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Improving Rural Bone Health and Minimizing Fracture Risk in West Virginia: Validation of the World Health Organization FRAX® Assessment Tool as a Phone Survey for Osteoporosis Detection

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Abstract

West Virginia ranks second nationally in population ≥ 65 years old placing our state at greater risk for osteoporosis and fracture. The gold standard for detecting osteoporosis is dual X-ray absorptiometry (DXA), yet over half of West Virginia's counties do not have this machine. Due to access barriers, a validated phone-administered fracture prediction tool would be beneficial for osteoporosis screening.

The World Health Organization's FRAX® fracture prediction tool was administered as a phone survey to 45 patients; these results were compared to DXA bone mineral density determination.

Results confirmed that the FRAX® phone survey is as reliable as DXA in detecting osteoporosis or clinically significant osteopenia: 92% positive predictive value, 100% negative predictive value, 100% sensitivity and 91% specificity when compared to the gold standard. These promising results allow for the development of telephone-based protocols to improve osteoporosis detection, referral and treatment especially in areas with health care access barriers.

Introduction

Osteoporosis detection in West Virginia is limited by resources and our rural population. West Virginia is the second most rural state in the nation with over 67% of our population living in towns of less than 2500 people and 50 of our 55 counties federally designated, either in part or full, as Health Professional Shortage Areas or Medically Underserved areas.[1-3] Additionally, 16.5% of our population is 65 years of age or older (second in the nation).[4,5] This large cohort means that the risk of osteoporosis and osteoporosis-related fracture, two age-related conditions, is increased for West Virginia.[6] It is surprising to note that over a quarter of a million (77%) of West Virginia's female residents over 50 years of age have osteoporosis or diminished bone mass.[7] Nationally, osteoporosis remains a public health threat to almost 55% of the people aged 50 years and older.[8] The National Osteoporosis Foundation (NOF) estimates that in the United States, 10 million people already have the disease, while 34 million more are estimated to have low bone mass, increasing their risk of fracture.[8] In addition to the personal and local burden of osteoporosis, there is also a national burden in terms of healthcare dollars. Currently, total costs in the United States are more than $19 billion dollars and this number is expected to rise by almost 50% by 2025. These frightening statistics argue for a low cost, widely applicable method of screening large populations in rural areas where the availability of sophisticated diagnostic tools such as the dual-energy x-ray absorptiometry (DXA) scanner is limited.

A DXA scan is considered the gold standard to assess bone mineral density (BMD) and detect osteoporosis.[9] By calculating BMD, physicians are able to evaluate for osteoporosis, to assess for risk of fracture, and to monitor response to treatment. However, in West Virginia,

Objectives

1. *To raise awareness about the burden of osteoporosis among elder West Virginians.*
2. *To examine the validation of the phone based administration of FRAX as an effective, alternative tool for osteoporosis screening.*
3. *To consider incorporation of FRAX as an alternative to formal DXA bone mineral density determination to predict those at greatest risk for fracture facilitating appropriate osteoporosis detection and management in rural populations.*

Figure 1: ***Map of West Virginia's 55 counties with highlighted counties indicating the presence of a free standing DXA unit. 7***

