Combined Clinical Risk Indices with Quantitative Ultrasound Calcaneus Measurement for Identifying Osteoporosis in Thai Postmenopausal Women

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Objective: *To examine the diagnostic performance of clinical risk indices combined with quantitative ultrasound calcaneus measurement (QUS) for identifying osteoporosis in Thai postmenopausal women.*
Material and Method: *The present study was designed as a cross-sectional investigation in 300 Thai women, aged between 38 and 85 years (mean age: 58). Femoral neck bone mineral density (BMD) was measured by DXA (Hologic QDR-4500; Hologic, Bedford, MA, USA). A BMD T-scores ≤ -2.5 was defined as "osteoporosis"; otherwise, "non-osteoporosis". QUS was measured by Achilles+ (GE Lunar, Madison, WI, USA) and converted to T-score. The OSTA and KKOS score was calculated for each woman using her age and weight Women with OSTA/KKOS scores ≤ -1 and > -1 were classified as "high risk" and "low risk", respectively.*
Results: *Using DXA as the gold standard, the sensitivity of QUS to identify osteoporosis was lower than the sensitivity of OSTA/KKOS (60 vs. 71/74%) but the specificity and PPV of QUS were higher than OSTA/KKOS. The sensitivity increased when using OSTA/KKOS combined with QUS to identify osteoporosis (~87-89%) while the specificity, PPV and NPV were comparable with using clinical risk indices alone. The risk (odds ratio; OR) of osteoporosis when QUS T-score ≤ -2.5 alone was 9.94 (95%CI: 4.74-20.87), which was higher than high risk by OSTA/KKOS alone (OR: 6.35, 95%CI: 2.99-13.47 for OSTA and 8.15, 95%CI: 3.76-17.66 for KKOS). Furthermore, individuals were classified "high risk" from OSTA/KKOS with QUS T-score ≤ -2.5SD, the risk of osteoporosis was increased (OR: 43.68, 95%CI: 13.89-137.36 and OR: 60.92, 95%CI: 17.69-209.76 for OSTA and KKOS, respectively).*
Conclusion: *Using the clinical risk indices combined with QUS could improve the accuracy of osteoporosis identification. This approach could be used in a primary care setting or community-based hospital where a DXA machine is not available.*

Keywords: *Bone mineral density, Clinical risk index, Epidemiology, Osteoporosis, Quantitative ultrasound measurement*

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With the on-going aging global population, osteoporosis has rapidly become a worldwide concern because of its age-associated, exponentially increased prevalence, morbidity, mortality and costs[1]. The ultimate aim of identifying individuals with osteoporosis is to prevent fracture by intervention. Bone mineral density (BMD) measured by dual energy X-ray absorptiometry (DXA) is widely recognized as the strongest predictor for future fracture occurrence[2], but the instrument is relatively expensive and is not widely available in most developing countries including Thailand.

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Therefore, using DXA for mass screening in postmenopausal women is not cost-effective and recommended without some selection of the target population[3-8].

Effort to use clinical risk indices to identify subjects likely to have low BMD is regarded as an attractive and cost-effective approach to the prevention of osteoporosis. For Asians particularly in Thai postmenopausal women, there are two clinical risk indices; 1) Osteoporosis Self-Assessment Tools for Asians (OSTA)[9] and 2) Khon Kaen Osteoporosis Study score (KKOS)[10] were used in identifying osteoporosis. However, the sample in which OSTA was developed largely came from the Chinese population, among whom lifestyles and behavioral factors are likely to be different from other developing populations such as Thai. Moreover, the OSTA score had a high sensitivity but low specificity and low positive predictive value (PPV) in the identification of osteoporotic Thai women[11] and can result in high false positive rates when used on the general population. While KKOS, a Thai-specific clinical risk score was more sensitive and specific, and had modest PPV, it also required further research and evaluation[10].

