EVALUATION OF DECISION RULES FOR IDENTIFYING LOW BONE DENSITY IN POSTMENOPAUSAL AFRICAN-AMERICAN WOMEN

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Objective: While African-American women tend to have greater bone mineral density (BMD) than caucasian women, they are still at risk of developing osteoporosis later in life. Clinical decision rules (i.e., algorithms) have been developed to assist clinicians identify women at greatest risk of low BMD. However, such tools have only been validated in caucasian and Asian populations. Accordingly, the objective of this study was to compare the performance of five clinical decision rules in identifying postmenopausal African-American women at greatest risk for low femoral BMD.

Methodology: One hundred-seventy-four (n=174) postmenopausal African-American women completed a valid and reliable oral questionnaire to assess lifestyle characteristics, and completed height and weight measures. BMD at the femoral neck was measured via dual energy x-ray absorptiometry (DXA). We calculated sensitivity, specificity, positive predictive value, and negative predictive value for identifying African-American women with low BMD (T-Score ≤-2.0 SD) using five clinical decision rules: Age, Body Size, No Estrogen (ABONE), Osteoporosis Risk Assessment Instrument (ORAI), Osteoporosis Self-Assessment Tool (OST), Simple Calculated Osteoporosis Risk Estimation (SCORE), and body weight less than 70 kg.

Results: Approximately 30% of African-American women had low BMD, half of whom had osteoporosis (BMD T-Score ≤-2.5 SD). Sensitivity for identifying women with a low BMD (T-Score ≤-2.0 SD) ranged from 65.57–83.61%, while specificity ranged from 53.85–78.85%. Positive predictive values ranged from 80.95–87.91%, while negative predictive values ranged from 48.44–58.33%.

Conclusion: Our data suggest that the clinical decision rules analyzed in this study have some usefulness for identifying postmenopausal African-American women with low BMD. However, there is a need to establish cut-points for these clinical decision rules in a larger, more diverse sample of African-American women. (*J Natl Med Assoc.* 2004;96:290–296.)

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INTRODUCTION

Osteoporosis is a systemic disease in which bone density is reduced, leading to weakness of the skeleton and increased susceptibility to fractures. Osteo-

porosis presents an enormous burden on an increasing elderly population, since fractures are associated with a considerable reduction in quality of life, loss of independence, and substantial costs to the health care system.[1] Current estimated cost of treating osteoporotic fractures ranged from $10- to $18 billion per year in the United States,[1] with total medical costs estimated at $40,000 (2001 dollars) for each hip fracture.[2]

An estimated 10 million Americans suffer from osteoporosis, of which 80% are women.[1] While African-American women tend to have higher bone mineral density (BMD) than caucasian women throughout life, they are still at risk of developing osteoporosis with advanced age.[1,3,4] Data from the third National Health and Nutrition Examination Survey (NHANES III) indicated that 10% of African-American women aged >50 years have osteoporosis.[5] However, African-American women receive BMD screening less frequently[6] and are less likely to receive treatment upon diagnosis of low BMD[6,7] than caucasian women. Moreover, Kotzan et al.[8] using the Georgia Medicaid database, reported that postmenopausal African-American women had a 42% increased risk of death within three years of hip fracture, compared with 13% for postmenopausal caucasian women.

