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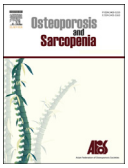

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Original article

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.

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 $\pm$ 6.04 years

Table 1
Baseline demographic data.

Characteristics	Mean ± SD or median
Age (y)	66.16 ± 6.04
BMI (kg/m^2)	24.66 ± 3.98
OSTA score, median (min to max)	−2.15 (−7.32 to 9.60)

BMI: body mass index (kilogram per meter square).

(range, 47–84) and 24.66 ± 3.98 kg/m^2 (range, 17–48), respectively. The median OSTA score was −2.15 (range −7.32 to 9.60) as shown in Table 1.

Using WHO criteria, the prevalence of osteoporosis in this study was 13.3% (53/400), 21.3% (85/400), 2.5% (10/400), and 27% (108/400) at the lumbar spine, femoral neck, total hip, and osteoporosis at any site, respectively. There were 39 participants (9.8%) with either wedge or compressive vertebral fractures without history of significant trauma. All of these vertebral fractures were asymptomatic. There were 10 participants (2.5%) with a history of prolonged use of glucocorticoid (prednisolone ≥5 mg/day or equivalent medications for over 3 months), and only 3 women of this group were diagnosed of osteoporosis. None of the participants in this study had excessive caffeine intake (>4 cups coffee/day) [11], rheumatoid arthritis, chronic anticonvulsant therapy (more than 6 months), or chronic heparin therapy (more than 6 months).

The sensitivity, specificity, and predictive values of the whole TOPF and RCOST guideline for detecting osteoporosis are shown in Table 2, and the sensitivity, specificity, and predictive values of the TOPF guideline for each item are shown in Tables 3–6 for lumbar spine, femoral neck, total hip, and any site osteoporosis, respectively.

OSTA ≤−1 and age ≥65 year were found to have high sensitivity but low specificity whilst the other indications were found to have low sensitivity but high specificity (early menopause, estrogen deficiency more than a year before menopause, long term glucocorticoid intake, parental history of hip fracture, body mass index less than 19 kg/m^2, radiographic osteopenia by X-ray, history of low trauma bone fracture, decrease in height (>4 cm or >2 cm/year). We used multiple logistic regression analysis to identify significant clinical risk factors and the **β** (coefficient of variable) of each particular indication for detecting osteoporosis at any site as shown in Table 7. Only Osteopenia on X-ray, low trauma fracture after age of 40, and OSTA ≤−1 were significantly clinical risk indicators (significant value are less than 0.05).

Table 2
Sensitivity, specificity, and predictive values of the whole TOPF and RCOST guideline for detecting osteoporosis.

Skeletal sites	Sensitivity	Specificity	PPV	NPV
Lumbar spine osteoporosis	96.2	16.7	15.0	96.7
Femoral neck osteoporosis	98.8	18.7	24.7	98.3
Total hip osteoporosis	90.0	15.1	2.65	98.3
Osteoporosis at any site	97.2	19.5	30.9	95.0

NPV: negative predictive value, PPV: positive predictive value, RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

Table 3
Sensitivity, specificity and predictive values of the TOPF and RCOST guideline of each particular indication for detecting lumbar spine osteoporosis.

Indicators	Sensitivity	Specificity	PPV	NPV
OSTA ≤−1	83.0	35.7	16.5	93.2
Age ≥65 y	62.3	33.4	12.5	85.3
Osteopenia on X-ray	26.4	72.3	12.7	86.6
Early menopause	26.4	90.2	29.2	88.9
Low trauma fracture after age 40	9.4	99.4	71.4	87.8
BMI <19 kg/m^2	9.4	96.3	27.8	87.4
Parental hip fracture	11.3	91.4	16.7	87.1
Height loss	7.5	93.1	14.3	86.8
Estrogen deficiency >1 y	5.7	99.4	60.0	87.3
Steroid use >3 mo	3.8	98.8	33.3	87.1

NPV: negative predictive value, OSTA score: Osteoporosis Self-Assessment Tool for Asian score = 0.2 × [Body weight (kg) − Age (y)], PPV: positive predictive value, RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

The logistic regression model estimation can predict the probability (event) for osteoporosis diagnosis in the patient according to this equation:

$$\text{Probability (event)} = \frac{e^z}{1+e^z}$$

where e = the base of natural logarithms (approx 2.72).

$$Z = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p$$

β = the coefficient of the predictor variables

The Receiver Operating Characteristics (ROC) curve was used to obtain the optimum probability value (for optimum sensitivity and specificity) for detecting postmenopausal osteoporosis at any site as shown in Fig. 1.