Quantitative ultrasound (QUS) calcaneus measurement, a portable, less expensive, less time-consuming without radiation technique; has been developed as an alternative method for assessment of BMD. However, the diagnostic performance of QUS for identifying osteoporosis was equivocal[12-14]. A recent study on Thai postmenopausal women reported that the diagnostic performance of QUS calcaneus measurement in case findings for osteoporosis had a low sensitivity but high specificity[15].

Therefore, this present study was designed to determine the diagnostic performance when using clinical risk indices (OSTA or KKOS) combined with QUS of the calcaneus for identifying osteoporosis in Thai postmenopausal women.

Material and Method

Setting and Subjects

The present study was designed as a cross-sectional investigation in 300 consecutive newly postmenopausal women (defined by no menstruation normally for at least 1 year) who came to evaluate possible osteoporosis at the outpatient clinics of the Nuclear Medicine Division, Phramongkutklao Hospital, Bangkok, Thailand. All women were of Thai background and were excluded from analysis if they had a history of metabolic bone disorders (other than postmenopausal bone loss), presence of cancer(s) with known metastasis to bone, history of previous hip or calcaneal fracture, history of hip or knee prosthesis, abnormal features of bone at the calcaneus on physical examination, or history of calcification at the calcanal bone from disease of the calcaneus, *i.e.*, plantar fasciitis, plantar fibroma, retrocalcaneal bursitis or ankle sprain/strain. The present study was approved by the Ethics Committee of Phramongkutklao College of Medicine and informed consent was obtained from all subjects. The present study was conducted in accordance with the Helsinki Declaration in 1975 and as revised in 2000 (Edinburgh).

Measurements

Subjects were invited to meet with a trained research nurse who completed a questionnaire and an informed consent form. Body weight (including light indoor clothing) was measured using an electronic balance scale (accuracy 0.1 kg) and standing height (without shoes) with a stadiometer (nearest 0.1 cm).

The OSTA and KKOS scores were then calculated for each woman by using her age and weight[9,10]. The OSTA score was calculated as follows: 0.2 (weight-age)[9]. Whereas, the KKOS score was shown in Table 1, the summation scores (age and weight) was used to evaluate risk[10]. Individuals with OSTA/KKOS scores being $\leq$ -1 were classified as "high risk", and otherwise, a "low risk" classification was made[9,10].

Bone mineral density (g/cm^2) was measured at the femoral neck by DXA using a Hologic QDR-4500

Table 1. KKOS scoring system

Age (y)	Score	Weight (kg)	Score
< 45	+7.5	< 30	-14
45-49	+6.0	30-34	-12
50-54	+4.5	35-39	-10
55-59	+3.0	40-44	-8
60-64	+1.5	45-49	-6
65-69	0	50-54	-4
70-74	-1.5	55-59	-2
75-79	-3.0	60-64	0
80-84	-4.5	65-69	+2
85-89	-6.0	70-74	+4
> 90	-7.5	75-79	+6
		80-84	+8
		85-89	+10
		> 90	+12

Note; The KKOS score was calculated by the summation of age and weight scores
KKOS score $\leq$ -1: high risk, KKOS score >-1: low risk

densitometer (Hologic, Bedford, MA, USA). The BMD measurement was expressed in T-score and used as a gold standard. QUS of the calcaneus was measured using an Achilles express ultrasound device (Lunar, Madison, WI, USA). In the present study, the QUS was measured twice for test-retest reliability by the same technologist. The first was carried out before the DXA and the second after the DXA was carried out. The duration of both measurements did not exceed 30 minutes. The QUS measurement was expressed in T-score, which was provided by the instrument.