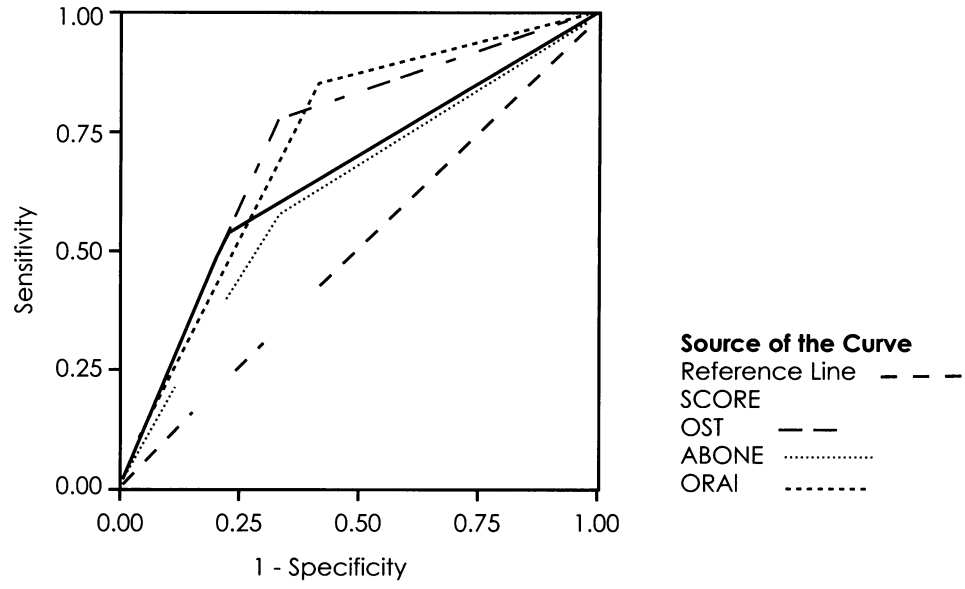
Simple decision rules (i.e., algorithms) have been developed and validated to help identify those with potentially low BMD. However, such tools have previously focused on caucasian[9-14] and Asian[15-17] women and men.[18] Although information from clinical decision rules does not allow direct diagnosis of

Table 1. Selection Criteria from Five Clinical Decision Rules for Bone Mineral Testing Among Postmenopausal Women

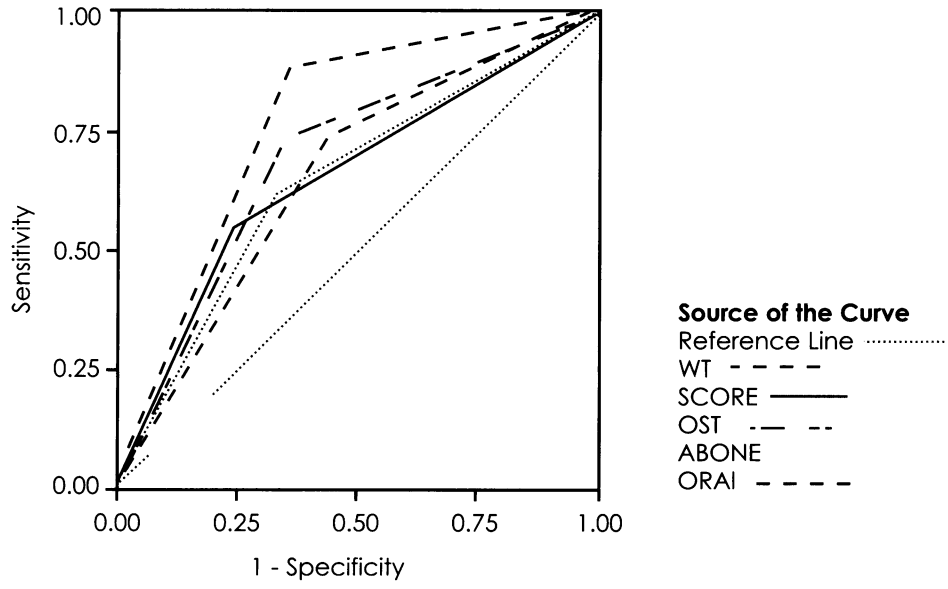
Decision Rule	Scoring System	Selection Cut-Point*
Age, Body Size, No Estrogen[12] (ABONE)	Points are given for: *age:* 1 if >65 years *weight:* 1 if <63.5 kg *estrogen use:* 1 if never used oral contraceptives or estrogen therapy for at least six months	Score ≥2
Osteoporosis Risk Assessment Instrument[14] (ORAI)	Points are given for: *age:* 15 if ≥75 years, 9 if 65–74 years, 5 if 55–64 years *weight:* 9 if <60 kg, 3 if 60.0–69.9 kg *estrogen use:* 2 if currently not taking estrogen	Score ≥9
Osteoporosis Self-Assessment Tool[15] (OST)	0.2* (weight in kg–age in years)	Score <2
Simple Calculated Osteoporosis Risk Estimation[13] (SCORE)	Points are given for: *race:* 5 if not black *rheumatoid arthritis:* 4 if applicable *history of minimal fracture after age 45:* 4 for each fracture of the wrist, rib, or hip (maximum points = 12 points) *age:* Three times first digit of age in years *estrogen*: 1 if never used *weight:* -1 times weight in pounds (lb)/10 and truncated to an integer	Score ≥6
Body Weight[10] (Weight Criterion)		Weight <70 kg

