Original article

Validation of the Thai Osteoporosis Foundation and Royal College of Orthopaedic Surgeons of Thailand Clinical Practice Guideline for bone mineral density measurement in postmenopausal women

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Abstract

Objective: The primary objective of this study was to determine the sensitivity, specificity, and predictive values of the Thai Osteoporosis Foundation (TOPF) and Royal College of Orthopaedic Surgeons of Thailand (RCOST) Clinical Practice Guideline for bone mineral density (BMD) measurement for the detection of postmenopausal osteoporosis. Its secondary objective was to find better indicators to detect postmenopausal osteoporosis.
Methods: Postmenopausal women were enrolled in this study between June and December 2014. The clinical risk factors following TOPF and RCOST Clinical Practice Guideline for BMD measurement were collected. Bone mineral density was measured using dual energy X-ray absorptiometry.
Results: Four hundred postmenopausal women were enrolled in the study. The mean age of the studied population was 66.16 ± 6.04 years. Twenty-seven percent of the participants had either osteoporosis of the lumbar spine, femoral neck, or total hip, of which 13.3% had osteoporosis at the lumbar spine, 21.3% had osteoporosis at the femoral neck, and 2.5% had osteoporosis of the total hip. The sensitivity and specificity for detecting osteoporosis of the whole TOPF and RCOST guideline were 96.2% and 16.7%, 98.8% and 18.7%, 90.0% and 15.1%, and 97.2% and 19.5% at the lumbar spine, femoral neck, total hip, and any sites, respectively. Multiple logistic regression analysis revealed that only OSTA ≤ -1, osteopenia on X-ray and low trauma fracture after age of 40 years were significant clinical risk factors in the detection of postmenopausal osteoporosis. The Receiver Operating Characteristics (ROC) curve was used to obtain the optimum probability value of osteoporosis at any sites which revealed that the probability value of 0.2222236 would have a sensitivity of 67% and specificity of 62% as the optimal cut point to detect osteoporosis. A simple flow diagram of "OSTA ≤ -1", "Osteopenia on X-ray" and "A history of low trauma fracture after age of 40 years" was developed as a better trade-off guideline for BMD measurement.
Conclusions: This study revealed that the TOPF and RCOST guideline for BMD measurement provided a high true positive rate of disease detection but with an expense of high false positive rate. The simple flow diagram was proposed as a more appropriate guideline for BMD measurement in postmenopausal women.
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Keywords: Thai Osteoporosis Foundation (TOPF) Clinical Practice Guideline; Postmenopausal osteoporosis; Clinical risk factors

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1. Introduction

Osteoporosis is one of the major public health problems among Thai postmenopausal women [1]. A report on the prevalence of osteoporosis in Thai women ranging from 40 to 80 years of age found that approximately twenty percent had osteoporosis of the lumbar spine and fourteen percent had osteoporosis of the femoral neck [2]. The incidence of osteoporosis-related fracture is expected to rise in Thailand as it has already throughout Asia [3]. Osteoporotic fractures can have a devastating impact on quality of life, leading to chronic pain, further illness, disability, or even death [4,5]. This illustrates that early diagnosis of osteoporosis is of great importance, especially since pharmacological treatment has proved to be cost effective.

In 1994, the World Health Organization has proposed to use the operational definition of osteoporosis by BMD T-score criteria. By Dual Energy X-ray Absorptiometer (DXA), osteoporosis is defined as a BMD that lies 2.5 standard deviations or more below the average value for young healthy women (a T-score of <-2.5 SD) [6]. Nevertheless, DXA is costly and is unavailable in most of the health-care centers in Asia, including Thailand. It is not cost effective to measure BMD in all women entering menopause. Clinicians are generally recommended to look for clinical risk factors in order to determine which patients are at an increased risk for osteoporosis which may need further testing with DXA [7]. The appropriate screening tools should be simple, well-validated, and safe to the population [8].