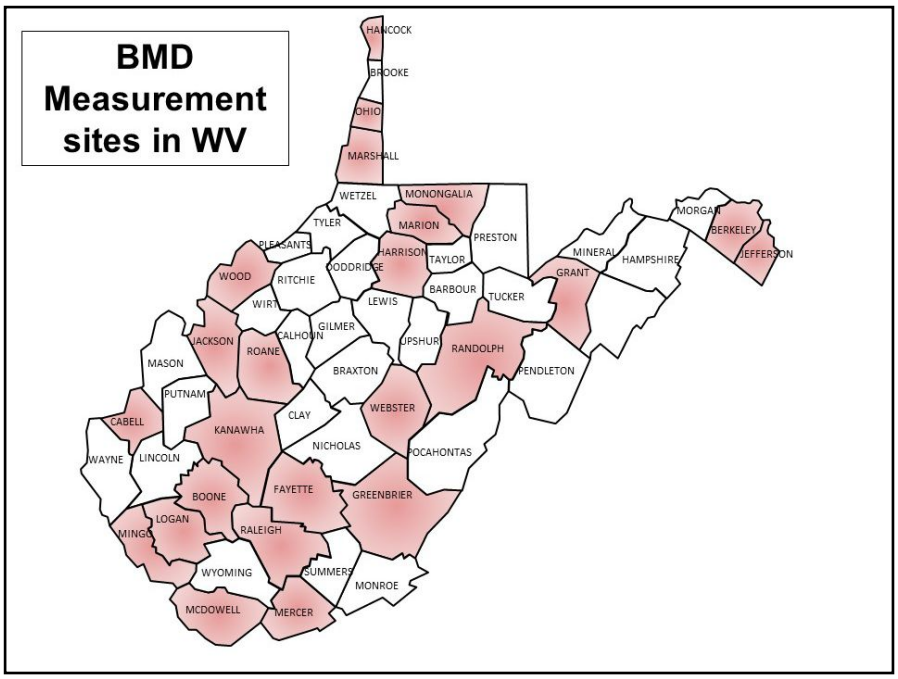
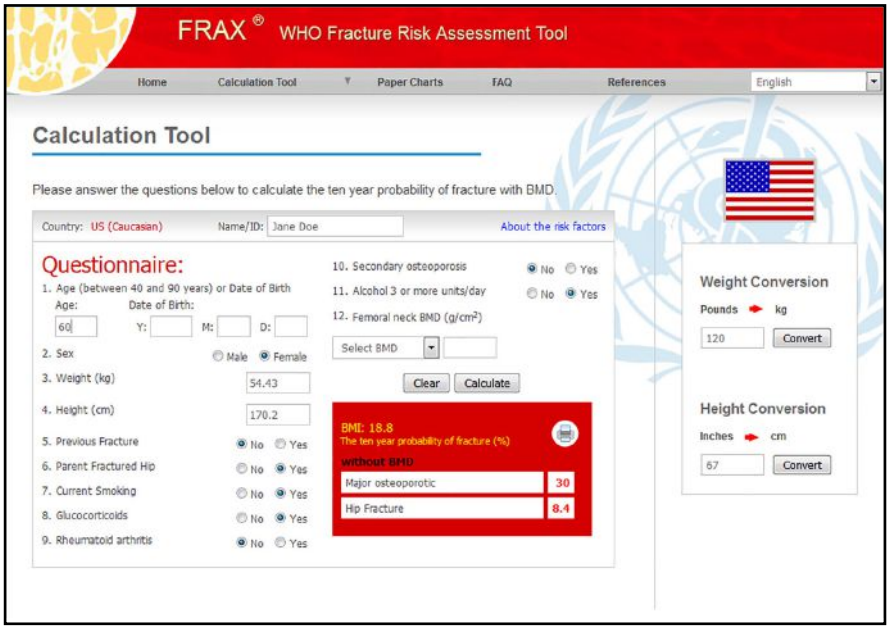


Figure 2: ***The World Health Organization (WHO) fracture prediction tool (FRAX®).[13] Adapted with permission from International Osteoporosis Foundation, Fracture Risk Assessment Tool Educational Slide-kit. Available at http://www.iofbonehealth.org/health-professionals/frax.html.***



access to DXA scanners is limited, with the most recent data suggesting only 24 of 55 counties having a free standing DXA unit (Figure 1).[10] In addition to limited access, distance is a factor that negatively impacts the delivery of rural healthcare.[11] A 20% drop in osteoporosis screening rates occurs when a DXA is located over 5 miles from a patient.[12] This combination of a rural and aging population places West Virginia at the forefront of an "osteoporosis epidemic" and effective strategies need to be developed to better serve the needs of this population. This is where FRAX could play a role in improving access and detection of osteoporosis.

The World Health Organization (WHO) has a validated, internationally accepted fracture prediction tool -- FRAX®-- which is used to detect individuals at risk for fracture. Independent risk factors of the patient are incorporated into the FRAX® algorithm and consist of: country of origin, age, gender, weight, height, previous fracture, parental history of hip fracture, current smoking, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis, alcohol consumption (3 or more units/day) and, when available, BMD at the femoral neck (g/cm2) obtained by DXA (Figure 2).[13] The algorithm corrects for the different contributions of each independent risk factor to yield the ten year probability of sustaining either a hip fracture or other major osteoporotic fracture.[13] When the absolute risk of sustaining a hip fracture within the next ten years is 3% or above, or the risk of major orthopaedic fracture is 20% or above, treatment is considered cost effective and has been shown to decrease the rate of subsequent fractures.[14-21] Because this tool can be used without BMD data, we hypothesized that FRAX could be used as a phone screening tool and would correlate very well with osteoporosis detection using the gold standard of BMD using DXA.