The relevant ROC curve data (Fig. 2) showed multiple predicted probability value that produced variation in each sensitivity and specificity. We considered the probability value of 0.2222236 (produce sensitivity 67%, specificity 62%) as the optimal statistical cut point for detecting osteoporosis at any site (neither for too high sensitivity with low specificity nor too low sensitivity with high specificity). Then, we developed a simple flow diagram from these

Table 4
Sensitivity, specificity, and predictive values of the TOPF and RCOST guideline of each particular indication for detecting femoral neck osteoporosis.

Indicators	Sensitivity	Specificity	PPV	NPV
OSTA ≤−1	77.6	36.2	24.7	85.7
Age ≥65 y	69.4	34.9	22.3	80.9
Osteopenia on X-ray	41.2	76.2	31.8	82.8
Parental hip fracture	16.5	93.0	38.9	80.5
Early menopause	10.6	87.6	18.8	78.4
Height loss	9.4	93.7	28.6	79.3
Low trauma fracture after age 40	4.7	99.0	57.1	79.4
BMI<19 kg/m^2	5.9	95.9	27.8	79.1
Estrogen deficiency >1 y	2.4	99.0	40.0	79.0
Steroid use >3 mo	1.2	98.4	16.7	78.7

NPV: negative predictive value, OSTA: Osteoporosis Self-Assessment Tool for Asian score = 0.2 × [Body weight (kg) − Age (y)], PPV: positive predictive value, RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

Table 5
Sensitivity, specificity, and predictive values of the TOPF and RCOST guideline of each particular indication for detecting total hip osteoporosis.

Indicators	Sensitivity	Specificity	PPV	NPV
Age ≥65 y	70.0	34.1	2.7	97.8
OSTA ≤−1	40.0	32.6	1.5	95.5
Osteopenia on X-ray	50.0	73.1	4.5	98.3
Steroid use >3 mo	10.0	98.7	16.7	97.7
Early menopause	10.0	87.9	2.1	97.4
BMI<19 kg/m^2	10.0	95.6	5.6	97.6
Parental hip fracture	0.0	98.2	0.0	97.5
Estrogen deficiency >1 y	0.0	98.7	0.0	97.5
Low trauma fracture after age 40	0.0	98.2	0.0	97.5
Height loss	0.0	92.8	0.0	97.3

NPV: negative predictive value, OSTA: Osteoporosis Self-Assessment Tool for Asian score = 0.2 × [Body weight (kg) − Age (y)], PPV: positive predictive value, RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

important indicators to determine BMD measurement for postmenopausal women (Fig. 3). According to the ROC curve, BMD measurement will be considered suitable if the probability >0.22. With this diagram, those who have only "OSTA ≤−1" or "Osteopenia on X-ray" may not be a good candidate for BMD measurement (probability of 0.18 and 0.21, respectively). Nevertheless, those who have either "A history of low trauma fracture after the age of 40 years" or "OSTA ≤−1" with "Osteopenia on X-ray" are found to be a good candidate for BMD measurement (probability of 0.71 and 0.47, respectively).

5. Discussion

This study was initiated to validate the TOPF and RCOST guideline for BMD measurement for the detection of postmenopausal osteoporosis. The results of this study revealed that the guideline, as a whole, had high sensitivity or true positive rate but with the tradeoff of low specificity or high false positive rate in detecting postmenopausal osteoporosis (false positive rate = 1 − specificity). In other words, a sizable number of postmenopausal women without osteoporosis would be indicated for BMD measurement. This would cause patients unnecessary exposure to radiation and healthcare cost for the measurement.

Table 6
Sensitivity, specificity, and predictive values of the TOPF and RCOST guideline of each particular indication for detecting osteoporosis at any site.