Statistical analyses

Descriptive statistics were used to describe study subjects' characteristics. In the present study, BMD from DXA was used as a gold standard. Each woman was classified as having "osteoporosis" if her BMD T-score was equal to or less than -2.5; otherwise the woman was classified as "non-osteoporosis". The concordance between the QUS, OSTA and KKOS alone, or OSTA/KKOS score combined with QUS classification and the actual BMD-based classification (by DXA) can be summarized by a 2x2 table, from which index or concordance, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were derived. Sensitivity is defined as the proportion of osteoporotic individuals who are identified as "high risk" by the OSTA/KKOS score and/or QUS T-score $\leq$ -2.5SD. Specificity is the proportion of non-osteoporosis individuals who are identified by the OSTA/KKOS score as "low risk" and/or QUS T-score > -2.5SD. PPV is the probability that an individual with a "high risk" by OSTA/KKOS and/or QUS T-score $\leq$ -2.5SD indeed has osteoporosis. NPV is the probability that an individual with a "low risk" by OSTA/KKOS and/or QUS T-score > -2.5SD indeed has non-osteoporosis. The intra-class correlation coefficient (ICC) was calculated based on the degree of correspondence between the first and second QUS measurements. The association between osteoporosis defined by DXA (outcome) and QUS/OSTA/KKOS (predictor) was assessed, in which the odds ratio (*OR*) and 95% confidence interval (CI) were presented. A p-value of less than 0.05 was considered statistical significant.

Results

Three hundred Thai women, aged between 38 and 85 years were included in the present study; of those, 21.7% (n = 46) were aged 65 years or older. The mean $\pm$ SD of age and body weight was 57.9 $\pm$ 8.7 years and 57.5 $\pm$ 9.1 kg, respectively. The mean age at menopause was 46.7 $\pm$ 5.5 years, with the average duration of menopause being 11 years. Femoral neck BMD by DXA was normally distributed with mean 0.69 $\pm$ 0.12 g/cm^2. The average T-score for femoral neck BMD and calcaneal BMD was -2.04 $\pm$ 1.16 and -1.26 $\pm$ 1.54, respectively. The prevalence of osteoporosis in the entire sample was 12.7% (n = 38/300) by femoral neck BMD and 19.3% (n = 58/300) by QUS of calcaneus. In the present study, osteoporotic women were, on average, older, had shorter height, and lower body weight than those with non-osteoporosis. Furthermore, all QUS measurement was significantly lower in the osteoporosis group compared to the non-osteoporosis group and the differences persisted even after adjusting for age (Table 2). In the present study, the ICC of two QUS measurement was 0.976 ($p < 0.001$), which indicated that the measurements of QUS had high reliability.

Using DXA as the gold standard, the sensitivity of QUS to identify osteoporosis was lower than

Table 2. Characteristics of study subjects

Variable	Non-osteoporosis	Osteoporosis	p-value
N	262 (87.3%)	38 (12.7%)	
Age	56.8 (8.1)	65.7 (9.4)	<0.0001
Weight	58.3 (8.9)	51.7 (8.5)	<0.0001
Height	155.5 (5.8)	151.3 (6.6)	0.0002
Body mass index	24.1 (3.4)	22.5 (3.0)	0.0065
Femoral neck BMD	0.72 (0.10)	0.51 (0.06)	<0.0001
Femoral neck T-score	-1.00 (1.01)	-3.10 (0.58)	<0.0001
QUS T-score	-1.06 (1.49)	-2.59 (1.24)	<0.0001
OSTA score	0.37 (2.26)	-2.79 (2.99)	<0.0001
KKOS socre	1.69 (4.13)	-3.63 (5.07)	<0.0001

Notes: Values are mean (SD)

Table 3. Diagnostic performance of QUS, OSTA, KKOS and OSTA/KKOS with QUS to define osteoporosis using BMD-based DXA as the gold standard

