Using Quantitative Ultrasound and OSTA Index to Increase the Efficacy and Decrease the Cost for Diagnosis of Osteoporosis

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According to the WHO criteria for diagnosing osteoporosis, DXA is presently the best method for measuring and diagnosing osteoporosis, but it is relatively expensive, non-portable and emits low-level radiation. Alternatively, the Osteoporosis Risk Assessment Tool for Asians (OSTA) and quantitative ultrasound (QUS) are simpler, less expensive and emit no radiation, but are less accurate. However, the use of OSTA index corroborated by QUS was proposed as an alternative method of diagnosing osteoporosis. The combined diagnostic strength of an OSTA index ≤ -1 and a QUS T-score ≤ -4.5 had comparably high accuracy relative to the gold standard DXA T-score ≤ -2.5, especially for the femoral neck (80%) and total femur (89%). We conclude that the sequential use of the OSTA index followed by QUS is an efficacious alternative for diagnosing osteoporosis, especially in rural areas or in developing countries where resources are limited.

Keywords: *Asian continental ancestry group, Absorptiometry, Photon, Osteoporosis, Ultrasonography*

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Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture[1]. It is estimated that ~90% of all spine and hip fractures can be attributed to osteoporosis[2] and approximately one-third of Caucasian women over the age of 50 will suffer a fracture of the spine, hip or wrist[3].

In 1994, the World Health Organization (WHO)[4] introduced a new epidemiological definition of osteoporosis based on measurements of bone mineral density (BMD) expressed in SD units called a T-score. Osteoporosis was defined by a T-score threshold of ≥ 2.5 SD below the healthy, young adult mean of the spine hip or radius. DEXA or DXA (dual energy X-ray absorptiometry) is presently the best method for measuring bone mass and for diagnosing osteoporosis because of its high accuracy and low precision error, but it is relatively expensive, non-portable and usually restricted to tertiary-care hospitals, and involves a low exposure to ionizing radiation.

In recent years, quantitative ultrasound (QUS) studies have been developed as an alternative non-invasive assessment of skeletal status. This technique is less expensive and more time-saving and free from radiation[5,6]. Many studies, however, indicate that QUS has a very low sensitivity for predicting BMD-defined osteoporosis, albeit a high specificity[5,7]. The use of a T-score threshold of -2.5 may, therefore, be inappropriate for QUS for the diagnosis of osteoporosis.

Another simple tool (OSTA) was developed in 2001 to identify Asian women at increased risk of osteoporosis[8]. Of the different risk factors identified and considered, the risk index yielded a final tool based only on age and body weight after multiple variable regression analysis. The respective sensitivity and specificity of OSTA at an index cut-off of -1 is 95 and 47 percent.

The aim of our study was to evaluate the effectiveness of the using the OSTA index and QUS as

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a combined diagnostic tool for the identification osteoporosis in elderly Thai women.

Material and Method

Study population and protocol

A total of 100 community-dwelling participants were recruited consecutively from the central district of Khon Kaen Province, Thailand, between 2006 and 2007. This study was approved by our institutions Ethics Committee, and participants signed informed consent.

The inclusion criteria were: healthy elderly Thai women, 60 or more years of age, living in Khon Kaen Province, Thailand, with an OSTA index of $\leq$ -1. The exclusion criteria included: participants who had any paralysis or debility, history of bone tumor, metabolic or hormonal disorders which might affect calcium and bone metabolism, history of osteomyelitis of the calcaneus, spine, hip or distal radius, or adjacent bone that might affect the QUS measurement of the calcaneus or bone density measurement by DXA of any other site.

All of the participants were first pre-screened using the OSTA index with cut-off level of $\leq$ -1 and the participants who passed then had their calcaneal measured by QUS (Achillis Express®) and their BMD at the hip, spine and distal forearm measured by DXA (Lunar Prodigy®).

OSTA index

The Osteoporosis Risk Assessment Tool for Asians (OSTA)[8] is based on: age multiplied by -2 and body weight multiplied by 2. The last digit is dropped from each and the resulting values added together. The subjects with OSTA values $\leq$ -1 were classified as having an increased risk of osteoporosis: these then were the participants enrolled in the study.

Ultrasound bone densitometer

In this study, we used Achillis Express® to measure the Stiffness Index (SI) of the calcaneus which is an index that combines BUA and SOS into a single clinical measure that has a lower precision error than either variable alone. The precision *in vivo* was a 2.0% CV in osteoporotic patients. All QUS were performed by two trained assistants.

DXA measurements

BMD (g/cm^2) was measured by DXA (Prodigy, Lunar Corp., USA) on the lumbar spine (L1-L4), left proximal femur and left distal forearm, with a precision error of 1-2%.

Both QUS and DXA measurements were only performed in participants that had an OSTA index $\leq$ -1.

