Validation of the OSTA Index for Discriminating between High and Low Probability of Femoral Neck and Lumbar Spine Osteoporosis among Thai Postmenopausal Women

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Rationale : *Bone mineral density (BMD) measurement of postmenopausal women is needed to diagnose osteoporosis. This is an expensive procedure and available in only a few hospitals in Thailand. The Osteoporosis Self-Assessment Tool for Asians (OSTA) index, based on age and weight, has been developed for screening of postmenopausal Asian women to identify women for whom there is little advantage in undergoing bone densitometry. This index was developed for prediction of neck of the femur osteoporosis and did not include spinal osteoporosis, which is also common. Furthermore, the index was based on data from a sample of mainly ethnic Chinese. There is evidence that the BMD of Thai women is significantly higher for the same age and weight than that of women of several other Asian ethnics, thus there is a need to validate the appropriateness of the OSTA index for both femur and spinal osteoporosis among the Thai population.*
Objective : *To determine the properties of the OSTA index as a screening tool among postmenopausal women in southern Thailand.*
Patients : *Three-hundred-and-eighty-eight postmenopausal women, with no history of disease or use of drugs associated with secondary osteoporosis and no history of treatment for osteoporosis, attending the postmenopausal clinic or internal medicine out-patient department of Songklanagarind Hospital, a teaching hospital in southern Thailand, between November 2000 and April 2002.*
Method : *BMD t-scores of the neck of the femur and lumbar spine were collected retrospectively and a diagnosis of osteoporosis made according to WHO criteria. Sensitivity and specificity and their 95% confidence limits were calculated for the dichotomized OSTA index.*
Results : *Thirty-one percent of the women were detected as having osteoporosis, comprising neck of the femur (12 percent) and lumbar spine (31 percent). Twenty nine women (7.5 percent) had evidence of spinal fracture. The OSTA index at the standard cut-point of $\leq$ -1 had a sensitivity and specificity of 0.93 (95% CI: 0.82 - 0.99) and 0.61 (95% CI: 0.56-0.66) respectively for neck of the femur but only 0.80 (95% CI: 0.72-0.87) and 0.70 (95% CI: 0.64-0.75) respectively for lumbar spine. Raising the cut-point to $\leq$ 0 reduced the high false negative rate (0.20) in prediction of lumbar spine osteoporosis to 0.07 (95% CI: 0.03-0.13) and identified 27 percent (95% CI: 23-32 percent) of all women at low risk of osteoporosis at either site. These women may not need to undergo BMD measurement.*
Conclusion : *The standard cut-point of the OSTA index could identify most Thai postmenopausal women with osteoporosis of the neck of the femur. However, to improve the sensitivity of detection of osteoporosis of the lumbar spine, the cut-point of $\leq$ 0 may be more appropriate.*

Keywords : *OSTA index, Thai postmenopausal women, Femoral neck, Lumbar spine, Osteoporosis*

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Osteoporosis is a systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. In the past, diagnosis was made only after the occurrence of bone fracture, which is a complication of osteoporosis, together with assessment of bone density from plain x-ray film, which lacked both sensitivity and specificity. Thus, treatment was started only in a late stage of the disease and, therefore, could not prevent primary fracture[1]. However, at present, the technology is available for measuring bone density, and this is now the standard for examination and diagnosis of osteoporosis. The World Health Organization (WHO) has established the diagnostic criteria for osteoporosis to be the existence of a bone mineral density (BMD) that is more than 2.5 standard deviations below the young adult reference range or the occurrence of a fracture in response to minute trauma[2].

The consequences of fracture incur considerable expense, and increased probability of morbidity and mortality. Fracture is common in the lumbar spine, femur and extremities and results in long periods of hospitalization. It has been reported that the prevalence of osteoporosis in postmenopausal women is as high as 30 percent and the probability of fracture of the neck of the femur increases 40 percent per 5 years increase in age[3]. There is no reliable report of the incidence of vertebral fracture, because a large proportion of vertebral fractures are asymptomatic[4]. However, it is reported that the prevalence of vertebral fracture in women over 50 years of age is between 16 and 27 percent[5]. Mortality following vertebral fracture has been estimated to be 1.6 times that of women with no such fracture[6]. In the United States, there are 1.5 million fractures per year associated with osteoporosis, with an average total cost of treatment of 1200 dollars per case or a national expenditure of up to 6 billion dollars per year[7-9].