Methods

This study was IRB approved (#396973) and involved four steps: (1) identification of a pool of rural patients "at risk" for fracture; (2) randomly contacting patients to see if they would like to participate in the research protocol; (3) obtaining FRAX and DXA information for each patient enrolled; and (4) communicating these results to the patient and primary care provider (PCP).

Identification of Patients

We determined the variables used to screen "at risk" populations in Marshall Health's Allscripts EMR by consulting an expert in the field of osteoporosis detection and screening -- Dr. Richard Dell of Kaiser Permanente. Dr. Dell was contacted because he uses an EMR to automatically identify patients for bone health screenings in their 11-hospital system. Patients were screened for inclusion by using the population health management tool within Allscripts. There were 6 inclusion criteria and 1 exclusion criteria. Inclusion criteria included (1) all women 65+ years old; (2) all men 70+ years old; (3) all patients over 50 years of age with a fracture of the proximal humerus, distal radius, hip or vertebral compression fracture; (4) patients on 3+ months of steroids; (5) patients on Lupron; and (6) including only patients that live within rural and urban designations (RUCA's) consistent with rural (requirement of the funding mechanism). Exclusion criteria included patients already completing a DXA scan within the past two years. A total of 572 potential study patients were identified. From this list, we excluded patients not living within a rural RUCA zip code designation.

Contact for Study Participation

From the list of potential study patients living in rural RUCA's, two of the authors (FS, KS) randomly contacted the patient by phone to see if they would like to participate in the research protocol. A standardized phone discussion was generated indicating that we were contacting the patient from the Department of Orthopaedic Surgery at Marshall University and conducting a research study on weak bones (osteoporosis) and this study would include a brief 2-3 minute phone conversation and by participation a free DXA scan would be arranged at our testing facility. Response was impressive with the first 57 phone calls producing 55 people willing to participate. Consultation with a statistician was completed as part of the granting mechanism and sample size needed was determined to be n=45.

FRAX and DXA Completion

Fifty-five study patients completed FRAX with the phone survey taking an average of two minutes. The 10-year absolute risk of fracture for the patient was then generated and recorded and the patient was immediately notified of their fracture risk. This information was printed and mailed to the patient along with a voucher for a free DXA scan at the Erma Byrd Clinical Center on a set date in June or August 2013. The free voucher was developed in conjunction with the Senior Services Division and Cabell Huntington Hospital Radiology with the study protocol paying for the DXA scans with no charges to the study patients. A total of 45 patients were able to complete the DXA scans. Those unable to complete the scans on the study dates were contacted by the research team nurse (LM) and alternative arrangements were made including a letter sent to their PCP containing their FRAX data.

Communication of Results

All patients received their FRAX test results including a professional interpretation of the DXA scan (n=45) by an International Society for Clinical Densitometry (ISCD) certified endocrinologist (OO). These results were sent by mail to the patient and also forwarded to the participant's PCP. The research study nurse's (LM) phone number was provided to the study participants and she assisted with any questions or interpretations of the results including coordination of follow up if needed. A three month follow up phone call was completed on all patients (LM).

Results

The total number of patients completing the study protocol was 45 (June 19, 2013- August 27, 2013). There were 6 males and 39 females. The age range was 52-81 years of age with a mean age of 65.8 years. Results of the FRAX phone-screening tool and DXA scan were analyzed by two authors (TWB, FS). When the absolute risk of sustaining a hip fracture in a study participant within the next ten years was 3% or above, or the risk of major osteoporosis fracture was 20% or above, the FRAX screening was considered positive for osteoporosis/clinically significant osteopenia and treatment was recommended.[14-21] FRAX results demonstrated 25 patients requiring pharmacological management (presence of osteoporosis/ clinically significant osteopenia). Of note, the FRAX scores were re-calculated for all participants using the empirically determined height and weight data obtained during DXA scanning. These "corrected" scores were used in the final data analysis. For the DXA results, 23 patients were recommended to receive pharmacological management (Table 1).

