measurement of bone mineral density and fracture probability calculation

When conducting the survey, we based on the measurement and interpretation of BMD with the 2007 International Society for Clinical Densitometry (ISCD) official positions and guidelines for BMD testing with quality control [14]. BMD of the lumbar spine, femur neck, and total femur was measured in g/cm^2 using DXA scanning (DISCOVERY-W fan-beam densitometer, Hologic Inc., USA). Coefficients of variation (CVs) were used for precise assessment of BMD; these were 1.9% for the lumbar spine, 2.5% for the femur neck, and 1.8% for the total femur. Although all 3 measurements were used for the diagnosis of osteoporosis and osteopenia, only the femur neck BMD was used to calculate the FRAX value and investigate the percentage of the population at high risk of fracture.

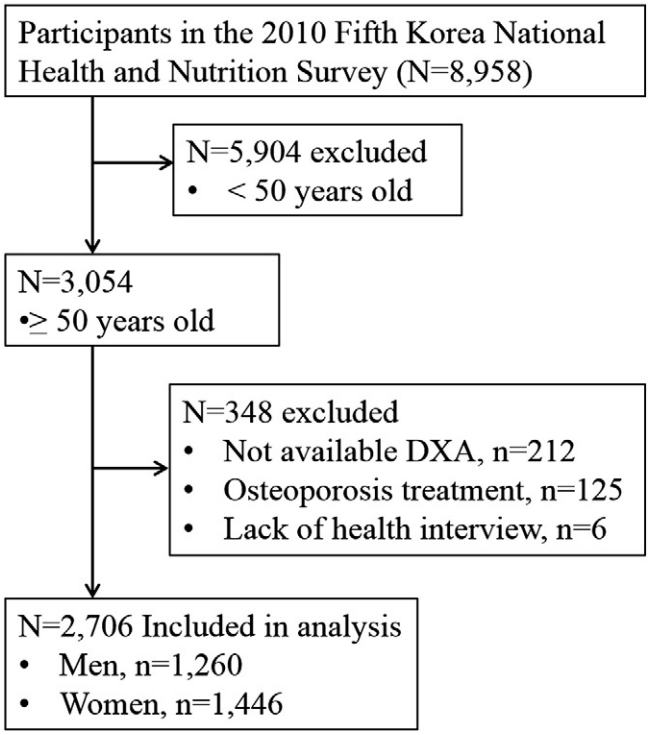

Fig. 1. Flowchart of participant inclusion and exclusion.

The 10-year probability of osteoporotic fracture was calculated using the FRAX tool (web version 3.7, South Korean model), which estimates the probability based on age, sex, femur neck BMD, and clinical risk factors including individual and parental history of fracture, current tobacco use, rheumatoid arthritis, alcohol consumption (≥3 units/day), secondary osteoporosis, and long-term use of glucocorticoids. Data regarding individual history of fracture, current tobacco and alcohol use, rheumatoid arthritis, and secondary osteoporosis were collected from the health interview surveys of KNHANES V-1. As KHANES V-1 did not collect data regarding the long-term use of glucocorticoids or parental history of hip fracture, a negative answer ("no") was entered into the FRAX tool for both factors. Major osteoporotic fracture probabilities and hip fracture probabilities were calculated with and without the femoral neck BMD data.

Statistical analysis

Statistical analysis was performed using Predictive Analytics Software version 18.0 (SPSS Inc., Chicago, IL, USA). All results were reported as mean ± standard deviation (SD) unless otherwise stated, and a p-value <0.05 was considered statistically significant. To analyze the correlation between the fracture probabilities calculated with and without BMD, intraclass correlation coefficients (ICCs) for average measure was used. ICCs were analyzed using the Cochran test, which assesses for the presence of a linear correlation between probabilities with and without BMD. An ICC <0.4 indicates poor agreement, 0.4–0.75 indicates fair agreement, 0.75–0.9 indicates good agreement, and >0.9 indicates excellent agreement [9]. The paired *t*-test was used to analyze whether significant differences could be detected in the average fracture probabilities calculated with and without BMD. The participants were divided into 10-year age groups, and the ICC and paired *t*-test were also used for subanalyses by age and sex. We evaluate statistical power to compare the average between two results in each group. Based on a power of 95%, significant level of 5%, and Cohen's d = 0.5, the inclusion of 54 patients is estimated as an effective sample size. The number of participants of each age group satisfied the criteria.

Results

In male participants, the FRAX model without BMD produced 10-year predicted fracture probabilities of 3.8 ± 1.5% and 1.3 ± 1.2% for major osteoporotic and hip fractures, respectively (Table 1). The addition of BMD data into the model produced 10-year probabilities of 3.9 ± 1.8% and 1.3 ± 1.4%, respectively. These probabilities were comparable between two groups (p = 0.702 and p = 0.559, respectively), and the results from the two models were significantly correlated (all, p < 0.001). The ICC was 0.732 for major osteoporotic fractures and 0.640 for hip fractures (Table 2).

In female participants, the FRAX model without BMD produced 10-year predicted fracture probabilities of 7.3 ± 4.0% and 2.4 ± 2.5% for major osteoporotic and hip fractures, respectively (Table 1). The model with BMD data produced 10-year probabilities of 7.7 ± 4.4% and 2.6 ± 2.9%, respectively. Although the two results were significantly correlated (all, p < 0.001; ICC = 0.834 and 0.792, respectively) (Table 2), the probabilities of major osteoporotic and hip fractures in the model with BMD data were significantly higher than those in the model without BMD data (p < 0.001 and p = 0.001, respectively).

The percentage of population who need osteoporotic medications by definition of more than 20% probability of major osteoporotic fractures