Postmenopausal women form a group of the population with a high risk of osteoporosis owing to a deficiency of oestrogen. Ideally all postmenopausal women should be screened using BMD measurement for diagnosis of osteoporosis and follow-up of treatment [10]. However, as bone densitometers are not widely available, it would be of benefit to introduce a screening tool to identify those women at low risk of osteoporosis, for whom BMD measurement is not worthwhile.

Koh et al[11] investigated 860 postmenopausal women, without known disease or other conditions affecting bone density other than postmenopausal status, from 7 Asian countries, including 11 percent from Thailand, to identify variables associated with osteoporosis of the neck of the femur. From their analysis, they developed the Osteoporosis Self-Assessment Tool for Asians (OSTA), based on the OSTA index defined as:

OSTA index = INTEGER ([2 x bodyweight in kg]/10)
– INTEGER ([2 x age in years]/10)

Women with an OSTA index lower than <= -1 were more likely to have neck of the femur osteoporosis. This cut-point gave a sensitivity of 91 percent and a specificity of 45 percent.

There are some concerns regarding the adoption of the OSTA index in the Thai setting, as Koh's study revealed that the BMD of Thai women, after adjustment for age and bodyweight, was higher than that of other Asian women. Furthermore, Koh's study did not address the prediction of spinal osteoporosis, which is also common. The objectives of the current study, therefore, were 1) to determine the sensitivity and specificity of the OSTA index in predicting both osteoporosis of the neck of the femur and osteoporosis of the lumbar spine, and 2) if necessary, to derive an alternative index or modification of the OSTA index with improved sensitivity in identifying postmenopausal women with osteoporosis at each of these sites.

Material and Method

The registry of all BMD measurements made at Songklanagarind Hospital between 10th November 2000 to 20th April 2002 was reviewed and data pertaining to women whose indication for BMD measurement was postmenopausal status retrieved. The BMD registry included the following data: past history of diseases which may be associated with osteoporosis (disease of the thyroid, parathyroid, liver and kidney, AIDS, Cushing syndrome), and exposure to drugs associated with osteoporosis (corticosteroids, oestrogens, thyroid hormones, bisphosphonate, calcitonin and vitamin D). Women were excluded from the analysis if they had a history of any of these diseases or exposure to any of these drugs, or if they had already received treatment for osteoporosis.

Data obtained from the BMD measurement and used for analysis comprised the neck of the femur t-score, lumbar spine t-score, and evidence of a lumbar spine fracture. Lumbar spine fracture was recorded as positive if the height of any vertebral body was more than 20% less than that of the adjacent vertebrae[12]. Women were classified as having osteoporosis of the

neck of the femur and/or lumbar spine according to WHO criteria[2]. Other variables used in the analysis were age, height, bodyweight and place of residence. Subjects were considered to be an urban resident if their recorded address was located in a provincial capital or in the city of Hatyai; otherwise they were considered as having a rural residence.

The OSTA index was calculated from age and weight and its relationships with the neck of the femur and lumbar spine t-scores explored. The recommended cut-point of -1 was used to calculate the sensitivity and specificity for osteoporosis at each site.

Bone densitometry

Bone density was measured on the neck of the femur on the non-dominant side unless the woman had a history of fracture of the femur or had received a hip prosthesis on that side, in which case bone density measurement was done on the dominant side. Bone density measurement of the lumbar spine was done at L1 to L4. All measurements were made using a dual energy x-ray absorptiometer (DEXA) (Lunar, Madison, WI, USA). Measurements were output from the equipment as the t-score of bone mineral density standardized against the peak reference range for young healthy Asian women, data for which are incor-porated into the programme supplied with the DEXA equipment. As data for healthy young Thai women are not available, the reference data provided were those for Japanese.

Statistical analysis

Comparisons between women with and without osteoporosis of age, bodyweight, height and body mass index were made using Student's unpaired t-test. Place of residence was compared using Pearson's chi square test. P-values of ≤ 0.05 were considered statistically significant. The relationships between OSTA index and t-scores of the neck of the femur and of the lumbar spine were examined using scatter plots and Pearson correlation coefficient. Sensitivity and specificity were calculated for the dichotomized OSTA index and for alternative indices based on the study data, together with their 95% confidence limits based on the binomial distribution. Logistic regression modeling was used to create alternative indices in order to compare their predictive ability with that of the OSTA index using receiver operating characteristics curves.

