

Prescreening Tools to Determine Who Needs DXA

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Clinical decision rules (CDRs) are designed to help physicians practice better. A number of CDRs to assist in identifying women with low bone mass have been developed since the mid 1990s, including SCORE, OST (OSTA), OSIRIS, SOFSURF, NOF, ABONE, pBW, ORAI, and weight-only-EPIDOS (which we have termed WO-E). This review discusses these CDRs in terms of development and validation cohorts and their sensitivity and specificity. The sensitivities of the available CDRs exceed 80% and specificities are about 50%. After much analysis, it appears that most experts prefer OST for its simplicity and SCORE for its flexibility, but there is no consensus on what risk factors to use in the CDRs and what regions of interest (spine, total hip, femoral neck, or a combination) to test with dual-energy x-ray absorptiometry (DXA). Because of the lack of consensus, there are barriers to the clinical application of these CDRs. Agreement on a single CDR for worldwide use is required to optimally fulfill the objective of identifying low bone mass.

Introduction

Beginning in the mid 1990s, a number of articles appeared in the literature on the topic of prescreening instruments to select patients for bone densitometry. These instruments were based on decision rules incorporating various risk factors known to be associated with low bone mineral density (BMD) [1] and risk factors for fracture [2]. These instruments involve the use of clinical decision rules (CDRs), which are defined as “a clinical tool that quantifies the individual contributions that various components of the history, physical examination, and basic laboratory results make toward the diagnosis, prognosis, or likely response to treatment in an individual patient” [3]. According to McGinn et al. [3], CDRs “attempt to

formally test, simplify, and increase the accuracy of clinicians’ diagnostic and prognostic assessments and are most likely to be useful in situations where decision making is complex, the clinical stakes are high, or there are opportunities to achieve cost savings without compromising patient care.”

It takes three steps to create and validate a CDR: developing the rule, validating the rule, and testing the impact of the rule on clinical behavior. The validation studies may have to be performed in a number of different populations of different sizes and at different clinical sites [3].

The purpose of these risk-assessment instruments is to choose one or more easily obtainable patient characteristics that can be used to divide the population in question—in this case, postmenopausal women—into two groups: 1) those who have the characteristic or characteristics that fit the CDRs and thus are likely to have low bone density and to be a candidate for bone density testing and 2) those who don’t have the characteristic or characteristics and thus would be unlikely to have low bone density and therefore do not need bone densitometry. Each of these instruments has chosen to focus on different characteristics (with some overlap) and to reach different decision points with different cut points.

Review of Instruments

The major instruments that have been developed are the Simple Calculated Osteoporosis Risk Estimation (SCORE) [4]; Age, BOdy size, No Estrogen (ABONE) [5]; Weight/Body Composition (pBW) [6]; the OSteoporosis Index of RISK (OSIRIS) [7]; the Study of Osteoporosis Fractures—Study Utilizing Risk Factors (SOFSURF) derived from data of the Study of Osteoporotic Fractures [8]; the Osteoporotic Self-assessment Tool (OST/OSTA) [9]; the National Osteoporosis Foundation (NOF) guidelines, from the *Physician’s Guide to Prevention and Treatment of Osteoporosis* [10]; the Osteoporosis Risk Assessment Instrument (ORAI) [11]; and Weight-Only-EPIDOS (WO-E) [12]. Each will be reviewed.

SCORE

The Simple Calculated Osteoporosis Risk Estimation (SCORE) [4] was one of the earliest and most completely

Table 1. Calculation of Simple Calculated Osteoporosis Risk Estimation (SCORE)

Variable	Score	Conditions
Race	+5	Woman is not black
Rheumatoid arthritis	+4	Woman has rheumatoid arthritis
History of fractures	+4	For each type (wrist, rib, hip) of nontraumatic fracture after age 45 (maximum score = 12)
Age	+3	Times first digit of age in years
Estrogen therapy	+1	Woman has never received estrogen therapy
Weight	-1	Times weight in pounds divided by 10 and truncated to nearest integer

(Adapted from Lydick et al. [4].)

validated questionnaires attempting to facilitate the identification of women likely to have low bone density. This instrument was developed by Merck & Co. at about the time of the launch of alendronate (Fosamax®) to assist physicians in ordering bone density tests to identify women who would be appropriate for treatment based on NOF guidelines [10].

The development of the SCORE document [4] involved 106 investigators in different specialties, including family practice, geriatrics, and internal medicine. Investigators enrolled women who were seen for routine check-ups or routine follow-ups of any medical condition between October, 1994, and February, 1996. Study participants were community-dwelling perimenopausal and postmenopausal women aged 45 years or older.