Tools	Sensitivity	Specificity	PPV	NPV	Odds ratio (95%CI)
	(%)	(%)	(%)	(%)	
QUS	60.5	86.4	39.7	93.8	9.94 (4.74-20.87)
KKOS	73.7	74.4	29.5	95.1	8.15 (3.76-17.66)
OSTA	71.1	72.1	27.0	94.5	6.35 (2.99-13.47)
KKOS and/or QUS	89.5	65.6	27.4	97.7	16.24 (5.59-47.20)
OSTA and/or QUS	86.8	63.7	25.8	97.1	11.60 (4.38-30.72)
KKOS and QUS	81.0	93.5	58.6	97.7	60.92 (17.69-209.76)
OSTA and QUS	77.3	92.8	56.7	97.1	43.68 (13.89-137.36)

PPV; positive predictive value, NPV; negative predictive value

the sensitivity of OSTA and KKOS but the specificity and PPV of QUS were higher than OSTA and KKOS. In the presented population, the sensitivity, specificity and PPV of OSTA and KKOS were equivalent. The sensitivity increased when using OSTA/KKOS combined with QUS to identify osteoporosis while the specificity was lower. However, the PPV was comparable with using clinical risk indices alone (Table 3). Individuals were classified "high risk" by OSTA/KKOS and also had QUS T-score $\leq$ -2.5SD, the sensitivity and specificity were high (77.3, 92.8 and 81.0, 93.5% for OSTA and KKOS, respectively) while the PPV were modest (56.7 and 58.6% for OSTA and KKOS, respectively).

In the present study, the risk (odds ratio; *OR*) of osteoporosis was 9.94 (95%CI: 4.74-20.87) when using QUS alone, which was greater than using OSTA or KKOS alone. However, subjects were classified "high risk" from OSTA/KKOS and had QUS T-score $\leq$ -2.5SD, the risk was increased (*OR*: 43.68, 95%CI: 13.89-137.36 for OSTA and *OR*: 60.92, 95%CI: 17.69-209.76 for KKOS), (Table 3, Fig. 1-2).

Discussion

According to Thai health promotion policy, osteoporosis has become a major concern. Ideally, all postmenopausal women, high risk for osteoporosis, should be screened by BMD measurement for diagnosis and follow-up of treatment. However, as DXA machines are available in only a few hospitals in Thailand and this measurement is an expensive procedure. Thus, simple clinical risk indices (OSTA and KKOS) have been developed in identification of osteoporosis for cost-effective approach[9,10]. Notwithstanding, there are some limitations for these tools[10,11]. QUS is potentially a new method of BMD measurement with low cost might be used for screening osteoporosis instead of DXA. However, a recent meta-analysis of the accuracy of QUS concluded that "the current available literature suggests that results of QUS alone at commonly used cut-off thresholds do not definitely exclude or confirm DXA-determined osteoporosis"[16]. The present study aimed to determine the diagnostic performance of osteoporosis when using clinical risk indices combined with QUS.

In the present study, QUS calcaneus measurement was found to have high specificity and NPV, but modest sensitivity and low PPV. The diagnostic performance of OSTA and KKOS were equivalent. However, both simple tools had a higher sensitivity, lower specificity and PPV compared with QUS alone. Using OSTA/KKOS combined with QUS, the sensitivity increased up to 89%, but the specificity decreased a bit (~9%). In this present study, the sensitivity, specificity, and NPV when individuals were classified "high risk" by OSTA/KKOS and QUS T-score $\leq$ -2.5SD were high but the PPV was modest (Table 3).

The strength of association between osteoporosis defined by DXA and tools (QUS/OSTA/KKOS) observed in the present study. That is, the presence of QUS T-score $\leq$ -2.5SD and/or a "high risk" classified by OSTA/KKOS increased the risk of osteoporosis by between 6.3 and 9.9-fold. Moreover, the risk of osteoporosis increased up to 44- and 61-fold in individuals with "high risk" by OSTA or KKOS and had QUS T-score $\leq$ -2.5SD.