Results

Data were obtained for 388 women. Mean age was 60.5 years (SD 9.7, range 43 to 91 years), average bodyweight was 57.2 kg (SD 10.3, range 33 to 106 kg), mean height 152.6 cm (SD 6.3, range 135 to 184 cm). Osteoporosis of the neck of the femur was found in 11.8 percent and osteoporosis of the lumbar spine in 30.8 percent. Lumbar spine fracture was detected in 7.4 percent of all women. Seventy-six percent of women had an urban residence.

Compared with the non-osteoporosis group, women with osteoporosis had significantly higher mean age, lower mean bodyweight, lower mean height and lower mean OSTA index (P value for all comparisons < 0.00005). They also had a lower body mass index (P=0.015 and P=0.021 for femur and spinal osteoporosis respectively) (Table 1). Place of residence did not differ significantly among the groups.

Bone mineral density measurements are shown in Table 2. Femoral neck t-score ranged from -

Table 1. Physical characteristics of the study women

	Neck of femur		Lumbar spine	
	Osteoporosis	No osteoporosis	Osteoporosis	No osteoporosis
Number	46	342	119	269
Age (years)	71.3 ± 9.4	59.1 ± 8.9	68.1 ± 9.0	57.3 ± 8.1
Mean ± SD	P < 0.00005		P < 0.00005	
Bodyweight (kg)	50.7 ± 8.7	58.0 ± 10.3	53.5 ± 8.3	58.8 ± 10.8
Mean ± SD	P < 0.00005		P < 0.00005	
Height (cm)	143.9 ± 7.4	153.2 ± 6.0	149.8 ± 6.7	153.8 ± 5.8
Mean ± SD	P < 0.00005		P < 0.00005	
BMI	23.2 ± 3.7	24.7 ± 4.1	23.8 ± 3.4	24.9 ± 4.2
Mean ± SD	P = 0.015		P = 0.021	
OSTA index	-3.76 ± 2.55	-0.19 ± 2.49	-2.62 ± 2.43	0.28 ± 2.40
Mean ± SD	P < 0.00005		P < 0.00005	
Rural residence	22	24	25	23
(%)	P = 0.708		P = 0.651	

Table 2. Bone densitometry values

BMD determination	min	max	mean	SD
Femoral neck t-score	-4.23	4.46	-1.11	1.24
Lumbar spine t-score	-4.95	3.44	-1.35	1.63

4.23 to 4.46 and lumbar spine t-score ranged from -4.95 to 3.44.

BMD t-score of both the neck of the femur and lumbar spine showed a positive relationship with OSTA index (Fig. 1, 2), with Pearson correlation coefficients of 0.66 and 0.53, respectively. Forty six percent of the women had an index less than or equal to the recommended cut-point of -1 and were at higher risk of osteoporosis than the remaining 54 percent. Among the higher risk group, 24 percent had osteoporosis of the neck of the femur compared with only 1 percent among the lower risk group. The discrimination was somewhat less marked for lumbar spine osteoporosis, namely 53 percent compared with 11 percent.

Alternative indices which might more accurately predict the risk of osteoporosis of the neck of the femur and of the lumbar spine were explored by using logistic regression models. For both neck of the femur and lumbar spine osteoporosis, only age and bodyweight contributed significantly to the predictive models. However, whereas the OSTA index was constructed using age in years and bodyweight in kilograms with equal weighting, the logistic models suggested unequal weightings for these two variables. The discriminative ability of the alternative indices was compared with that of the OSTA index by examining the receiver operating characteristics curves, as shown in Fig. 3 and 4. The congruence of the curves for the OSTA and alternative indices shows that the alternative indices were not superior in predictive ability.

