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Original Article

Evaluation of Different Screening Tools for Predicting Femoral Neck Osteoporosis in Rural South Indian Postmenopausal Women

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Abstract

The measurement of bone mineral density by dual-energy X-ray absorptiometry scan is the "gold standard" for the diagnosis of osteoporosis, which has limited availability in many parts of India. This study was done to assess the diagnostic performance of 6 internationally validated tools (Simple Calculated Osteoporosis Risk Estimation [SCORE], age, bulk, one or never estrogen [ABONE], Osteoporosis Risk Assessment Instrument [ORAI] and Osteoporosis Self-Assessment Tool for Asians [OSTA], Fracture Risk Assessment Tool [FRAX®], and calcaneal quantitative ultrasound [QUS]) for the diagnosis of osteoporosis at the femoral neck (FN). This was a cross-sectional study conducted in 2108 ambulatory South Indian rural postmenopausal women who were assessed with SCORE, ABONE, ORAI, OSTA, and FRAX® tools. QUS was performed in 850 subjects. Bone mineral density was estimated by dual-energy X-ray absorptiometry scan at the FN, and sensitivity and specificity were calculated for all tools for predicting FN osteoporosis. The receiver operating characteristic curve was constructed for each tool and the area under the curve (AUC) was calculated. FN osteoporosis was seen in 27%. The sensitivities of SCORE, ABONE, OSTA, ORAI, FRAX®, and QUS were 91.3%, 91.0%, 88.5%, 81.0%, 72.7%, and 81.9%, and the specificities were 36.0%, 33.5%, 41.7%, 52.0%, 60.5%, and 50.3%, respectively, for the FN osteoporosis. When the receiver operating characteristics were constructed, the AUC was good only for SCORE (0.806), and the performance of the rest was under fair category (0.713–0.766). In our large cohort of rural postmenopausal women, the SCORE screening tool was found to be useful with good sensitivity and good AUC for predicting FN osteoporosis. Thus, this tool may be used in resource-limited countries to screen the population at risk and to enable treating physicians to make appropriate management decisions.

Key Words: Osteoporosis; postmenopausal women; risk assessment tools SCORE.

Introduction

The number of Indian women diagnosed with osteoporosis is on the rise, paralleling the increase in their life expectancy *(1)*. Postmenopausal osteoporosis is the most common metabolic bone disease and occurs following the cessation of the ovarian function, leading to a dramatic decrease in female sex hormones. In addition, the poor dietary intake of calcium and vitamin D deficiency has been widely reported in the Indian subcontinent, which further contributes to adverse bone health *(2)*.

Osteoporosis is characterized by a reduction in bone density and poor bone quality, leading to an increased fragility and the development of fractures. Osteoporosis is defined by the World Health Organization *(3)* as a value of bone mineral density (BMD), 2.5 standard

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deviations (SDs) below the young female adult mean (a *T*-score of ≤–2.5). The number of postmenopausal women above 50 yr of age is about 100 million, and more than two-thirds of them reside in the rural area. About 40%–50% of postmenopausal women have osteoporosis. The gold standard tool for the diagnosis of osteoporosis is the dual-energy X-ray absorptiometry (DXA) scan. However, the restricted availability of DXA *(4)*, coupled with a lack of portability and poor affordability, make it inaccessible to the majority of older women in rural and suburban areas, which bear the brunt of this debilitating condition. Osteoporosis is a clinically silent disease unless complicated by fractures *(5)*, and this calls for active surveillance to establish the diagnosis early and with certainty. The crude incidence rate of osteoporotic fractures at the hip was approximately estimated to be 159/100,000 women per year in a study done by Dhanwal et al in northern India *(6)*.

Osteoporotic fractures pose a tremendous burden on the community, in terms of loss of productivity, increased morbidity *(7)*, prolonged hospital stay, and the huge costs involved in the treatment and rehabilitation of those affected. A recent study from south India has shown that about one-fifth of those who had sustained a hip fracture died by the end of 1 yr *(8)*.

It is therefore imperative to employ reasonably priced alternatives that will cater to the meager resources of rural-dwelling women. The use of quantitative ultrasound (QUS) and multiple risk scoring systems may enable a cost-effective mass screening for osteoporosis in the community.

There has been some interest in the use of clinical risk assessment tools to screen for osteoporosis before a DXA scan *(9)*. These tools serve to analyze the various risk factors for individual patients and thereby assess as to whether the presence of these risk factors warrant further evaluation with a DXA scan. A total of 48 such risk assessment tools have been identified, of which 20 have been externally validated. Eight of these tools were designed to identify subjects at risk of low BMD and 12 were developed to predict fractures *(10)*. There was a significant trade-off seen between sensitivity and specificity for most of the screening tools in previously published literature.

However, there is a paucity of information with regard to the application of these tools in an Indian context. If these tools are found to be appropriate with good sensitivity and acceptable specificity, they can be utilized as effective screening tools. So, we attempted to study the performance characteristics of 6 internationally validated screening tools in predicting osteoporosis at the femoral neck (FN) in rural postmenopausal Indian women.

Methodology

This was a cross sectional study done from October 1, 2014, to March 31, 2016. The study was approved by the institutional review board.

Study Subjects

All ambulatory rural postmenopausal women aged 50 yr and above were recruited from the Vellore district of southern India. Women with a prior diagnosis of osteoporosis, malignancy, stroke, or other conditions leading to immobilization, chronic kidney disease, and chronic liver disease were excluded. Those women on treatment with bisphosphonates and anabolic agents were also excluded.

Sample Size

The number of rural postmenopausal woman in the study area was 180,688. The sample size of 2149 was calculated, keeping a power $(1 - \beta)$ of 80% to produce a statistically significant (α level) 5% based on the sensitivity of Simple Calculated Osteoporosis Risk Estimation (SCORE) that has been published in a previous study *(9)*.

Data Collection

DXA Scan

After obtaining informed consent from the subjects, the estimation of BMD was done at the FN using the DXA scanner (Hologic-QDR 4500-W Discovery-A; Hologic Inc, Bedford, MA, USA). The National Health and Nutrition Examination Survey (NHANES) III Caucasian normative data were used as the reference database in this Hologic machine *(11)*. The subjects were classified as osteoporosis, osteopenia, and normal, depending on the World Health Organization *T*-scores (at the FN) of ≤–2.5, –2.5 to –1.0, and normal ≥–1, respectively. The precision of the DXA scanner for this measurement was about 2%.

Tools

The various screening tools used in this study were

1. SCORE *(12,13)*
2. Age, Bulk, One Or Never Estrogen (ABONE)*(14)*
3. Osteoporosis Self-Assessment Tool for Asians (OSTA) *(15)*
4. Osteoporosis Risk Assessment Instrument (ORAI) *(16)*
5. Fracture Risk Assessment Tool (FRAX®) India (without BMD) *(12)*
6. QUS: BMD estimation with quantitative heel ultrasound (QUS) has been shown to be a predictor for osteoporosis in various studies *(17,18)*. In our study, we used the Japanese-made CM-200 ultrasound bone densitometer, which has been utilized previously *(19)*. The CM-200 measures the speed of sound transmitted through the calcaneum. Sound waves generated from 1 transducer passed through the subject's right heel and were received by the other transducer. The footpad was individually adjusted according to the size of the foot *(19)*. QUS was performed in 850 subjects and had a CV of 3%.

SCORE was developed in a cohort of 1102 postmenopausal women and used the parameters of race, the