Forty-three of 45 patients had the CORRECT diagnosis of either presence or absence of fracture risk threshold requiring treatment with **100% sensitivity, 91% specificity; 92% positive predictive value**

Table 1: Results of DXA Scan versus FRAX Predicted Risk of Fracture

		DXA Scan Results	
		Positive	Negative
FRAX Predicted Risk of Fracture	Positive	23	2
	Negative	0	20

and 100% negative predictive value (Table 1). In two patients FRAX over-predicted the need for pharmacological management. In both patients the recommendation for pharmacological management was reversed if FRAX was recalculated using the BMD of the femoral neck empirically determined with DXA. For these two patients additional information is presented.

The first patient was a 77-year-old female with only one FRAX parameter above threshold -- 3.6% risk for femoral neck fracture (above the treatment threshold of 3%). Using the BMD data this risk was reduced to 2.1% and was consistent with the formal DXA reading of no recommendation for pharmacological management. The second patient was a 64-year-old female with two FRAX parameters above threshold – 4% risk for femoral neck fracture and 21% risk of major osteoporotic fracture (above the treatment threshold of 20%). Using the BMD data these risks were reduced to 2.3% and 16%, both below thresholds for pharmacological management and consistent with the formal DXA reading.

Previously, treatment decisions for osteoporosis management were based solely on BMD testing and T-score generation with previous publications highlighting that identical T-scores can produce vastly different fracture risks.[22-24] In this study cohort, only 10 patients had a T-score of -2.5 or lower. In the 23 patients with final recommendation for pharmacological management for osteoporosis/clinically significant osteopenia, only 39% (9/23) had a T-score of -2.5 or lower.

It is worth noting that the three-month follow-up on all patients resulted in 100% returning for further osteoporosis evaluation and management with their PCP (n=45).

Discussion

In this study, FRAX has been used and validated as an effective phone-screening tool to determine "at risk" populations for osteoporosis/clinically significant osteopenia. There was a 4.4% risk (2/45) of over-prediction of fracture risk above pharmacological treatment thresholds using FRAX algorithms calculated without BMD data. This risk was reduced to 0% when FRAX was recalculated using BMD data obtained from DXA. It is clear from a recent review that FRAX is useful for prediction of pharmacological interventions where facilities for BMD determination are sparse like in West Virginia; but BMD should be used in calculations on "those close to a probability-based intervention threshold".[25] In the two patients where FRAX over-prediction occurred, both were within 1% of the threshold value for treatment and in each, DXA was performed, which changed the recommendations for pharmacological management. It is worth noting that osteoporosis is a skeletal disorder characterized by low bone strength and increased risk of fracture; therefore, treatment decisions should not be based on T-score alone. [22] In this study cohort, the majority (61%) of the study patients receiving a recommendation for pharmacological management

for osteoporosis/clinically significant osteopenia actually had T-scores above -2.5 (14/23).

In summary, detection of patients at greatest risk for fracture is facilitated by the FRAX tool and can be easily accomplished by a phone call with nearly equivalent results to that of the gold standard DXA scan. In a state with limited resources and multiple barriers to health care access, incorporation of a simple phone screening tool will help to improve osteoporosis screening, detection and treatment which has been shown to reduce fracture incidence and the fiscal burden associated with fracture care.[14-21,26,27]

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CME Post-Test

21. According to the WV Osteoporosis and Arthritis Program, how many WV counties have DXA scanners?
    a. 55 counties
    b. 40 counties
    c. 24 counties
22. The FRAX fracture prediction tool provides an absolute 10-year risk of hip or major osteoporotic fracture. Can this tool be used without having BMD of the femoral neck?
    a. Yes
    b. No
23. Current recommendation for treatment of osteoporosis and clinically significant osteopenia are based on the risk of fracture. Which strategy below would provide the most utility at determination of those greatest at risk for fracture?
    a. T score alone
    b. Z score alone
    c. Physical examination
    d. FRAX score (>3% for hip frature and >10% risk for major osteoporosis fracture)
    e. FRAX score (>3% for hip fracture and >20% for major osteoporosis fracture)