The initial study group was a development cohort of 1279 individuals. They were given a 60-question pamphlet on issues and factors related to osteoporosis. Blood and urine specimens were also collected for bone turnover markers. Hip and spine BMD was measured. Low BMD was defined as at least 2 SD below the mean bone density at the femoral neck in young, healthy white women.

More than 350 variables were considered. Univariate analysis comparing these variables with femoral neck BMD was performed. The screening characteristics of the candidate linear and logistic regression models were studied by evaluating the sensitivity and specificity for the values that gave 90% sensitivity. The model was then reviewed for the probability that a woman with a T-score of -2.0 or lower had low BMD. Using the factors selected by the linear regression model, a sample form of the model was developed. Variables were modified to use whole integers, which were then added to give a final SCORE (Table 1). Subsequently, a validation cohort of 208 women was selected in September and October, 1995, to assess

the model. Because of further evaluation, bone markers were not included in SCORE. If a threshold of 6 was chosen, sensitivity in the development cohort was 0.89 and in the validation cohort was 0.91; specificity was 0.50 and 0.40, respectively.

SCORE is unique in that it has the flexibility to be adjusted to various clinical situations by adjusting the sensitivity or specificity desired or by adjusting the BMD level desired. (For example, in the development cohort, 62% of the women with osteopenia were identified.) In addition, it is possible to adjust SCORE for different ethnic groups. For Asian women, for instance, the score given to the ethnicity variable is adjusted from +5 to +3 by readjusting for the lower weight of Asian women [13]. In a random sample of 4035 white women from Belgium, SCORE had a sensitivity of 91.5% and a specificity of 26% [14].

SCORE has also been looked at in an actual clinical setting [15]. As part of a worksite program at a major industrial site in Northern California, employees and retirees underwent a large osteoporosis education program that included calculating SCORE, answering questions, and having BMD measured by peripheral and central bone densitometers. An economic concept, the efficient frontier, was used to study various strategies for cost effectiveness and savings utilizing SCORE. Using SCORE as a prescreening instrument resulted in more efficient use of resources, more efficient use of bone densitometry, and financial savings.

Age, BODy size, No Estrogen (ABONE)

A questionnaire was developed [5,16] and given to 1610 menopausal women before they underwent testing with dual-energy x-ray absorptiometry (DXA). Multivariate logistical regression analysis showed age and years of menopause to be positive predictors and weight to be a negative predictor of low bone mass. The CDR developed was for detection of T-score of less than or equal to -2.5 SD below the peak mean of young, normal controls at the posteroanterior spine, total hip, or femoral neck. The criteria comprise age greater than 65 years, weight less than 140 lb, and estrogen use less than 6 months. Each criterion is given one point and meeting any two of the three criteria justifies BMD measurement. Thus, the defining score of this CDR is 2.

Weight criterion (pBW)

A study was conducted of 175 women aged 28 to 74 years in Uppsala, Sweden, in 1991 [6]. Different body measures, corrected for relevant confounding factors, were recorded and BMD of the total body, lumbar spine, and femoral neck was measured in order to relate the body measures to BMD. The BMD measurements were divided into those above -1 SD below the mean of young normal controls and those below -1 SD, including both osteopenia and osteoporosis by the World Health Organization (WHO) classification. Weight and height were measured

with a scale and a wall-mounted stadiometer. Other body composition measures recorded included approximate weight at age 18 years, body mass index, minimum waist girth, maximum hip girth, and waist-to-hip ratio. Weight explained the greatest proportion of the variance in BMD at all sites. Michaëlsson et al. [6] determined that the best sensitivity was achieved in women weighing 70 kg or less. Thus, this CDR proposes measuring BMD at the femoral neck or lumbar spine if weight is less than 70 kg to determine those with BMD at least 2.5 SD below the mean of young, normal controls.

Osteoporosis Index of Risk (OSIRIS)

This CDR was developed in 1999 using a logistic model of regression on a retrospective database of 1303 postmenopausal women [7]. It was subsequently validated using a final sample of 798 postmenopausal women recruited by 464 rheumatologists in France in 2001 [17]. DXA was performed on the spine (L2–L4) and the femoral neck. Subjects taking hormone replacement therapy (HRT) were allowed in the validation cohort. The final multiple-variable regression model incorporated four factors: age, body weight, current HRT use, and history of previous low-impact fracture.