There is evidence that results of BMD measurement can influence a women's use of therapeutic alternatives[3,5,7]. For example, postmenopausal women with low BMD are more likely to take an anti-resorptive agent as a prevention or treatment[4,5]. Therefore, iden-

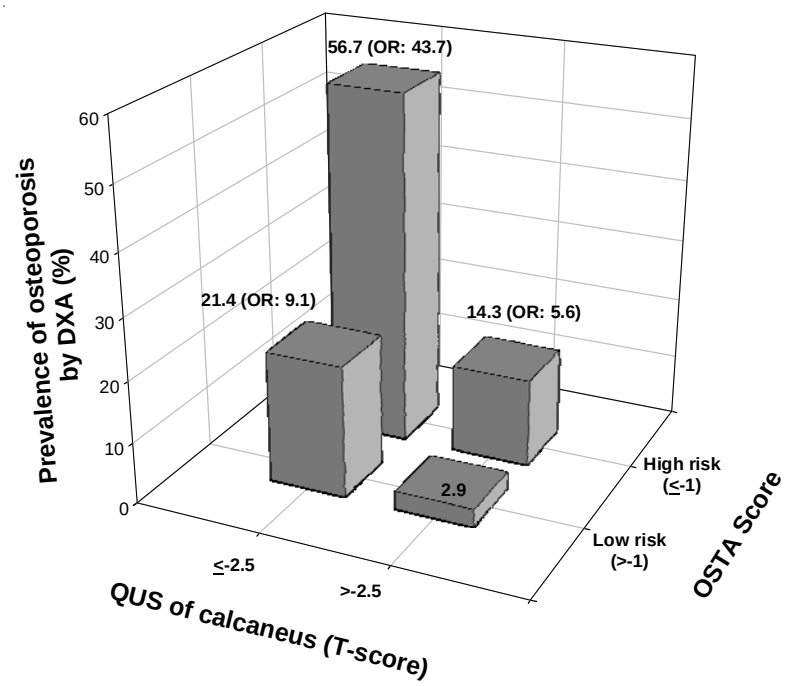

Fig. 1 Prevalence of osteoporosis (by DXA) according to QUS of calcaneus and OSTA score

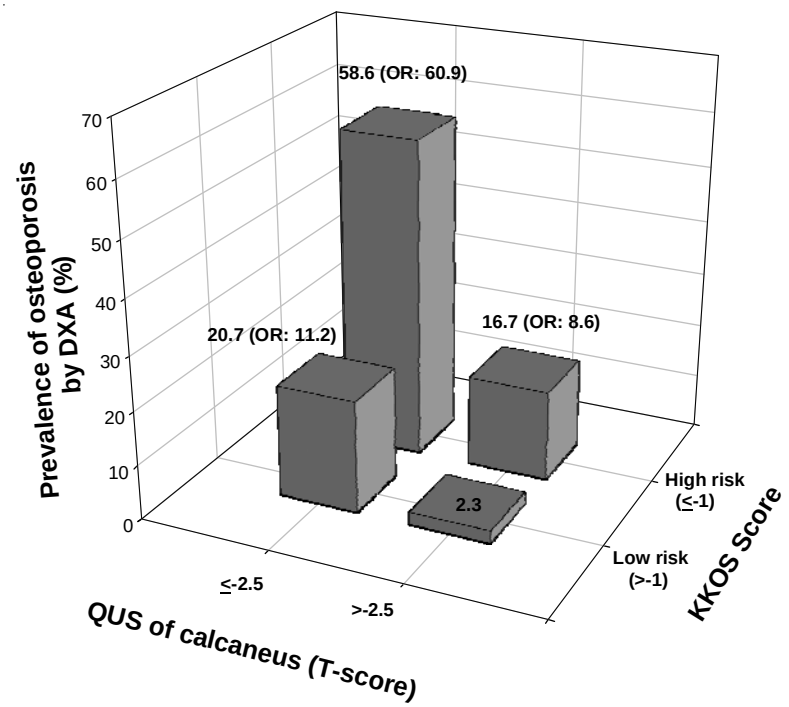

Fig. 2 Prevalence of osteoporosis (by DXA) according to QUS of calcaneus and KKOS score