Sample size

This was a diagnostic study using a sequential method. Firstly, all of the participants were pre-screened using the OSTA index which had a sensitivity of > 90%[8]. Then all of the participants with an OSTA index $\leq$ -1 had their SI of the calcaneus measured by QUS, which had a specificity > 90%[7] to confirm the diagnosis and compare the results with DXA (the gold standard) of the spine, proximal femur and distal forearm.

We assumed the prevalence of osteoporosis after the OSTA index screening was 25% and the specificity of QUS ~75% with an accepted precision of estimation of 10%. The sample size was 100 cases.

Statistical analysis

The median (SE), mean (SE), minimum and maximum of the baseline demographic and clinical characteristics (including age, weight, height and BMI) were calculated.

The diagnostic characteristics of the combination of the OSTA index and QUS vs. BMD of spine L1-L4, proximal femur and distal forearm were described with respect to sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio positive and accuracy of each T-score of QUS in order to discover the most appropriate T-score of QUS for use as the optimum diagnostic value.

Table 1. Baseline characteristics of the participants (n = 100 cases)

	Mean (SE)	Median (SE)	Minimum	Maximum
Age (years)	69.97 (0.62)	70.00 (0.62)	60.00	89.00
Weight (kg)	49.24 (0.76)	50.00 (0.76)	30.00	81.00
Height (cm)	148.61 (0.48)	149.00 (0.48)	135.00	162.00
BMI (kg/m^2)	22.31 (0.34)	22.51 (0.34)	15.75	35.06

Results

All 100 participants with an OSTA index ≤ -1 underwent the calcaneal ultrasound measurement by QUS (Achillis Express®) and BMD measurement over the proximal femur, spine and distal forearm by DXA (Lunar Prodigy®). Table 1 presents the baseline clinical characteristics of the participants and Table 2 the prevalence of osteoporosis of the spine, proximal femur and distal forearm in all of the participants.

Tables 3 to 5 present the diagnostic features of QUS for diagnosing osteoporosis of various sites compared to the gold standard BMD of each site. It was found that the optimal QUS t-score of ≤ -4.5 had the highest accuracy for diagnosing osteoporosis of the spine, hip and distal radius, with an accuracy of 80% for diagnosis of osteoporosis of the femoral neck and 89% for total femur osteoporosis.

Table 6 presents a comparison of the diagnostic characteristics of the QUS t-score ≤ -4.5 and BMD at various part of the body.

Table 2. Prevalence of osteoporosis of the spine L1-L4, femoral neck, total femur and ultradistal radius diagnosed by BMD t-score ≤ -2.5 (n = 100)

Site	Osteoporosis	Non-osteoporosis	Total
L1-L4	47	53	100
Femoral neck	21	79	100
Total femur	12	88	100
Ultradistal radius	72	28	100

Discussion

According to the WHO criteria, the diagnosis of osteoporosis or low bone mass prior to fracture requires assessment of bone mass. Unfortunately, access to DXA machines to measure BMD is limited in most parts of Asia. To help target the use of BMD measurements to women at increased risk of osteoporosis, methods such as the QUS and risk assessment tools have been developed.

OSTA[8] is free and easy to use as a clinical risk assessment tool for assessing osteoporosis. It can only serve as screening tool because it has a high sensitivity (91%) and low accuracy (51%). DXA is still required to establish a diagnosis of osteoporosis. To compare, QUS has very low sensitivity (39%), but high specificity (91%).

Our protocol applied a combination of the two methods. By using a cut-off of ≤ -1 for the OSTA index and ≤ -4.5 for the QUS t-score, we had very high accuracy of osteoporosis diagnosis of the femoral neck (80%) and total femur (89%). This compares

Table 3. Diagnostic characteristics of the QUS t-score from ≤ -2.5 to ≤ -5 vs. the gold standard BMD t-score ≤ -2.5 of the spine L1-4 for diagnosing osteoporosis

QUS t-score	1-specificity	Sensitivity	Specificity	PPV	NPV	LR+	Accuracy
≤ -2.5	64.15	74.47	35.85	50.72	61.29	1.16	54
≤ -3	56.60	68.09	43.40	51.61	60.53	1.20	55
≤ -3.5	37.74	63.83	62.26	60.00	66.00	1.69	63
≤ -4	22.64	38.30	77.36	60.00	58.57	1.69	59
≤ -4.5	9.43	25.53	90.57	70.59	57.83	2.71	60
≤ -5	5.66	8.51	94.34	57.14	53.76	1.50	54

Table 4. Diagnostic characteristics of the QUS t-score from ≤ -2.5 to ≤ -5 vs. the gold standard BMD t-score ≤ -2.5 of the femoral neck for diagnosing osteoporosis

QUS t-score	1-specificity	Sensitivity	Specificity	PPV	NPV	LH+	Accuracy
≤ -2.5	63.29	90.48	36.71	27.54	93.55	1.43	48
≤ -3	54.43	90.48	45.57	30.65	94.74	1.66	55
≤ -3.5	41.77	80.95	58.23	34.00	92.00	1.94	63
≤ -4	24.05	52.38	75.95	36.67	85.71	2.18	71
≤ -4.5	10.13	42.86	89.87	52.94	85.54	4.23	80
≤ -5	3.80	19.05	96.20	57.14	81.72	5.02	80