There have been lots of attempts worldwide to develop screening tools to guide physicians in detecting osteoporosis [9]. In 2010, the Thai Osteoporosis Foundation (TOPF) and Royal College of Orthopaedic Surgeons of Thailand (RCOST) developed the Clinical Practice Guideline for BMD measurement [7]. Although the guideline has been available nationwide for over 4 years, it has never been validated in clinical practice. As a matter of fact, it is of practical importance to know which screening tools are appropriate for people living in each particular region. Accordingly, this study was primarily intended to determine the sensitivity, specificity, and predictive values of the TOPF and RCOST guideline for BMD measurement to detect postmenopausal osteoporosis. It was secondarily aimed to find better indicators for the condition.

2. Material and methods

Postmenopausal women exhibiting at least 12 months of amenorrhea were recruited from the Menopause Clinic, King Chulalongkorn Memorial Hospital from June to December 2014. Women were eligible if they were $\geq$40 years and had no previous BMD measurement. Women were excluded if the measurement of BMD could not be performed, e.g. inability to get on the examining table, presence of skeletal structural abnormalities, osteoarthritis, surgical prosthesis, or lumbar scoliosis.

This study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University,

Bangkok, Thailand. After being informed about the objective and methodology of the study, all subjects provided written informed consent before enrollment. The clinical risk factor history was individually assessed. These included those appeared in the TOPF and RCOST indications for BMD measurement which comprised of 1) Female age 65 and older, 2) Early menopause (<45 years), 3) Estrogen deficiency for more than a year before menopause except for women in pregnancy and breast-feeding, 4) Long term glucocorticoid intake (prednisolone 5 mg/day or equal for above 3 months), 5) Parental history of hip fracture, 6) Menopausal women with a body mass index (BMI) less than 19 kg/m^2, 7) Radiographic osteopenia and/or vertebral deformity as shown by X-ray, 8) History of low trauma bone fracture, 9) Decrease in height (>4 cm by hearsay or >2 cm./year by annual measurement), 10) Vulnerable group by OSTA score (OSTA score ≤-1) [OSTA score: Osteoporosis Self-Assessment Tool for Asian score $= 0.2 \times$ [Body weight (kg) $-$ Age (years)] [10].

Weight and height were measured, OSTA score and BMI were calculated then thoraco-lumbar (TL) spine X-ray was performed. The BMD was measured utilizing the DXA system (Hologic Discovery W., Bedford, MA, USA) at the Nuclear Medicine Division, King Chulalongkorn Memorial Hospital. The DXA machine was calibrated every morning with the hip and spine phantoms. The coefficient of variation during the year in which the study was undertaken was less than 1.5%. The results given were those for the mean values of L1 $-$ L4 at the spine, the femoral neck, and the total hip of the non-dominant side. We complied with the WHO criteria of osteoporosis (BMD ≤-2.5 SD) to diagnose osteoporosis in this study.

3. Statistical analysis

The sample size was calculated using the sensitivity and specificity of each of the clinical risk factors, resulting in the maximum sample size for the calculation. Estimation of the prevalence of osteoporosis by expert opinion was 25%. In all, 384 subjects were obtained using a 95% confidence interval and 10% acceptable error rate. Statistical analysis was performed using the SPSS software for Windows, version 17.0. Patient characteristics were calculated by descriptive statistics. Sensitivity, specificity and positive and negative predictive values of both the whole TOPF and RCOST guideline and each item of clinical risk factors were calculated by a 2 x 2 table. Multiple Logistic Regression analysis was used to find the only important clinical risk factors for detecting any site postmenopausal osteoporosis. The Receiver Operating Characteristics (ROC) curve was used to find the optimum probability value for detecting any site postmenopausal osteoporosis. Finally, we developed the simple flow diagram for clinical consideration of patient selection for BMD measurement.

4. Results

A total of 400 postmenopausal women were recruited for the analysis. The mean age and BMI were 66.16 ± 6.04 years