The OSIRIS score was calculated by adding the index value weighted for each variable: weight (kg) \times 2 and remove last digit; age (y) \times -2 and remove last digit; +2 if a current HRT user; -2 if the woman has a history of low-impact fracture. OSIRIS uses cutoff points of -3 and +1 to identify high-risk, intermediate-risk, and low-risk groups.

The sensitivity of the OSIRIS score at the cutoff level of +1 (the low-risk category) is 85.1% and its specificity is 38.9%. In this category, which contained 30.6% of the study subjects, the prevalence of osteoporosis was 16.8%. Among women in the high-risk category, with a score below -3 (21% of the study population), the prevalence of osteoporosis was 62%, and only 3% had normal DXA results. For women in the intermediate category, with OSIRIS numbers between -3 and +1, the prevalence of osteoporosis was 34%. This group made up 49% of the study population.

Reginster et al. [17] propose the division of the population into low-risk, intermediate-risk, and high-risk groups, implying that treatment can be avoided in the low-risk category (30% of the population). Additional investigations of the remaining 70% might be indicated and the 20% of the population in the high-risk category might be offered therapy.

SOFSURF

The CDR known as SOFSURF (Study of Osteoporosis Fractures—Study Utilizing Risk Factors) has been published in abstract form only [8]. It was developed using the Study of Osteoporotic Fractures cohort. The CDR was developed to find women with a total hip BMD 2.5 SD or more below the peak mean of young, normal controls. It

gave a value of 1 to weight less than 150 lb, to current smoking, and to fractures if they occurred after age 50. It gave a value of 2 if the individual weighed less than 130 lb, and it added 0.2 for each year above age 65. A sum greater than 3 identified a high likelihood that the total hip BMD would be osteoporotic by WHO criteria.

Osteoporotic Self-assessment Tool (OST)

The OST (known as OSTA in Asian women) was based on age and weight to identify Asian women at increased risk of low BMD (specifically, a femoral neck BMD at least 2.5 SD below the peak mean for young, normal Asian women) [9]. Community-dwelling women were recruited from 21 clinics in eight Asian countries. Exclusion criteria related to other metabolic bone diseases were applied. The population studied was 860 women, of which 59% were Chinese, 18% Korean, 11% Thai, 9% Filipino, and 4% were Indian, Malay, or other ethnicity. The final model included 11 variables but eventually all except age and weight were dropped. Calculations for this CDR subtract age in years from weight in kilograms, multiply by 0.2, and truncate the result to an integer. The cutoff value is -1; those with values of -1 or less are at high risk; a higher value indicates low risk. This cutoff resulted in a sensitivity of 91% and specificity of 45%. In a Japanese validation cohort ($n = 1123$) using the same cutoff value, the sensitivity of this CDR was 98% and specificity was 29% [9]. This tool was also validated in a white population from Belgium [18], in which the performance was similar to other groups evaluated.

NOF guidelines

In a review of decision rules, Cadarette et al. [19] have included as a CDR the National Osteoporosis Foundation (NOF) guidelines from the *Physician's Guide to Prevention and Treatment of Osteoporosis* [10]. They did this by instituting a scoring system of one point each for age at least 65 years; weight less than 57.6 kg; personal history of minimal-trauma fracture after 40 years of age; family history of hip, wrist, or spine fractures in a parent aged 50 years or older; and current cigarette smoking. They used a selection cut point of 1. There does not seem to be a development cohort or validation cohort study.

Osteoporosis Risk Assessment Instrument (ORAI)

The ORAI tool was developed from the database of the Canadian Multicentre Osteoporosis Study (CaMos) using Ontario baseline data from three centers [11,19]. The study comprised 926 women in the development cohort and 450 women in the validation study. It was found that age, weight, and current estrogen use were common independent variables associated with low BMD. The objective was to identify women with femoral neck or lumbar spine BMD T-scores of less than or equal to -2. The scoring system for this CDR includes age (> 75 y, 15 points; 65–74 y, 9 points; 55–64 y, 5 points) and weight (< 60 kg, 9 points;

Table 2. Sensitivity and specificity of clinical decision rules for osteoporosis

Clinical decision rule	Cutoff	Femoral neck BMD T-score ≤ -2.5		Femoral neck BMD T-score ≤ -2.0	
		Sensitivity, %*	Specificity, %*	Sensitivity, %*	Specificity, %*
OST	< 2	88	52	84	59
ORAI	> 8	90	52	82	58
SCORE	> 7	89	58	80	65
SOFSURF	> -1	92	37	88	42

*At 95% CI, based on a clinic sample in the United States.
 BMD—bone mineral density; ORAI—Osteoporosis Risk Assessment Instrument; OST—Osteoporotic Self-Assessment Tool;
 SCORE—Simple Calculated Osteoporosis Risk Estimation; SOFSURF—Study of Osteoporosis Fractures—Study Utilizing Risk Factors.
 (Data from Geusens et al. [22])

60.0–69.9 kg, 3 points). A score of 9 or higher indicates that bone densitometry should be performed.

