Osteoporosis Risk Assessment and Ethnicity: Validation and Comparison of 2 Clinical Risk Stratification Instruments

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BACKGROUND: Dual energy x-ray absorptiometry (DXA), coupled with early treatment, may reduce morbidity and mortality associated with osteoporosis. Clinical tools to enhance selection of women for DXA screening have not been developed or validated in an ethnically diverse population.

OBJECTIVE: To compare the performance of the osteoporosis risk assessment instrument (ORAI) and the simple calculated osteoporosis risk estimation (SCORE) instrument across 3 racial/ethnic groups to identify women who would benefit from DXA scans.

DESIGN: Blinded comparison of the instruments in a cross-sectional sample.

PARTICIPANTS: Two-hundred twenty-six postmenopausal women were recruited from a university-based family medicine clinic. Women with a prior diagnosis of osteoporosis or those taking bone active medications were excluded.

MEASUREMENTS: Participants completed a questionnaire that contained the ORAI and the SCORE questions; 203 completed a DXA scan.

RESULTS: The sensitivity and specificity for the ORAI (0.68, [0.49 to 0.88, 95% CI]; 0.66, [0.59 to 0.73, 95% CI]) and the SCORE instrument (0.54, [0.34 to 0.75, 95% CI]; 0.72, [0.65 to 0.78, 95% CI]) differed significantly from previous reports. Overall, the accuracy of the ORAI (66.5%) and SCORE instrument (70.0%) were similar (McNemar’s test P value = .37). The accuracy between instruments differed significantly in African-American women (McNemar’s test, P value < .001). In African Americans, the SCORE instrument correctly identified more women without osteoporosis, but missed 70% of those with osteoporosis.

CONCLUSIONS: The performance of the ORAI and SCORE instrument differed significantly from previous reports. Although both can reduce the use of DXA scans for screening for osteoporosis, lower sensitivities resulted in underrecognition of osteoporosis and may limit their clinical usefulness in an ethnically diverse population.

KEY WORDS: osteoporosis; diagnosis; women’s health; cross-cultural medical issues.
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Osteoporosis, characterized by low bone mineral density (BMD) and loss of structural integrity, increases with age and is more prevalent in women than men. In the elderly, osteoporosis is a major risk factor for fractures of the wrist, vertebrae, and hip and accounts for substantial morbidity and mortality. Based on 1995 data, total direct medical expenditures for the treatment of osteoporotic fractures were estimated at $13.8 billion.1 Adjusting for inflation, expenditures exceeded $17 billion in 2001 dollars.

Effective screening modalities for osteoporosis are available, as are effective prevention and treatment strategies.2–12 However, these clinical options may be underutilized. In 2002, the U.S. Preventive Services Task Force (USPSTF) recommended that women in all racial/ethnic groups who are 65 years of age and older should be offered osteoporosis screening with dual energy x-ray absorptiometry (DXA)13; however, the National Osteoporosis Foundation (NOF) estimated that only 12% of women in this age group had been screened with DXA.14 In 2003, a survey of patients receiving care in an academic setting reported that only 34% of white women who met NOF criteria, which are similar to the USPSTF screening recommendations, had received a DXA scan. Furthermore, only 8% of African-American women who met these criteria had received a DXA scan.15 These findings demonstrate that DXA screening is underused, despite evidence that early recognition and treatment reduce osteoporotic fractures and the associated morbidity and mortality.

Several clinical risk stratification or screening instruments have been developed for identifying women who would most benefit from measurement of BMD by DXA scan16–22 to diagnose osteoporosis. These instruments were developed in primarily white populations and have not been validated in multiethnic populations. In light of the 2002 USPSTF recommendations, these instruments may be useful in identifying postmenopausal women under 65 years of age at increased risk of unrecognized osteoporosis. Their role in women over 65 is debatable. This study compares the simple calculated osteoporosis risk estimation (SCORE) instrument16–22 and the osteoporosis risk assessment instrument (ORAI)16–22 across 3 racial/ethnic groups. We selected these instruments because the initial development and validation studies were methodologically sound and afforded an opportunity to compare 1 instrument that included race/ethnicity (SCORE) to another that did not (ORAI). In this study, we compared the operating characteristics of these instruments in postmenopausal women to identify women for screening versus not screening for osteoporosis with a DXA scan. We also compared our results with results from previous reports. Finally, we compared the accuracy of the screening decisions based on results of both instruments. We report findings for the entire sample and for each of the 3 racial/ethnic groups.

METHODS

Design
We designed a cross-sectional study of primary screening for osteoporosis that was conducted as a comparison of 2 clinical

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risk stratification instruments designed to assign postmeno-
pausal women to 1 of 2 groups: (1) those likely to have os-
teoporosis and therefore most likely to benefit from DXA
screening and (2) those unlikely to have osteoporosis and
therefore least likely to benefit from DXA screening. The Hu-
man Subjects Institutional Review Board approved this study.
All subjects signed a written informed consent.

Participants

We enrolled a sample of postmenopausal women, 45 years of
age and older, receiving usual care at a university-based family
practice clinic, which is a combined faculty and resident prac-
tice. Women, including non-Hispanic white, African American,
and Hispanic participants, were recruited during a regularly
scheduled visit. Since this study focused on detecting os-
teoporosis in women without a prior diagnosis of osteoporosis,
we excluded women who previously had been diagnosed with
osteoporosis. In addition, we excluded women who were taking
bone active medication (e.g., bisphosphonates, calcitonin, etc.)
for osteoporosis or osteopenia because of potential effects on
BMD; women who had other bone disease (e.g., Paget’s dis-
case, hip replacement surgery) that could interfere with inter-
pretation of the DXA scans; and women who exceeded the
weight limit of the DXA scanner.