Note: Postmenopausal women with these scores denoted by an asterisk (*) would be recommended for bone mineral density testing. Selection cut points for the ABONE, ORAI, SCORE, and weight criterion were established in caucasian women, while the cut point for the OST was established in Asian women.

Figure 1. Area Under the Receiver Operating Characteristic (AUROC) Curves for Moderate Osteopenia (BMD T -Scores of -2.0 to -2.5 SD) and Osteoporosis (≤-2.5 SD)



AUROC Curves for Moderate Osteopenia (BMD T–Score -2.0 to -2.5 SD)



AUROC Curves for Osteoporosis (BMD T–Score ≤-2.5 SD)

ABONE = age, body size, no estrogen; ORAI = ostcoporosis risk assessment instrument; OST = osteoporosis self-assessment tool; SCORE = simple calculated osteoporosis risk estimation; WT = body weight.

low BMD or osteoporosis, they are evidence-based criteria that can help reduce uncertainty in medical practice by increasing clinicians' diagnostic and prognostic assessments.[19] This study evaluated and compared the performance of five clinical decision rules in identifying postmenopausal African-American women at greatest risk for low femoral BMD. To the best of our knowledge, this is the first study to apply clinical decision rules for BMD assessment in a sample of African-American women.

METHODOLOGY

Study Sample

Subjects for this study were recruited as part of an ongoing osteoporosis study among African-American women in the east Texas region. The original study was cross-sectional in nature with the primary purpose of assessing the extent of low BMD and associated risk factors for osteoporosis in postmenopausal African-American women. The results of the cross-sectional analyses, in addition to a comparison of African-American and caucasian women, have been reported elsewhere.[20-22]

Subjects were recruited primarily from African-American churches throughout east Texas by a well-respected African-American nurse (PhD in nursing) in the local community. All subjects were given $50 cash for their participation and provided transportation to the testing site if desired. The Institutional Review Board at the University of Texas Health Center at Tyler approved the study protocol.

All women were screened by their personal physician to determine eligibility for the study. A radiologist at the testing site provided medical screening to women who did not have a personal physician. Inclusion criteria were: 1) apparently healthy, 2) ≥5 years postmenopause (no menstruation for at least five years), 3) native to the United States, and 4) between the ages of 35 and 80 years. Exclusion criteria consisted of the following: 1) renal disease, 2) gastrointestinal disorders which affect digestion and absorption of nutritional components (i.e., calcium, vitamin D) associated with bone metabolism, and 3) long-term use of medications known to affect bone metabolism (i.e., corticosteroids, anticoagulants).

Procedures

After providing written informed consent, women completed a valid and reliable oral questionnaire,[20-22] BMD measurements, and had height and weight measured. The second author administered the oral questionnaire to assess demographic characteristics and lifestyle behaviors. Demographic characteristics and lifestyle behaviors reported in this study are limited to those that were required for clinical decision rule calculations. Body weight was measured on a double-beam balance scale, and height was measured with a wall-mounted stadiometer with subjects wearing no shoes and light clothing.