Using the OSTA index with the original cut-point of -1 resulted in only 3 of the 46 women with osteoporosis of the neck of the femur not being detected,

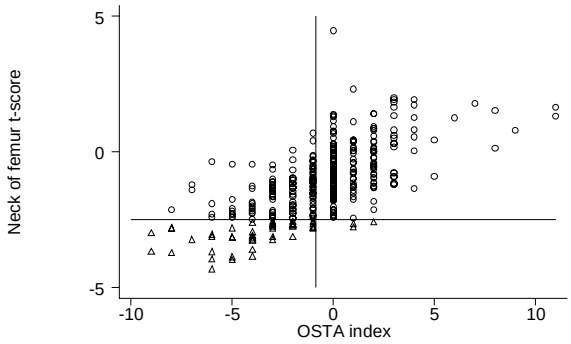

Fig. 1 Scatter-plot of neck of femur BMD t-score and OSTA index. The horizontal line represent a t-score of -2.5 and the vertical line the position of the conventional cut-point of -1. Triangles represent women with, and circles women without, osteoporosis of neck of femur

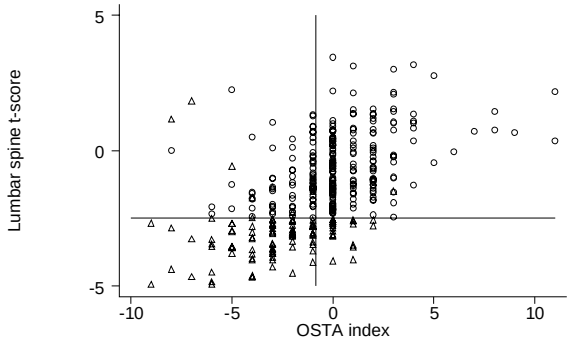

Fig. 2 Scatter-plot of lumbar spine BMD t-score and OSTA index. The horizontal line represent a t-score of -2.5 and the vertical line the position of the conventional cut-point of -1. Triangles represent women with, and circles women without, osteoporosis of lumbar spine

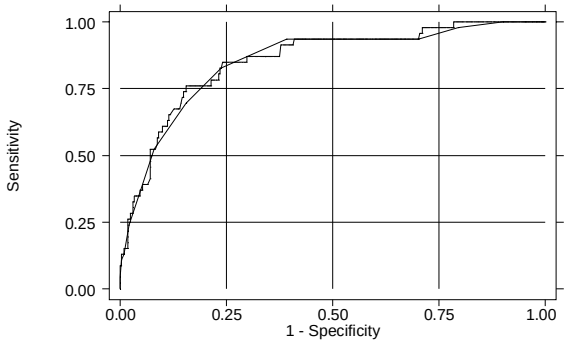

Fig. 3 ROC curves of OSTA index (smoother line) and logistic model (stepped line) for prediction of osteoporosis of neck of femur

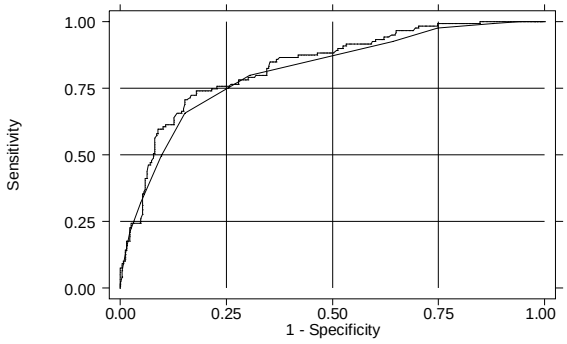

Fig. 4 ROC curves of OSTA index (smoother line) and logistic model (stepped line) for prediction of osteoporosis of lumbar spine

that is a false negative rate of 6.5 percent. However, among the 119 women with osteoporosis of the lumbar spine, 24 failed to be detected at this cut-point - a false negative rate of 20.1 percent (Table 3).

Raising the cut-point to zero reduced the false negative rate among women with osteoporosis of the lumbar spine 7.5 percent, with no effect on the false negative rate among women with osteoporosis of the neck of the femur. With the prevalences of osteoporosis in the present study sample, the probabilities of having osteoporosis of the neck of the femur and of the lumbar spine among women whose OSTA index was greater than zero were 0.03 and 0.09 respectively.

Discussion

The ultimate goal of applying a simple indicator of osteoporosis is to identify women at low risk of having osteoporosis who, therefore, need not undergo BMD measurement. Two major criteria for the successful application of such an indicator are that 1) to be of practical benefit, the "low risk" group must comprise a reasonable proportion of the postmenopausal women under consideration, and 2) the actual risk of having osteoporosis among the "low risk" group must be sufficiently low. The present findings suggest that the conventional application of the OSTA index adequately meets these criteria only for osteoporosis of the neck of the femur. In the case of osteoporosis of the lumbar spine, the lower sensitivity and the higher prevalence resulted in a low negative predictive value. This could be improved, however, by raising the cut-point from -1 to zero.