Table 5. Diagnostic characteristics of the QUS t-score from ≤ -2.5 to ≤ -5 *vs*. the gold standard BMD t-score ≤ -2.5 of the total femoral for diagnosing osteoporosis

QUS t-score	1-specificity	Sensitivity	Specificity	PPV	NPV	LH+	Accuracy
≤ -2.5	64.77	100.00	35.23	17.39	100.00	1.54	43
≤ -3	56.82	100.00	43.18	19.35	100.00	1.76	50
≤ -3.5	44.32	91.67	55.68	22.00	98.00	2.07	60
≤ -4	23.86	75.00	76.14	30.00	95.71	3.14	76
≤ -4.5	9.09	75.00	90.91	52.94	96.39	8.25	89
≤ -5	3.41	33.33	96.59	57.14	91.40	9.78	89

Table 6. Diagnostic characteristics of the QUS t-score ≤ 4.5 vs. the gold standard BMD t-score ≤ -2.5 of the spine, distal forearm and proximal femur for diagnosing osteoporosis

Site	Specificity	PPV	NPV	LH+	Accuracy
L1-4	90.57	70.59	57.83	2.71	60
Distal 1/3 radius	96.43	94.12	32.53	6.22	49
Ultradistal radius	92.11	82.35	42.17	2.86	43
Femoral neck	89.87	52.94	85.54	4.23	80
Total femur	96.20	52.94	81.72	5.02	89

favorably with the gold standard DXA t-score ≤ -2.5. Hence, in areas with limited resources, this protocol would be valuable for the identification of subjects most likely to have low bone mass or osteoporosis.

Conclusion

In rural areas or in developing countries where DXA is scarce or resources are limiting, the combination of an OSTA index ≤ -1 and a QUS t-score ≤ -4.5 is an appropriate method for diagnosing osteoporosis and a valuable tool for identifying subjects at risk of osteoporosis.

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การใช้เครื่อง quantitative ultrasound ร่วมกับ OSTA index เพื่อเพิ่มประสิทธิภาพ และลดค่าใช้จ่ายในการวินิจฉัยโรคกระดูกพรุน

ศุภศิลป์ สุนทราภา, สุกรี สุนทราภา, ศักดา ไชกิจภิญโญ

ตามเกณฑ์การวินิจฉัยโรคกระดูกพรุนโดยองค์การอนามัยโลกได้แนะนำให้ใช้เครื่อง DXA เพื่อเป็นเครื่องมือตรวจวัดและวินิจฉัยโรคกระดูกพรุนที่ดีที่สุดในปัจจุบันนี้ แต่ข้อจำกัดของเครื่อง DXA นี้คือมีราคาแพง เครื่องมือมีขนาดใหญ่ไม่สามารถเคลื่อนย้ายได้และผู้ป่วยยังต้องได้รับรังสีในขณะตรวจวัด มีเครื่องมือและอุปกรณ์อื่น ๆ ได้แก่ OSTA index และเครื่อง quantitative ultrasound (QUS) ซึ่งเป็นเครื่องมือที่ตรวจวัดง่าย สะดวก ราคาถูกและไม่มีรังสีในขณะตรวจ แต่จนถึงปัจจุบันนี้ยังพบว่าไม่เหมาะต่อการนำมาใช้แทนเครื่อง DXA เนื่องจากความสามารถในการวินิจฉัยโรคกระดูกพรุนและความน่าเชื่อถือยังต่ำ การศึกษาครั้งนี้ได้นำวิธีทั้งสองมารวมกัน โดยการประเมินผู้สูงอายุด้วย OSTA index ก่อน หากมีค่า ≤ -1 จะทำการตรวจวัดด้วยเครื่อง QUS เป็นขั้นตอนต่อไป ผลการศึกษาพบว่าที่ OSTA index ≤ -1 และ QUS T-score ≤ -4.5 มีความสามารถในการวินิจฉัยโรคกระดูกพรุนได้ดีมากเมื่อเทียบกับการใช้เครื่อง DXA ในการวินิจฉัยโรคกระดูกพรุน โดยพบว่ามีค่า accuracy ในการวินิจฉัยโรคกระดูกพรุนของคอกระดูกต้นขา (femoral neck) สูงถึงร้อยละ 80 และของ total femur สูงถึงร้อยละ 89 จึงสามารถสรุปได้ว่าการใช้ค่า OSTA index ร่วมกับเครื่อง QUS เป็นทางเลือกหนึ่งที่ใช้วินิจฉัยโรคกระดูกพรุนแทนเครื่อง DXA ซึ่งมีความเหมาะสมอย่างยิ่งในสถานพยาบาลที่อยู่ห่างไกลหรือในประเทศที่กำลังพัฒนา ที่ไม่สามารถหาเครื่อง DXA มาตรวจวัดได้