Indicators	Sensitivity	Specificity	PPV	NPV
OSTA ≤−1	78.7	37.7	31.8	82.7
Age ≥65 y	69.4	35.3	28.4	75.7
Osteopenia on X-ray	38.0	76.4	37.3	76.9
Early menopause	16.7	89.7	37.5	74.4
Parental hip fracture	13.9	92.8	41.7	74.5
Height loss	10.2	94.2	39.3	73.9
BMI<19 kg/m^2	6.5	96.2	38.9	73.6
Low trauma fracture after age 40	5.6	99.7	85.7	74.0
Estrogen deficiency >1 y	2.8	99.3	60.0	73.4
Steroid use >3 mo	1.9	98.6	33.3	73.1

NPV: negative predictive value, OSTA: Osteoporosis Self-Assessment Tool for Asian score = 0.2 × [Body weight (kg) − Age (y)], PPV: positive predictive value, RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

Table 7
Multiple logistic regression analysis of the TOPF and RCOST guideline of each particular indication for detecting osteoporosis at any site.

Clinical risk indicators	Significant value	Exponential (beta)
Osteopenia on X-ray	0.026	1.779
Low trauma fracture after age of 40	0.015	15.176
OSTA ≤−1	0.031	1.929

OSTA: Osteoporosis Self-Assessment Tool for Asian score = 0.2 × [Body weight (kg) − Age (y)], RCOST: Royal College of Orthopaedic Surgeons of Thailand, TOPF: Thai Osteoporosis Foundation.

When considered each particular indication for BMD measurement, OSTA ≤−1 and age ≥65 years revealed a high false positive rate while the other indications gave a high false negative rate (false negative rate = 1 − sensitivity), early menopause, estrogen deficiency more than a year before menopause, long term glucocorticoid intake, parental history of hip fracture, body mass index lower than 19 kg/m^2, radiographic osteopenia by X-ray, history of low trauma bone fracture, decrease in height (>4 cm or >2 cm/year). These may lead to inappropriate clinical decision for investigation and therapeutic intervention.

We used multiple logistic regression analysis to identify significant clinical risk factors in the detection of postmenopausal osteoporosis and the â (coefficient of variable) of each important clinical risk factor as shown in the Table 7.

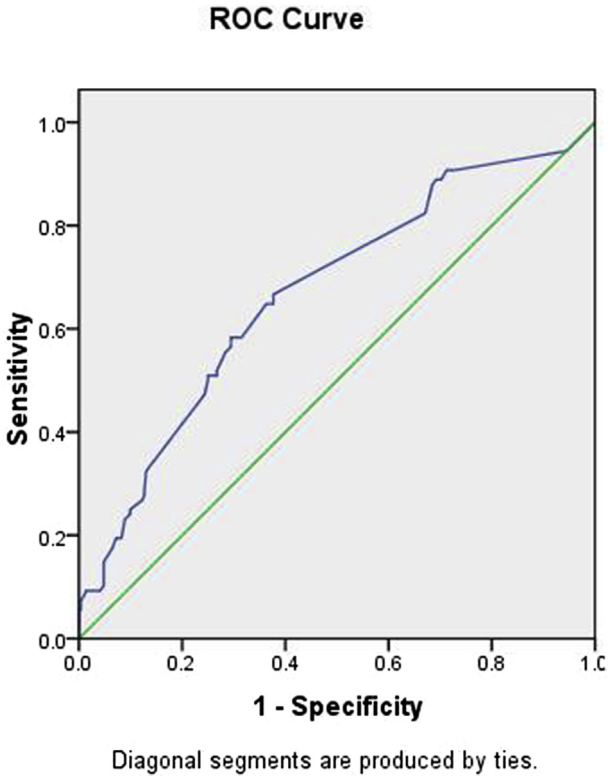

Fig. 1. Receiver Operating Characteristics (ROC) curve.

Coordinates of the Curve

Test Result Variable(s):Predicted probability

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
.0000000	1.000	1.000
.1337777	.944	.945
.1478693	.907	.729
.1678016	.907	.726
.1821651	.907	.719
.1839585	.907	.716
.1850236	.907	.712
.1918636	.889	.702
.1984038	.889	.699
.2010026	.889	.695
.2039619	.889	.692
.2050229	.880	.685
.2120065	.824	.671
.2222236	.667	.377
.2308617	.648	.377
.2381071	.648	.363
.2490133	.583	.315
.2582161	.583	.312
.2661300	.583	.308
.2776925	.583	.301
.2852082	.583	.298
.2935592	.583	.295
.3009187	.565	.295
.3045595	.556	.284
.3059997	.519	.267
.3091309	.509	.267
.3130618	.509	.264
.3218980	.509	.250

Fig. 2. Predicted probability.