The almost 3-fold higher prevalence of spinal osteoporosis compared with neck of the femur osteoporosis in the present series of women differs from the relative prevalence of osteoporosis at these two sites reported in an American population in which the prevalence of osteoporosis at each site among women aged 50 or over was about 16 percent[5]. However, the predominance of spinal osteoporosis among Thai postmenopausal women has been reported earlier (Korpchit). Osteoporosis of the lumbar spine increases the risk of spinal fracture, and in the present series 7.4 percent of women already showed evidence of spinal fracture on the BMD measurement. Mortality has been reported to be increased 1.6 times in women having spinal fracture compared with similarly aged women with no spinal fracture[6]. Thus, screening limited to femoral osteoporosis may miss a large number of patients at risk of spinal osteoporosis and might lead to considerable morbidity and mortality.

In applying a screening tool, the optimum characteristics need to be established for the particular setting. This is partly because the main desired properties (high sensitivity and identification of women at low risk) are in conflict - increasing the sensitivity and thereby reducing the number of false negatives also reduces the proportion of women identified as not needing to undergo BMD measurement. The authors' suggested increase in the cut-point to zero has the disadvantage of reducing the size of the "low risk" group (from 54 to 27 percent of all women), but has no effect on the number of false negatives among women with neck of the femur osteoporosis and decreases the number of false negatives among women with spinal osteoporosis to less than half (20 to 7.6 percent in the present study).

Until recently, few Thai postmenopausal women underwent BMD measurement, as the equip-

Table 3. Distribution of OSTA index according to conventional cut-point of -1

OSTA index	Neck of femur		Lumbar spine	
	osteo-porosis	no osteo-porosis	osteo-porosis	no osteo-porosis
≤ -1	43	134 (FP)	95	82 (FP)
> -1	3 (FN)	208	24 (FN)	187
Total	46	342	119	269

FP, false positive; FN, false negative

Table 4. Distribution of OSTA index according to the modified cut-point of zero

OSTA index	Neck of femur		Lumbar spine	
	osteo-porosis	no osteo-porosis	osteo-porosis	no osteo-porosis
≤ 0	43	240 (FP)	110	173 (FP)
> 0	3 (FN)	102	9 (FN)	96
Total	46	342	119	269

FP, false positive; FN, false negative

Table 5. Sensitivity and specificity of the OSTA index using cut-points of -1 and zero

Cut point	Site	Sensitivity % (95% CI)	Specificity % (95% CI)
-1	neck of femur	93.5(82.1-98.6)	60.8(55.4-66.0)
	lumbar spine	79.8(71.5-86.6)	69.5(63.6-75.0)
0	neck of femur	93.5(82.1-98.6)	29.8(25.0-35.0)
	lumbar spine	92.4(86.1-96.5)	35.7(30.0-41.7)

ment was not available. With the introduction of bone densitometers in a number of tertiary level hospitals, the question of who to advise to undergo BMD measurement and who need not will become increasingly relevant and a screening test such as the modified OSTA suggested by the present study may provide a useful aid in decision-making. The impact of false negatives will need to be considered, but this depends to a large extent on the risks of fracture in undetected osteoporosis cases. Little information is currently available on these risks in the Thai population.

This study has a number of limitations. The use of routinely collected data restricted the number of variables available for developing an alternative index to predict BMD. Identification of spinal fracture at BMD measurement is not the gold standard, and in the present study only the antero-posterior view was employed rather than both antero-posterior and lateral plane x-ray, so that some less significant spinal fractures may have been undetected[12,13]. Finally, the representativity of the study sample should be considered. Women in the present study comprised mainly residents of Hatyai who attended the postmenopausal clinic voluntarily or themselves requested BMD measurement. All women had to cover the cost of the procedure. Thus, the study women were generally of mid-to high economic status and generally well-informed about the characteristics of menopause. Generalization to the population of Thai postmenopausal women in general should be made with caution.

In conclusion, the standard cut-point of the OSTA index could identify most Thai postmenopausal women with osteoporosis of the neck of the femur. However, to improve the sensitivity of detection of osteoporosis of the lumbar spine, a cut-point of ≤ 0 may be more appropriate.