Measures and Instruments

Each participant completed a survey that included demo-
ographic data, medical history, and risk factors identified by
each of the clinical risk stratification instruments under con-
sideration. Women subsequently underwent measurement of
BMD by DXA, which we used as the reference standard to
classify women as normal, osteopenic, or osteoporotic. Based
on the World Health Organization definitions, results from
DXA scans of total hip and total lumbar spine were designated
as follows: normal bone density (T score ≥ −1.0); osteopenia
(−1.0 > T score > −2.5); or osteoporosis (T score ≤ −2.5).
Participants’ BMD was classified based on the lower T score for
either the total hip or the total lumbar spine. Bone mineral
density and corresponding T scores were based on reference
standards provided by the Hologic DXA scanners (Hologic,
Inc., Bedford, MA) used in this study. All but 4 DXA scans
were performed on the same Hologic 1000 QDR 4500A ma-
chine in the General Clinical Research Center. The other 4
were performed on a similar machine, a Hologic 1000 QDR
4500W in the radiology department.

Osteoporosis Risk Assessment Instrument. The ORAI20 was de-
developed in a large cohort of predominately white women in
Canada and relies on age, weight, and estrogen replacement
therapy to classify women into screen and do not screen cat-
egories. The instrument was validated in a second sample of
Canadian women.20,24 Women with a score of 9 points or
greater are referred for DXA. The scoring algorithms are summarized
in Table 1.

Simple Calculated Osteoporosis Risk Evaluation. The SCORE
instrument also was developed in a predominantly white pop-
ulation.17 In addition to age, weight, and estrogen replacement
therapy, the SCORE instrument includes race/ethnicity, his-
tory of rheumatoid arthritis, and history of nontraumatic frac-
tures after age 45 to classify women into screen and do not
screen categories. Women with a score of 6 points or greater

are referred for DXA. The scoring algorithms are summarized
in Table 1.

Statistical Analysis

We used one-way ANOVA to compare interval-scaled continu-
ous variables (age and weight) and Pearson chi-square statistic
for categorical variables e.g., use of estrogen, history of frac-
ture, and history of rheumatoid arthritis, across the racial/
ethnic groups.

Based on cutoff values of 9 for the ORAI and 6 for the
SCORE instrument, we divided women into screen and do not
screen categories and constructed classification tables to cal-
culate sensitivities, specificities, predictive values, and accu-
racies for both instruments against DXA results. Blinded
classification was assured using a computer algorithm to cal-
culate and classify participants from results of the ORAI and
SCORE instrument and DXA results. We compared values
from our sample with values published by Lydick et al.17
and Cadarette et al.20,24 using the exact binomial test for a
single proportion. We report the area under the receiver oper-
ator characteristic curve (AUC) for both instruments.

To directly compare the overall accuracy of both instru-
mements, we constructed 2 × 2 tables comparing correct (true
positives plus true negatives) versus incorrect (false positives
plus false negatives) screening decisions for both instruments
and obtained values for McNemar’s test of equality of paired
proportions.25 We directly compared sensitivities and specific-
ities for both instruments overall and for each racial/ethnic
group using sample estimates and 95% confidence intervals.

<table>
<thead>
<tr>
<th>Table 1. Computation Rules for the ORAI and SCORE Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline/Rule</td>
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<tr>
<td>----------------------------------------------------------------</td>
</tr>
<tr>
<td>Osteoporosis Risk Assessment Instrument (ORAI)*</td>
</tr>
<tr>
<td>Points are given for:</td>
</tr>
<tr>
<td>Age:</td>
</tr>
<tr>
<td>&gt; 75</td>
</tr>
<tr>
<td>65 to 74</td>
</tr>
<tr>
<td>55 to 64</td>
</tr>
<tr>
<td>Weight:</td>
</tr>
<tr>
<td>&lt;60 kg (132 lbs)</td>
</tr>
<tr>
<td>60 to 69 kg (132 to 154 lbs)</td>
</tr>
<tr>
<td>≥70 kg (154 lbs)</td>
</tr>
<tr>
<td>Estrogen use</td>
</tr>
<tr>
<td>Not current</td>
</tr>
<tr>
<td>Current</td>
</tr>
<tr>
<td>Simple Calculated Osteoporosis Risk Estimation (SCORE)**</td>
</tr>
<tr>
<td>Points are given for:</td>
</tr>
<tr>
<td>Race/ethnicity</td>
</tr>
<tr>
<td>Other than African American</td>
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<tr>
<td>H/O of rheumatoid arthritis</td>
</tr>
<tr>
<td>Number of minimal trauma fractures of wrist, hip, or rib</td>
</tr>
<tr>
<td>multiplies (maximum of 12)</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>First digit of age in years multiplied by</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>Weight in pounds divided by 10 and truncated to integer</td>
</tr>
<tr>
<td>multiplies by</td>
</tr>
</tbody>
</table>

*ORAI threshold to refer for dual energy x-ray absorptiometry (DXA) scan is total points ≥ 9.
**Score threshold to refer for DXA scan is total points ≥ 6.