tifying women who are likely to have low BMD may increase awareness of osteoporosis treatment, and could contribute to the prevention of osteoporotic fracture. While DXA machines are not available and the clinical risk indices or QUS alone is not sensitive enough. From the results of the present study, using the clinical risk indices combined with QUS calcaneus for identifying osteoporosis showed higher sensitivity and comparable specificity, and suggests that its use in clinical practice may encourage women to take preventative measures to preserve their skeletal status and could ultimately reduce fracture incidence.

The present findings must be interpreted within the context of a number of potential strengths and weaknesses. A major strength of the present study lies in its validity and sampling scheme. The measurement of BMD in the present study was based on the DXA instrument, which is considered to be one of the most accurate and valid methods of measurement. The sample size was reasonably large to allow for a stable estimation for identify osteoporosis. Despite the fact that subjects in the present study were randomly selected, well characterized, the study subjects were Thai, among whom, body size, lifestyles, cultural backgrounds and environmental living conditions were different from other populations. Thus, care should be taken when extrapolating these results to other populations.

It is expected that the present results are likely to be valid in similar populations (i.e., Asian, postmenopausal women). Further validation of the current study is required to evaluate its discriminatory performance using data from completely independent populations. Although the OSTA/KKOS scoring and QUS results may help to guide a decision about the need for BMD measurement and intervention; clinical judgment in individual cases is always important. In addition, both clinical risk indices and QUS calcaneus measurement do not address follow-up DXA testing for future diagnostic evaluation, or the follow-up efficacy of treatment strategies[13,14]. Notwithstanding the fact that results from the present study can imply its use in community-based hospitals, DXA machines are not available. Individuals with high risk by OSTA/KKOS with QUS T-score $\leq$ -2.5SD should be considered for treatment, although BMD measurement by DXA is not evaluated, since the risk osteoporosis is very high. However, individuals who were classified as high risk by OSTA/KKOS or had QUS T-score $\leq$ -2.5SD, the BMD measurement by DXA is suggested before the treatment is started, since the PPV in this group was modest and could result in a high false positive rates in the general population (~30%).

In conclusion, identification of high-risk individuals for intervention is one of the priorities in osteoporosis research. The present study showed that using the clinical risk indices combined with quantitative ultrasound calcaneus measurement could improve the accuracy of osteoporosis prediction. This approach could be applied in a primary care setting or community-based hospital where DXA machines are not available.

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การใช้ดัชนีชี้วัดความเสี่ยงทางคลินิกร่วมกับอัลตราซาวด์ส้นเท้าในการวินิจฉัยโรคกระดูกพรุนในสตรีไทยวัยหมดประจำเดือน

ฉัตรเลิศ พงษ์ไชยกุล, สุธี พานิชกุล, ทวี ทรงพัฒนาศิลป์

วัตถุประสงค์: *เพื่อศึกษาความถูกต้องของการใช้ดัชนีชี้วัดความเสี่ยงทางคลินิกร่วมกับการตรวจอัลตราซาวด์กระดูกส้นเท้าในการวินิจฉัยโรคกระดูกพรุนในสตรีไทยวัยหมดประจำเดือน*