BMD at the femoral neck was assessed with a

Table 2. Summary of Demographics, Risk Factors for Osteoporosis, and Bone Mineral Density Status in the Study Sample (n=174)

Characteristic	Mean±SD or n (%)
Demographics	
Age (years)	59.4±12.5
Weight	79.8±20.7
Body Mass Index	29.6±7.7
Factors Influencing Osteoporosis Risk	
Minimal trauma fractures	40 (23.0%)
Estrogen therapy	104 (59.8%)
Rheumatoid arthritis	35 (20.1%)
Current smoker	46 (26.4%)
Bone Mineral Density	
Normal (T-score ≥-1.0 SD)	122 (70.1%)
Osteopenia (-1.0 SD >T-score >-2.5 SD)	26 (14.9%)
Osteoporosis (T-score ≤-2.5 SD)	26 (14.9%)

Note: Factors influencing osteoporosis risk are limited to those that are required for risk assessment calculations; SD = standard deviation

Hologic QDR 2000 (software version 7.20) using the manufacturer-supplied Third National Health and Nutrition Survey III (NHANES III) reference data to derive T-Scores for the femoral neck.[23] Subjects lay supine on the scanner table and were wearing no metal when the scan was performed. All DXA measurements were conducted by a single, certified densitometry technologist. The in vivo precision of DXA has been found to be approximately 1–2% for the proximal femur.[24] In-house coefficients of variation determined from a subsample of women similar to our study were 1.01% for the total hip.

Decision Rules

Table 1 presents the five clinical decision rules assessed in this study, which included: 1) Age, Body Size, No Estrogen[12] (ABONE), 2) Osteoporosis Risk Assessment Instrument[14] (ORAI), 3) Osteoporosis Self-Assessment Tool[15] (OST), 4) Simple Calculated Osteoporosis Risk Estimation[13] (SCORE), and 5) body weight less than 70 kg[10] (weight criterion). Selection cut-points that clinicians are recommended to use in deciding which women should undergo bone densitometry are based on recommendations set by the developers of each of the five clinical decision rules. These clinical decision rules were selected because they have been used in various studies over the past few years.[10,12-15]

Statistical Analyses

The Statistical Package for the Social Sciences (SPSS+) for Windows™ Version 11.0 was used for all statistical analyses. Alpha (α) was set at 0.05 *a priori*. Descriptive statistics (means, standard deviations, percentages) were calculated to describe demographic characteristics and lifestyle behaviors of the sample. Sensitivity, specificity, positive predictive values and negative predictive values were calculated at the recommended cut-point for each clinical decision rule. Low BMD was defined as T-Score ≤-2.0 SD, which carries some clinical relevance. For instance, the National Osteoporosis Foundation[1] has suggested use of bone-sparing medications for those with T-Score ≤-2.0 SD. Further, one Food-and-Drug-Administration-approved indication for postmenopausal osteoporosis is given in the package inserts for both alendronate (Fosamax®) and risedronate (Actonel®) is a T-Score ≤-2.0 SD.

Sensitivity refers to the ability to identify women with low BMD (i.e., osteopenia or osteoporosis) who score at or above the cut-off on the clinical decision rule (i.e., recommended for DXA screening). Specificity refers to the ability to identify women with normal BMD who score below the cut-off on the clinical decision rule (i.e., not recommended for DXA screening). Positive predictive value refers to the percentage of women with positive test results (i.e., scoring at or above the cut-off on the clinical decision rule) who actually have low BMD. Negative predictive value refers to the percentage of women with negative test results (i.e., scoring below the cut-off on the clinical decision rule) who have normal BMD.

RESULTS

Demographic characteristics of the sample are presented in Table 2. Approximately 30% of African-American women had low BMD, half of which had osteoporosis (BMD T-Score ≤-2.5 SD).

Table 3. Discriminatory Performance of Five Clinical Decision Rules for Identifying African-American Women with Low Bone Mineral Density

Decision Rule (Selection Cut Point)	Sensitivity	Specificity	PPV	NPV
ABONE (Score ≥2)	73.0	59.6	80.9	48.4
ORAI (Score ≥9)	65.6	78.9	87.9	49.4
OST (Score <2)	75.4	75.0	87.6	56.5
SCORE (Score ≥6)	83.6	53.9	81.0	58.3
Weight Criterion (<70 kg)	68.9	69.2	84.0	48.7

Data are percentages. BMD = bone mineral density; PPV = positive predictive value; NPV = negative predictive value; ABONE = age, body size, no estrogen; ORAI = Osteoporosis Risk Assessment instrument; OST = osteoporosis self-assessment tool; SCORE = simple calculated osteoporosis risk estimation; weight criterion = body weight. Low BMD was defined as T-score ≤-2.0 SD.