Weight-Only–EPIDOS (WO-E)

In France, Dargent-Molina et al. [12] used baseline data from almost 7000 women aged 75 years or older who were participants in the EPIDOS study to develop a CDR for the prediction of very low BMD (femoral neck T-score less than or equal to 3.5 SD below the peak mean of young, normal French controls). The choice of such a low T-score was related to the age of the population in EPIDOS and the relative risk of hip fracture in the high-risk group. The study population involved over 4600 women. The most predictive variables in the final model were weight, history of fracture after age 50 years, gait speed, balance score, grip strength, and the number of activities of daily living for which assistance was needed. The predictive value of weight is equal to the predictive value of a CDR containing the other factors listed. If they measured BMD in all the women weighing less than 59 kg, they would identify 80% of the women with very low BMD. Therefore, in an elderly group where the prevalence of low BMD is very high, weight alone (< 59 kg) may suffice as a single item to select subjects for bone densitometry.

Comparisons of the CDRs

Over the past several years, a number of articles have compared several of these instruments [9,19–23,24•,25•,26]. These articles compared two to four of the CDRs, usually OST, ORAI, SCORE, and SOFSURF. Any CDR with sensitivity better than 70% and specificity better than 50% creates adequate interrelationships of these variables. Table 2 shows the sensitivity and specificity of these four instruments using T-scores of -2.5 and -2.0. In another study, the areas under the receiver operating characteristic (ROC) curves for SCORE, ORAI, OST, and OSIRIS were all adequate for evaluating different BMD regions of interest (total hip, femoral neck, spine L2–L4, and any of these sites) at T-scores of less than or equal to -2.5 or -2.0 [17].

However, Cadarette et al. [20] make the point that further research is needed, especially a cost-effectiveness study to identify acceptable sensitivity and specificity for these CDRs. They stress the need to evaluate the utility of these instruments in clinical practice rather than in databases from epidemiologic studies. Ben Sedrine and Reginster [21] conclude that the performances of two of the CDRs for predicting low bone mass, OST (two variables) and SCORE (six risk factors), were similar. Therefore, they considered the OST “the most user-friendly tool for clinical practice.”

Sydney Lou Bonnick (Personal communication), who has also evaluated these CDRs for the International Society of Clinical Densitometry (ISCD), also felt that the OST was the easiest instrument to use. Cadarette et al. [19] considered SCORE and ORAI to be better decision rules than the NOF guidelines.

Conclusions

Under the leadership of Dr. John Kanis, the WHO has spent several years developing a better model for assessing fracture risk and deciding who should be treated [27]. Before deciding on treatment, however, we are left with the question of whom to test. Many CDRs have been developed using a number of risk factors. Some of these factors (eg, age, weight) appear in various models and some are unique to one model, such as rheumatoid arthritis in SCORE or family history of fracture in the NOF guidelines. The multiplicity of models and the need for different calculations, even though they are relatively simple, creates problems and barriers for their use by primary care physicians [28].

As in the WHO approach [27], we believe that the confusing multiplicity of CDRs has to end. We suggest that the WHO, the American Society for Bone and Mineral Research (ASBMR), the NOF, the International Osteoporosis Foundation (IOF), the International Society for Clinical Densitometry (ISCD), and other concerned organizations join in an effort to create one CDR for worldwide use to identify individuals with low bone mass. Variations may be needed for men and women and for different ethnic groups.

Another problem appears to be that the education of primary care physicians about CDRs is poor. In a quick, unscientific survey of primary care physicians in our medical office building, very few had heard of any of the CDRs reviewed in this article and some confused SCORE with T-score. Close to 300,000 physicians in the United States list themselves as primary care physicians [29]. When an optimal instrument is decided upon, educating them about it and disseminating an actual tool, such a pad or minicalculator with room for the patient's name, the instrument, the calculation, the cut point, and the end-decision (to test or not to test) will be a massive effort of tremendous expense. In the United States, it would require the participation of private insurance plans, the Centers for Medicare & Medicaid Services, the National Institutes of Health, and all of the societies listed above to coordinate and fund this effort, if the desire and national will to make it happen exist. Otherwise, the risk assessment tools will be valuable only as a source of studies and will have no practical role in the effort to halt osteoporosis and fractures.

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