

Prospective Study

Risk assessment instruments for screening bone mineral density in a Mediterranean population

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Abstract

AIM

To evaluate the power of six osteoporosis-screening instruments in women in a Mediterranean country.

METHODS

Data concerning several osteoporosis risk factors were prospectively collected from 1000 postmenopausal women aged 42-87 years who underwent dual-energy X-ray absorptiometry (DEXA) screening. Six osteoporosis risk factor screening tools were applied to this sample to evaluate their performance and choose the most appropriate tool for the study population.

RESULTS

The most important screening tool for osteoporosis status was the Simple Calculated Osteoporosis Risk Estimation, which had an area under the curve (AUC) of 0.678, a sensitivity of 72%, and a specificity of 72%, with a cut-off point of 20.75. The most important screening tool for osteoporosis risk was the Osteoporosis Self-assessment Tool, which had an AUC of 0.643, a sensitivity of 77%, and a specificity of 46%.

with a cut-off point of -2.9.

CONCLUSION

Some commonly used clinical risk instruments demonstrate high sensitivity for distinguishing individuals with DEXA-ascertained osteoporosis or reduced bone mineral density.

Key words: Osteoporosis; Bone mineral density; Risk assessment; Dual X-ray absorptiometry; Osteopenia

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Core tip: Bone mineral density (BMD) measurement using dual-energy X-ray absorptiometry (DEXA) is currently the most widely used method for osteoporosis screening, treatment and patient monitoring. Nevertheless, performing routine BMD measurements of all women is not feasible for most populations, and at present there is no universally accepted policy for population screening in Europe to identify patients with osteoporosis or those at high risk of fracture. Osteoporosis risk factor screening tools have been developed to identify postmenopausal women in need of DEXA screening and possible intervention for osteoporosis.

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INTRODUCTION

Osteoporosis is the most common bone disease, characterized by low bone mass and microarchitecture deterioration, which increase bone fragility and susceptibility to fracture^[1]. Distal forearm fractures, vertebra fractures and proximal femoral (hip) fractures are typical osteoporotic fractures. However, patients with low bone mineral density (BMD) are at high risk for all types of fractures, irrespective of fracture site^[2].

An estimated 50% of Caucasian women and 20% of Caucasian men older than 50 years will experience a fragility fracture in their lifetime^[3]. This is an important public health issue because many of these fractures are associated with increased mortality, morbidity or permanent disability, as well as high societal and personal costs^[4]. Identification and treatment of patients, particularly women, at risk for osteoporosis is of great importance for the prevention of osteoporotic fractures^[5].

BMD measurement using dual-energy X-ray absorptiometry (DEXA) is currently the most widely used method to diagnose osteoporosis (*i.e.*, provide criteria for fracture risk), to guide treatment decisions and to monitor patient course after receiving or not receiving

treatment^[6]. Nevertheless, routine BMD measurement of all women is not feasible for most populations because of lack of scanners, lack of awareness or lack of widely accepted guidelines. At present, there is no universally accepted policy for population screening in Europe to identify patients with osteoporosis or those at high risk of fracture.

Additionally, the various osteoporosis-screening instruments that exist to help clinicians identify women at increased risk for osteoporosis who should undergo further testing in combination with DEXA screening^[7].

The aim of this survey was to evaluate the power of six osteoporosis-screening instruments^[8-13] in identifying postmenopausal women at risk of developing osteoporosis in a Mediterranean country. More specifically, our aim was to evaluate these clinical risk estimation instruments in distinguishing individuals with DEXA-identified osteoporosis or reduced BMD while sustaining specific levels of sensitivity and specificity for select cut-off values to identify individuals with BMD T-scores beneath a defined DEXA score.

MATERIALS AND METHODS

Patients

This cross-sectional study utilized prospectively collected data from the Bone Density Measurement Unit of the Department of Orthopaedic Surgery at University General Hospital of Alexandroupolis, a tertiary hospital. The study was approved by the Ethics Committee of the hospital, and informed consent was obtained from all participants.