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การทดสอบการใช้ OSTA index ในการคัดกรองหญิงไทยวัยหมดประจำเดือนที่มีโอกาสเสี่ยงที่จะมีภาวะกระดูกพรุน

ศรายุทธ ลูเซียน กีเตอร์, รัตนา ลีลาวัตนา, อลัน กีเตอร์

บทนำ : การวัดมวลกระดูก (bone mineral density, BMD) ในผู้หญิงวัยหมดประจำเดือนมีความจำเป็นเพื่อที่จะค้นหาผู้ที่มีภาวะกระดูกพรุน (osteoporosis) แต่เนื่องจากการตรวจดังกล่าวมีค่าใช้จ่ายสูงและสามารถทำการตรวจได้เพียงไม่กี่โรงพยาบาลในประเทศไทย The Osteoporosis Self-Assessment Tool for Asians (OSTA) index ได้คิดขึ้นโดย Koh และคณะ โดยใช้ อายุและน้ำหนัก มาช่วยทำนายการเป็นภาวะกระดูกพรุนสำหรับผู้หญิงวัยหมดประจำเดือนชาวเอเชียเพื่อแบ่งกลุ่มตามโอกาสที่จะเป็นภาวะกระดูกพรุนอย่างไรก็ตาม OSTA ได้ถูกสร้างมาเพื่อทำนายเฉพาะภาวะกระดูกพรุนของส่วนคอของกระดูกต้นขา (neck of femur) อย่างเดียว และในรายงานดังกล่าวแสดงให้เห็นว่ามวลกระดูกของชาวไทยและมาเลย์จะมีค่าสูงกว่าชนชาติเอเชียชาติอื่นจึงเป็นที่มาของข้อสงสัยที่ว่า OSTA index จะสามารถใช้ได้อย่างเหมาะสมในภาคใต้ของไทยหรือไม่ และ OSTA index สามารถใช้ทำนายภาวะกระดูกพรุนของส่วนคอของกระดูกสันหลังส่วนเอว (lumbar spine) ได้หรือไม่

จุดประสงค์ : เพื่อหาความไวและความจำเพาะของการใช้ OSTA index ในประชากรไทยในภาคใต้ และปรับเปลี่ยน OSTA index เพื่อให้มีความไวเพิ่มขึ้น

วิธีการ : ค้นหาข้อมูลการวัดค่ามวลกระดูกของ neck of femur และ lumbar spine ของผู้หญิงวัยหมดประจำเดือนซึ่งไม่มีประวัติเป็นโรคหรือใช้ยาที่อาจทำให้เกิดภาวะกระดูกพรุนและไม่ได้รับยารักษาภาวะกระดูกพรุนอยู่ก่อน ในช่วง พ.ย. 2543 ถึง เม.ย. 2545 การวินิจฉัยภาวะกระดูกพรุนใช้ตามคำจำกัดความขององค์การอนามัยโลก (World Health Organization, WHO)

ผลการศึกษา : จากข้อมูลของผู้หญิงวัยหมดประจำเดือนทั้งหมด 388 คน มีความชุกของภาวะกระดูกพรุนของ ร้อยละ 31 โดยเกือบทั้งหมดเป็นภาวะกระดูกพรุนของ neck of femur ร้อยละ 31 ความชุกของภาวะกระดูกพรุนของ lumbar spine เท่ากับร้อยละ 12 และมีความชุกของกระดูกสันหลังหักเท่ากับร้อยละ 7 เมื่อใช้ OSTA index โดยใช้ cut point ที่ -1 จะมีความไว (sensitivity) และความจำเพาะ (specificity) เท่ากับร้อยละ 93 (95% CI: 82-98) และร้อยละ 61 (95% CI: 56-66) ตามลำดับสำหรับ neck of femur และร้อยละ 80 (95% CI: 72-87) และร้อยละ 70 (95% CI: 64-75) สำหรับ lumbar spine สำหรับ lumbar spine มี false negative rate เท่ากับร้อยละ 20 ซึ่งการเปลี่ยน cut point จาก -1 เป็น 0 จะสามารถช่วยลด false negative rate เป็นร้อยละ 7 ได้

สรุป : ในหญิงไทยการเปลี่ยน cut point ของ OSTA เป็น 0 จะช่วยลด false negative rate ได้ ในขณะที่เรายังสามารถคัดกรองคนที่ไม่จำเป็นต้องส่งไปตรวจมวลกระดูกได้ร้อยละ 27 (95% CI: 23-32)