Sensitivity for identifying women with low BMD (T-Score ≤-2.0 SD) ranged from 65.6–83.6%, while specificity ranged from 53.85–78.85%. Positive predictive values ranged from 81.0–87.9%, while negative predictive values ranged from 48.4–58.3%. Discriminatory performance of the OST for identifying women with low BMD (T-Score ≤-2.0 SD) at selection points of ≤-1, 0, and 1 are presented in Table 4.

DISCUSSION

To date, primary care physicians have been slow to recommend BMD screening among postmenopausal women. For instance, data from the National Ambulatory Medical Care Survey (1993–1997) revealed that fewer than 2% of women (N=7977) received diagnoses of osteoporosis or vertebral fracture by their primary care physician.[25] Moreover, in a cross-sectional study of U.S. primary care physicians, self-reported barriers for referring women to BMD testing included cost, unfamiliarity with guidelines, uncertainty with clinical applicability, minimal impact on treatment decisions, and availability of measurement equipment.[26]

Almost 15% of our study sample had osteoporosis (T-Score ≤-2.5 SD), thus putting these African-American women at high risk for fracture in the future. Based on our findings and others,[3,27] it is important that clinicians recognize the importance of BMD screening among African-American women. Inexpensive clinical decision tools such as the ones discussed in this study can be used to aid clinical judgment and therefore increase the efficiency of BMD testing. It is important to remember that clinical decision rules are not meant to replace diagnostic tests, but rather complement them. Further, those with a history of a nontraumatic fracture as an adult should be referred for BMD testing and treated to prevent subsequent fractures irrespective of decision rule results.

Our findings support the results of others[9,28] where the combination of increased age and decreased body weight are risk factors strongly associated with low BMD. In interpreting our results, it is important to note that the clinical decision rules and corresponding selection cut-points used in this study were developed for use in other populations of women (i.e., caucasian and Asian). However, our results suggest that the same risk factors are important in predicting possible low BMD in African-American women. Although our sample size was relatively small in comparison to other studies using caucasian and Asian populations, data on BMD in African-American women are quite sparse. For example, the Study for Osteoporotic Fractures[29] includes a cohort of just 662 African Americans in their total study population of approximately 10,000 women.

Our data suggest that the clinical decision rules analyzed in this study have some usefulness for identifying postmenopausal African-American women with low BMD. Overall, the decision rules provided higher sensitivity than specificity. Using established cut-points, the discriminatory performance of these decision rules was lower than reported by others.[9-18] For this reason, we examined three selection cut-points for African-American women using the OST.

Sex- and race-specific selection cut-points have been developed using the OST,[15-18] and thus the OST may be a promising decision rule using African-American women. Based on our data, a cut-point of ≤-1 on the OST yielded a sensitivity of 91% and specificity of 48% (Table 4). These results should be confirmed using a large sample of postmenopausal African-American women.

Several limitations should be considered when interpreting our results. First, our sample was voluntary in nature, which may influence generalizability

Table 4. Discriminatory Performance of the Osteoporosis Self-Assessment Tool (OST) for Identifying African-American Women with Low Bone Mineral Density at Various Selection Cut-Points

Selection Cut-Point	Sensitivity	Specificity	PPV	NPV
≤-1	91.0	48.1	80.4	69.4
0	85.2	63.5	84.6	64.7
1	82.0	65.4	84.7	60.7

Data are percentages. BMD = bone mineral density; PPV = positive predictive value; NPV = negative predictive value. Low BMD was defined as T-score ≤-2.0 SD.

(external validity) to all postmenopausal African-American women. The prevalence of osteoporosis in our sample was greater than national estimates (according to NHANES III data[5]), which may in part be attributed to a high proportion at risk for secondary osteoporosis (i.e., rheumatoid arthritis).

Given the availability of newly developed bone sparing medications (i.e., calcitonin, biophosphonates) and the relatively high prevalence of low BMD and osteoporosis among postmenopausal African-American women, physicians should use a clinical decision rule, such as the OST, to identify those at potentially greatest risk of low BMD.

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