The study included postmenopausal women (> 12 mo since last menstrual period). Women receiving medication for either the prevention or treatment of diagnosed osteoporosis were excluded.

All the study subjects underwent DEXA screening between October 1, 2012 and October 1, 2014. Confirmation of osteoporosis occurred through BMD measurements, which were compared with the results of the other analytical tools used.

Additionally, the following information was obtained from each patient: Age, weight, height, various osteoporosis risk factors (*i.e.*, a history of fragility fractures of the spine or hip that occurred after age 50 years), parental hip fracture, ever or current long-term use of steroids (> 3 mo use), current smoking, small stature (body mass index < 21 kg/m²), medical history of rheumatoid arthritis, other medical causes of bone loss (*i.e.*, hyperthyroidism, hyperparathyroidism, kidney failure, or anorexia), use of long-term therapy with medications known to adversely affect BMD (*i.e.*, heparin or anticonvulsants), use of arms to stand up (as an indicator of physical activity), ever or current hormonal therapy, concomitant medications, and family and personal medical histories. The results from each DEXA screen were obtained and incorporated into the database.

Screening tools

In this study, six screening tools^[8-13] were applied to

Table 1 Criteria for clinical decision rules and osteoporotic risk factors

SCORE	Age, body weight (kg), race, hormone therapy use, fracture history, history of rheumatoid arthritis
ORAI	Age, body weight (kg), hormone therapy use
OST	Age, body weight (kg)
BW	Body weight (kg)
OSIRIS	Age, body weight (kg), hormone therapy use, fracture history
ABONE	Age, body size, lack of estrogen

SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; OST: Osteoporosis self-assessment tool; BW: Body weight; OSIRIS: Osteoporosis index of risk; ABONE: Age, body size, no estrogen.

evaluate a sample of Greek postmenopausal women. The performance of the tools was compared to select the most suitable instrument for this population.

The simple calculated osteoporosis risk estimation (SCORE) was formulated by Lydick *et al.*^[8] and accounts for 6 risk factors (Table 1). The SCORE possesses a sensitivity ranging from 0.80 to 1.00 and a specificity ranging from 0.40 to 0.50.

The osteoporosis risk assessment instrument (ORAI) was formulated by Cadarette *et al.*^[9] and accounts for 3 risk factors (Table 1). The ORAI has a sensitivity of 0.90 and a specificity of 0.45.

The osteoporosis self-assessment tool (OST) was formulated by Geusens *et al.*^[10] for evaluation of Asian and Caucasian women. It utilizes 2 factors (Table 1) and shows a sensitivity of 0.88 and a specificity of 0.52.

The body weight criterion (BW) was formulated by Michaëlsson *et al.*^[11] and accounts for only one factor (Table 1). It has a sensitivity of 0.94 and a specificity of 0.36.

The osteoporosis index of risk (OSIRIS) was formulated by Sedrine *et al.*^[12] using four factors (Table 1). It has a sensitivity of 0.79 and a specificity of 0.51.

Weinstein and Ullery^[13] formulated the Age, Body size, No Estrogen tool (ABONE) (Table 1), which has a high specificity of 0.84 but a low sensitivity of 0.56.

Statistical analysis

Data are expressed as the mean \pm SD or the median (IQR) for quantitative data and as percentages for qualitative data. The Kolmogorov-Smirnov test was utilized for normality analyses of the parameters. A receiver operating curve (ROC) analysis was conducted to determine the diagnostic abilities and obtain the cut-off levels of the various osteoporosis-screening tools in classifying patients as osteoporotic or at high osteoporotic risk. This was accomplished according to T-score classification by calculating the areas under the curve (AUC) and their standard errors and 95% CIs. To evaluate the internal credibility of the indices, sensitivity was delineated as the proportion of the population with reduced BMD who were correctly categorized by the risk index (true positive fraction), and specificity was delineated as the proportion

of the population with normal BMD who were correctly categorized by the risk index (true negative fraction).