The Receiver Operating Characteristics (ROC) curve was used to find the optimum probability (optimum sensitivity and specificity) value for detecting postmenopausal osteoporosis. Finally, we developed a simple flow diagram for clinical consideration of BMD measurement that may be a better tradeoff between the true and false positive rate. With this diagram, those who have only "OSTA ≤ -1" or "Osteopenia on X-ray" may not be a good candidate for BMD measurement as specified in the RCOST and TOPF guideline. Nevertheless, those who have either "A history of low trauma fracture after the age of 40 years" or "OSTA ≤ -1" with "Osteopenia on X-ray" are found to be a good candidate for BMD measurement. The simple flow diagram may be used as clinical decision algorithm for BMD measurement for the benefits of healthcare cost, reducing investigational risk and time consume. Cost-effective analysis should be further considered for the comparison of the current TOPF and RCOST guideline as a whole or for each particular indication with the simple flow diagram developed in this study.

Though the primary determination of the present study was to validate the TOPF and RCOST guideline using BMD as the gold standard, BMD is deemed to be the surrogate outcome of osteoporotic fracture [12]. It's a matter of fact that a half of osteoporotic fractures occurred in those without osteoporosis [13]. It is essential, therefore, for Thailand to have its own information about the risk of fracture once osteoporosis is diagnosed.

The participants of this study enrolled from the catchment area of the Hospital in Bangkok, may not be a good representative for the country which comprises of both rural and urban community. Multicenter study which enrolls people from different regions may increase the possibility to find some other risk factors that might not be included in the TOPF and RCOST guideline. One limitation in this study was the use of single radiologist for the interpretation of osteopenia and vertebral deformity. Though it could prevent inter-observer variations of the radiologic interpretation, the outcome may be subjective and depended on the radiologist. For the applicability of the simple flow diagram to other ethnicities, there may be differences in the prevalence of clinical risk factors used as BMD indicators and the prevalence osteoporosis which might influence the sensitivity, specificity, PPV, NPV and the simple flow diagram. Therefore, it would be more appropriate to validate each ethnicity indication for BMD

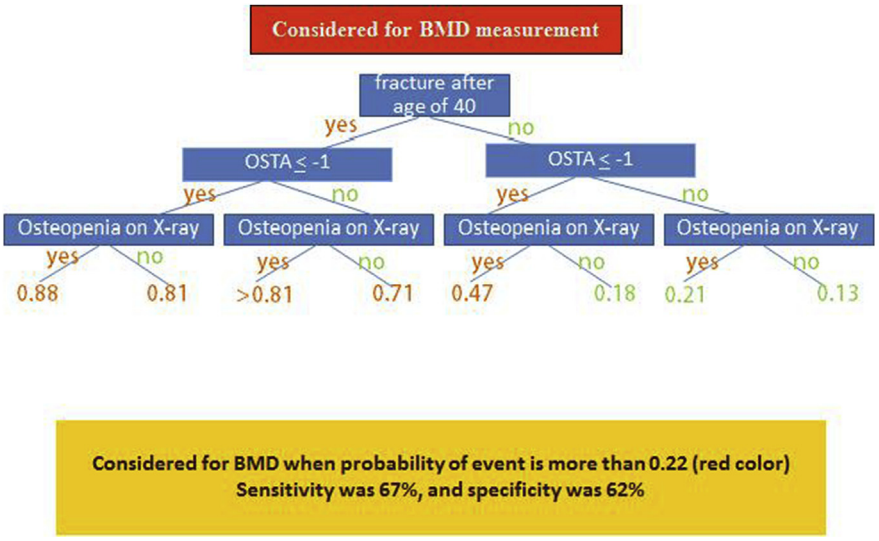

Fig. 3. A simple flow diagram to determine BMD measurement for postmenopausal women. BMD: bone mineral density.

measurement and the simple flow diagram before generalization of the findings to other ethnicity groups.

In conclusion, this study was intended to validate the currently used TOPF and RCOST guideline for BMD measurement in postmenopausal women. The results revealed a high false positive rate of the whole guideline. A simple flow diagram was developed from three significant clinical risk factors identified by the multiple logistic regression. This may be used as a clinical decision making algorithm for an appropriate BMD measurement in postmenopausal osteoporosis.

Conflicts of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing the paper.

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