วัสดุและวิธีการ: *เป็นการศึกษาแบบตัดขวางในสตรีไทยจำนวน 300 รายที่มีอายุระหว่าง 38-85 ปี (อายุเฉลี่ย 58 ปี) วัดความหนาแน่นของกระดูกที่ตำแหน่งกระดูกสะโพกโดยใช้เครื่อง DXA รุ่น Hologic QDR-4500 โดยผู้ที่มีความหนาแน่นของกระดูกเมื่อเทียบกับวัยหนุ่มสาว (T-score) ≤ -2.5 ของค่าเบี่ยงเบนมาตรฐาน (SD) จะได้รับการวินิจฉัยว่า เป็นโรคกระดูกพรุน การศึกษานี้ได้วัดความหนาแน่นของกระดูกส้นเท้าโดยใช้อัลตราซาวด์รุ่น Achilles+ (GE Lunar) และได้แสดงเป็นค่า T-score สำหรับดัชนีชี้วัดความเสี่ยงทางคลินิกใช้ OSTA และ KKOS คำนวณจากอายุและน้ำหนัก โดยผู้ที่มีคะแนนต่ำกว่า ≤ -1 จะจัดอยู่ในกลุ่มที่มีความเสี่ยงสูงในการเกิดโรคกระดูกพรุนและผู้ที่มีคะแนน > -1 จะจัดอยู่ในกลุ่มที่มีความเสี่ยงต่ำในการเกิดโรคกระดูกพรุน*

ผลการศึกษา: *เมื่อใช้ผลตรวจวัดความหนาแน่นของกระดูกจาก DXA เป็นเกณฑ์มาตรฐาน sensitivity ของการใช้อัลตราซาวด์กระดูกส้นเท้าจะต่ำกว่า sensitivity ของการใช้ดัชนีชี้วัดความเสี่ยงทางคลินิกทั้ง OSTA และ KKOS (ร้อยละ 60 เทียบกับร้อยละ 71/74) ในขณะที่มี specificity และ PPV สูงกว่า พบว่า sensitivity เพิ่มขึ้นเมื่อใช้ OSTA/KKOS ร่วมกับอัลตราซาวด์ส้นเท้า (ร้อยละ 87-89) ในขณะที่ specificity, PPV และ NPV ไม่แตกต่างกันเมื่อเทียบกับการใช้ดัชนีชี้วัดความเสี่ยงทางคลินิกอย่างเดียว การศึกษานี้พบว่าความเสี่ยงในการเกิดโรคกระดูกพรุนเมื่อ T-score ≤ -2.5SD จากการตรวจอัลตราซาวด์ส้นเท้าอย่างเดียวเท่ากับ 9.94 เท่า(ค่าความเชื่อมั่น 4.74-20.87) ซึ่งสูงกว่ากลุ่มที่จัดอยู่ในกลุ่มที่มีความเสี่ยงสูงจากการใช้ OSTA/KKOS โดยมีความเสี่ยงเท่ากับ 6.35 เท่า (ความเชื่อมั่น 2.99-13.47 สำหรับ OSTA) และความเสี่ยงเท่ากับ 8.15 เท่า (ความเชื่อมั่น 3.76-17.66 สำหรับ KKOS) สำหรับผู้ที่จัดอยู่ในกลุ่มที่มีความเสี่ยงสูงจาก OSTA/KKOS และมี T-score ≤ -2.5SD จากการตรวจด้วยอัลตราซาวด์ส้นเท้า ความเสี่ยงของการเกิดกระดูกพรุนจะเพิ่มขึ้นเป็น 43.68 เท่า (ความเชื่อมั่น 13.89-137.36) และ 60.92 เท่า (ความเชื่อมั่น 17.69-209.76) สำหรับ OSTA และ KKOS ตามลำดับ*

สรุป: *การใช้ดัชนีชี้วัดความเสี่ยงทางคลินิกร่วมกับการตรวจอัลตราซาวด์กระดูกส้นเท้าช่วยเพิ่มความถูกต้อง ในการค้นหาและวินิจฉัยผู้ป่วยโรคกระดูกพรุนในสตรีไทยวัยหมดประจำเดือน ผลการศึกษานี้สามารถนำไปใช้ในโรงพยาบาลหรือ สถานพยาบาลที่ไม่มีเครื่องวัดความหนาแน่นของกระดูกในการวินิจฉัยโรคกระดูกพรุนได้*