We also measured the positive predictive value (PPV) and negative predictive value (NPV) of each instrument to measure their external credibility. The PPV and NPV corresponded to the average numbers of women who were deemed as positive or negative (as compared by the four instruments), respectively, who truly had or did not have BMD values beneath the T-score cut-off.

The ROC curves were used to provide a graphical interpretation of the general quality of each test by plotting sensitivity against (1-specificity) for all thresholds, while the AUC values were used to indicate test quality. Multiple logistic regression analysis using the enter method was performed with the dependent variables (T-score \leq -2.5 vs T-score $>$ -2.5) and (T-score \leq -2 vs T-score $>$ -2) and the osteoporosis-screening indices as the independent variables. All the tests were two-sided, and statistical significance was set at $P < 0.05$. All analyses were carried out using SPSS ver 17.00 (Statistical Package for the Social Sciences, SPSS Inc., Chicago, Ill., United States).

RESULTS

One thousand women with a mean age of 63.41 years (minimum 42 years and maximum 87 years) were included in this study. The mean age at menarche was 13.2 years (minimum 8 years and maximum 18 years), and the mean weight and height were 73.52 kg (minimum 40 kg and maximum 120 kg) and 1.59 m (minimum 1.42 m and maximum 1.80 m). The mean number of pregnancies was 2.3 (0-12 pregnancies), the mean alcohol consumption was 0.37 drinks weekly (0-7 drinks), and the mean coffee consumption was 1.60 cups daily (0-6 cups). Additionally, 12.1% of the population were smokers, 64.5% had previously experienced a graduated fracture, 20% regularly exercised, 20% had kyphosis, 2.7% had rheumatoid arthritis, 3.8% had received hormone therapy, and 3.2% had received cortisone.

The following indicator values were obtained: BW: 73.52 \pm 11.32, OST: -2.02 \pm 2.94, ORAI: 10.05 \pm 5.02, SCORE: 20.54 \pm 3.70, OSIRIS: 0.68 \pm 3.14 and ABONE: 1.54 \pm 0.66. The AUC ratios and the sensitivities and specificities of the instruments for identifying high osteoporotic risk and osteoporosis were assessed using cut-off points from the literature. The tool with the highest AUC value was the ABONE (AUC: 0.628), followed by the ORAI (AUC: 0.608).

The highest levels of sensitivity and accuracy in identifying patients at high risk of osteoporosis were obtained by the ORAI (72%) and the ABONE (65%). The highest levels of sensitivity and accuracy in diagnosing osteoporosis were obtained by the OSIRIS (63%) and the BW (67%). The sensitivity for the OSIRIS was 0.631, and the specificity was 0.570. The sensitivity for the BW was 0.40, and the specificity was 0.667. These values are listed in Table 2.

Table 2 Receiver operating curve analysis using international guidelines

	AUC	95%CI		Sensitivity	Specificity	P-value
SCORE ¹	---	---	---	---	---	---
ORAI ¹	0.608	0.57	0.65	0.716	0.498	< 0.0005
ABONE ¹	0.628	0.59	0.67	0.650	0.610	< 0.0005
BW ²	0.535	0.49	0.58	0.400	0.667	0.109
OST ²	0.586	0.54	0.63	0.515	0.312	< 0.0005
OSIRIS ²	0.600	0.56	0.64	0.631	0.570	< 0.0005

¹Osteoporosis risk T-score < -2; ²Osteoporosis status T-score < -2.5. AUC: Area under the curve; SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; ABONE: Age, body size, no estrogen; BW: Body weight; OST: Osteoporosis self-assessment tool; OSIRIS: Osteoporosis index of risk.

The AUC, sensitivity, and specificity values and the cut-off points for the indicators of osteoporosis risk are presented in Table 3. The clinical tool with the highest AUC value was the OST (AUC: 0.643), followed by the ORAI (AUC: 0.640) and the ABONE (AUC: 0.631). The highest sensitivity in identifying patients at high risk for osteoporosis was obtained with the OST (77%), followed by the ORAI (72%) and the ABONE (65%). The highest accuracy for identifying individuals at high osteoporotic risk was obtained by the BW (61%), followed by the SCORE (60%). The sensitivity of the BW was 51%, and its specificity was 61%. The sensitivity and specificity for the SCORE were 61% and 60%, respectively.

The AUC, sensitivity, and specificity values and the cut-off points for the indicators of osteoporotic condition are shown in Table 4. The clinical tool with the highest AUC value was the SCORE (AUC: 0.678), followed by the OST (AUC: 0.644) and the OSIRIS (AUC: 0.641). The highest sensitivity in diagnosing osteoporosis was obtained with the OST (80%), followed by the OSIRIS (76%) and the SCORE (65%). The highest accuracy for assessing osteoporotic status was obtained with the ORAI (60%) and the SCORE (60%).

The sensitivity for the OST was 80%, and its specificity was 43%. The sensitivity and specificity for the OSIRIS were 76% and 44%, respectively. For the SCORE, the sensitivity and specificity were 72% and 60%, respectively. For the ORAI, the specificity and sensitivity were 65% and 60%, respectively.

The results from the multiple logistic regression analysis for the variable high osteoporotic risk are presented in Table 5. For this analysis, we introduced each of the variables into a multiple linear regression model (known as the enter method) to identify the independent effects of each instrument on the variable high osteoporotic risk. We found that the OST ($P = 0.012$), ABONE ($P = 0.051$) and SCORE ($P = 0.081$) each had a statistically significant effect on this variable.

The results from the multiple logistic regression analysis for the variable osteoporosis are presented in Table 6. Similar to the above, we used the enter method to identify the independent effects of each instrument on the variable osteoporosis. Only the SCORE ($P < 0.0005$)

had a statistically significant effect on this variable.

DISCUSSION

In this survey, we assessed the performance of six osteoporosis pre-screening models in evaluating a sample of Greek postmenopausal women and selected the most suitable instrument for that population. Our results exhibited that, assuming a -2.5 cut-off for T-score in three areas of concern, the OST and the OSIRIS had equal predictive precision (AUCs between 0.586 and 0.6). Additionally, assuming a -2 cut-off for T-score in three areas of concern, the ORAI and the ABONE had equal predictive precision (AUCs between 0.608 and 0.628). The least suitable and least useful model based on AUC was the BW, which had only 40% sensitivity. The ABONE and the ORAI were more suitable models, each with an AUC of approximately 0.628.

When considering the AUCs, sensitivities, specificities and cut-off points for the indicators of patients at high-risk of osteoporosis, the clinical tool with the highest AUC value was the OST (AUC: 0.643), followed by the ORAI (AUC: 0.640) and the ABONE (AUC: 0.631).

With regard to the AUCs, sensitivities, specificities and cut-off points for osteoporosis, the clinical tool with the highest AUC value was the SCORE (AUC: 0.678), followed by the OST (AUC: 0.644) and the OSIRIS (AUC: 0.641).

Combining the above criteria, in the Greek postmenopausal population, the most important screening tool for osteoporosis status is the SCORE, and for osteoporotic risk, it is the OST. In our study, the SCORE had an AUC of 0.678, a sensitivity of 72%, and a specificity of 72%, with a cut-off point of 20.75, for osteoporosis status. Additionally, the screening tool most important for osteoporosis risk was the OST. The OST had an AUC of 0.643, a sensitivity of 77%, and a specificity of 46%, with a cut-off point of -2.9.

These results must be interpreted with caution, as they are based on a sample of only 1000 patients and may not represent the entire Greek population.

As clinical decision tools, instruments used to predict osteoporosis risk and to identify osteoporosis should be straightforward and convenient to apply in clinical practice in addition to being accurate. Nevertheless, when applying such instruments to different countries or populations, their reported utility has varied amongst different studies. It has been found that they perform well in classifying the risk of osteoporosis and that applying them is more prudent than the use of the BMD^[14]. However, clinical decision-making tools were found to have limited utility for predicting osteoporosis in patients with rheumatoid arthritis^[15]. Wallace *et al*^[16] reported sensitivities of 83% for the SCORE and 65% for the ORAI. Martínez-Aguilà *et al*^[17] found sensitivities of 64% for the ORAI and 83% for the BW in Spanish women, while Cass *et al*^[18] reported sensitivities of 66% for the SCORE and 68% for the ORAI in a group of Caucasian (non-Hispanic and Hispanic) and African-

Table 3 Receiver operating curve analysis using Greek population values for osteoporosis risk

	Area	95%CI		Cut-off	Sensitivity	Specificity	PPV	NPV	P-value
SCORE ¹	0.613	0.576	0.650	20.75 >	61%	60%	46%	73%	< 0.0005
ORAI ¹	0.640	0.603	0.676	9.5 >	72%	52%	46%	76%	< 0.0005
ABONE ¹	0.631	0.595	0.668	10.5 >	62%	62%	48%	74%	< 0.0005
OST ¹	0.643	0.607	0.678	1.5 >	65%	41%	32%	85%	< 0.0005
BW ¹	0.592	0.555	0.630	-2.9 >	77%	46%	45%	78%	< 0.0005
OSIRIS ¹	0.609	0.572	0.645	70.5 <	51%	61%	42%	68%	< 0.0005
				0.5 <	59%	59%	44%	71%	< 0.0005

¹High risk for osteoporosis: T-score ≤ -2 . SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; ABONE: Age, body size, no estrogen; OST: Osteoporosis self-assessment tool; BW: Body weight; OSIRIS: Osteoporosis index of risk; PPV: Positive predictive value; NPV: Negative predictive value.

Table 4 Receiver operating curve analysis using Greek population values for osteoporosis status

	Area	95%CI		Cut-off	Sensitivity	Specificity	PPV	NPV	P-value
SCORE ¹	0.678	0.640	0.717	20.75 >	72%	60%	36%	87%	< 0.0005
ORAI ¹	0.632	0.591	0.673	10.5 >	65%	60%	33%	85%	< 0.0005
ABONE ¹	0.618	0.576	0.659	1.5 >	66%	60%	48%	75%	< 0.0005
OST ¹	0.644	0.604	0.684	-2.9 >	80%	43%	30%	87%	< 0.0005
BW ¹	0.591	0.549	0.633	75.5 <	69%	41%	26%	81%	< 0.0005
OSIRIS ¹	0.641	0.601	0.681	0.5 <	63%	57%	31%	83%	< 0.0005
				1.5 <	76%	44%	30%	86%	< 0.0005

¹Osteoporosis status: T-score ≤ -2.5 . SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; ABONE: Age, body size, no estrogen; OST: Osteoporosis self-assessment tool; BW: Body weight; OSIRIS: Osteoporosis index of risk; PPV: Positive predictive value; NPV: Negative predictive value.

Table 5 Multiple logistic regression model (T-score ≤ -2)

	Reference category	Odds ratio	95%CI		P-value
SCORE	20.75 <	1.36	0.96	1.91	0.081
ORAI	10.5 <	1.30	0.8	2.09	0.287
ABONE	1.5 <	1.64	1.00	2.70	0.051
OST	-2.9 <	1.81	1.14	2.88	0.012
BW	70.5 >	1.05	0.75	1.47	0.772
OSIRIS	0.5 >	0.78	0.52	1.16	0.214

SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; ABONE: Age, body size, no estrogen; OST: Osteoporosis self-assessment tool; BW: Body weight; OSIRIS: Osteoporosis index of risk.

Table 6 Multiple logistic regression model (T-score ≤ -2.5)

	Reference category	Odds ratio	95%CI		P-value
SCORE	20.75 <	2.87	1.92	4.29	< 0.0005
ORAI	10.5 <	1.42	0.81	2.48	0.215
ABONE	1.5 <	0.95	0.53	1.70	0.865
OST	-2.9 <	1.55	0.90	2.65	0.115
BW	70.5 >	1.10	0.76	1.60	0.600
OSIRIS	0.5 >	0.88	0.56	1.39	0.586

SCORE: Simple calculated osteoporosis risk estimation; ORAI: Osteoporosis risk assessment instrument; ABONE: Age, body size, no estrogen; OST: Osteoporosis self-assessment tool; BW: Body weight; OSIRIS: Osteoporosis index of risk.

American women. A recent systematic review concerning the performance of the OST found that this tool may be of clinical value in ruling out low BMD^[19], while another systematic review focused on accuracy that compared the OST to the SCORE and the ORAI produced similar results^[20].

When comparing the different studies that have focused on the performance of these instruments, two notable points arise. The first concerns the threshold for defining osteoporosis; in particular, some tools (such as the ORAI and the ABONE) were developed using as a T-score ≤ -2.0 as a threshold, while other tools (such as the BW and the OSIRIS) use a T-score ≤ -2.5 as a threshold. A lower threshold provides more robust and defined segmentation for prophylactic strategies and helps in assigning screening intervals^[21]. The second point concerns the skeletal site that is tested for BMD, as

different BMD values have been measured at different anatomic sites within the same patient. It has been suggested that a value beneath the determined threshold at any site (lumbar spine or hip) is sufficient^[22].

Study limitation

The main limitation of our study is the small population evaluated. The information we gathered specifically pertains to women who were seen at university hospital in Alexandroupolis, Eastern-Macedonia and Thrace. However, as a notable strength, our study is the most inclusive evaluation of clinical risk assessment instruments for distinguishing Greek postmenopausal women with osteoporosis or reduced BMD.

In conclusion, our study identified clinical risk instruments that showed high sensitivity for identifying individuals with DEXA-determined osteoporosis or low BMD.

We believe that further studies from other centers in our region concerning the effectiveness of these instruments are required.

COMMENTS

Background

Osteoporosis is the most common bone disease, characterized by low bone mass and microarchitecture deterioration, which increase bone fragility and susceptibility to fracture. Dual-energy X-ray absorptiometry (DEXA) is currently the most widely used method to diagnose low bone mass, but routine bone mineral density (BMD) measurement of all women is not feasible for most populations, and universally accepted guidelines do not exist.

Research frontiers

Clinical risk assessment instruments for distinguishing individuals with osteoporosis or reduced BMD have been formulated to identify postmenopausal women who should undergo DEXA measurement for osteoporosis. Nevertheless, applying these instruments in different countries or populations has shown varied utility amongst previous studies.

Innovations and breakthroughs

In the current study, the authors utilized six osteoporosis pre-screening instruments on a sample of Greek postmenopausal women to standardize their interpretation and select the most suitable instrument for that population. With consideration of the factors identified in other instrument validations, we showed that using -2.5 as a cut-off T-score in three areas of interest for the studied osteoporosis self-assessment tools and osteoporosis index of risk produced the highest precision [area under the curve (AUC) between 0.586 and 0.6]. At the same time, using -2 as a cut-off T-score in three areas of interest in the studied osteoporosis risk assessment instruments while accounting for age, body size, and lack of estrogen produced the highest precision (AUC between 0.608 and 0.628).

Applications

The purpose of this study was to measure the performance of a panel of clinical risk instruments in identifying individuals with DEXA-determined osteoporosis or reduced BMD in a Mediterranean population. Specifically, the authors measured the sensitivity and specificity associated with different cut-off values to identify individuals with BMD T-scores beneath a nominal DEXA threshold.

Terminology

Osteoporosis is a skeletal disease characterized by low bone mass and microarchitecture deterioration, which increase bone fragility and susceptibility to fracture. BMD measurement using DEXA is currently the most widely used method to diagnose osteoporosis (*i.e.*, provide criteria for fracture risk), guide its treatment and monitor patient course after receiving or not receiving treatment. Osteoporosis risk factor clinical risk assessment instruments for distinguishing individuals with osteoporosis or reduced BMD were formulated to identify postmenopausal women who should undergo DEXA measurement for osteoporosis.

Peer-review

This is an interesting paper with regards to the argument of screening tools for osteoporosis and identification of the patients that need to have DEXA measurement. Furthermore, it adds information missing in this area of the Mediterranean Sea.

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