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● *Original Contribution*

DOES QUANTITATIVE ULTRASOUND AT THE CALCANEUS PREDICT AN OSTEOPOROSIS DIAGNOSIS IN POSTMENOPAUSAL WOMEN FROM THE SILESIA OSTEO ACTIVE STUDY?

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Abstract—The aims of the study were to assess the clinical conformity between quantitative ultrasound (QUS) and densitometry with use of the standard World Health Organization *T*-score thresholds to determine optimal diagnostic cutoff values for QUS *T*-scores in different age groups. Three hundred sixty-five postmenopausal Caucasian women were enrolled into the study and divided into two age groups (<65 y and ≥65 y). Skeletal status was assessed using QUS measurements at the calcaneus and bone densitometry at the spine and proximal femur (Hologic Explorer, Bedford, MA, USA). QUS measurement results expressed as the stiffness index (SI) correlated significantly with both femoral neck bone mineral density ($r = 0.51$, $p < 0.0001$) and lumbar spine bone mineral density ($r = 0.52$, $p < 0.0001$). On the basis of receiver operating characteristic curve analyses, the thresholds for correspondence between QUS *T*-score values and *T*-score −2.5SD in dual X-ray absorptiometry (DXA) were established. They ranged between −1.63SD and −1.70SD in relation to femoral neck DXA and between −1.22SD and −1.51SD in relation to lumbar spine DXA, depending on age category. In conclusion, the study described here confirmed that QUS measurements at the calcaneus may provide information comparable to DXA examinations at the femoral neck and lumbar spine in postmenopausal women. (E-mail: piotrzagorski@yahoo.com) **© 2020 World Federation for Ultrasound in Medicine & Biology. All rights reserved.**

Key Words: **Bone densitometry, Osteoporosis, Quantitative ultrasound.**

INTRODUCTION

The National Institutes of Health (NIH) Consensus presented in 2000 defined osteoporosis as "a skeletal disorder characterized by compromised bone strength leading to an increased risk of fracture" (NIH 2001). The costs associated with treatment of low-energy osteoporotic fractures are rising rapidly in aging populations worldwide. In the European Union (EU), more than 22 million women and 5.5 million men with osteoporosis were identified in 2010, and the number of new fragility fractures was 3.5 million (Svedbom et al. 2013). The skeletal sites most often diagnosed with osteoporotic fracture are the proximal femur (hip), spine, proximal humerus and distal forearm, and these fractures are called "major osteoporotic fractures." The overall lifetime risk of fracture at any of these sites in postmenopausal women is estimated at ≥40% in countries of Western Europe (Kanis et al. 2000). Bone mineral density evaluation for diagnosis of osteoporosis can be performed by various methods. However, bone densitometry using dual X-ray absorptiometry (DXA) remains the gold standard examination for the diagnosis and quantification of osteoporosis (Punda and Grazio 2014).

Quantitative ultrasound (QUS) has been developed as an alternative diagnostic tool for the non-invasive assessment of bone status. The main advantages of QUS in comparison to DXA are lack of exposure to ionizing radiation and portability of the devices (Moayyeri et al. 2012). In contrast to DXA, QUS expresses both

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quantitative and qualitative features of bone tissue (Chin and Ima-Nirwana 2013).

On the other hand there are well-known errors in DXA examinations, including incorrect patient positioning (femur rotation), misplacement of the analysis frame and inclusion of vertebrae with large osteophytes. Also, the presence of metallic implants after lumbar spine transpedicular stabilization or hip prosthesis and severe obesity are factors limiting DXA accuracy (Messina et al. 2015). According to recommendations of the International Society for Clinical Densitometry (ISCD), the only validated skeletal site for the clinical use of QUS in osteoporosis management is the heel. Although central DXA measurements at the spine and femur are preferred for making therapeutic decisions, if the fracture probability assessed by heel QUS, using device-specific thresholds and in conjunction with clinical risk factors, is high, pharmacologic treatment can be initiated.

Ultrasound measurements at the calcaneus were able to identify postmenopausal women with different types of non-traumatic fractures (Drozdzowska and Pluskiewicz 2002). Large prospective fracture studies found that both broadband ultrasound attenuation (BUA) and speed of sound (SOS) at the calcaneal bone can predict the osteoporotic fracture as well as DXA at the spine and hip (Marshall et al. 1996; Stone et al. 2003; Moayyeri et al. 2009, 2012; Chin and Ima-Nirwana 2013). It is also reported that the stiffness index (SI) calculated as the derivative parameter based on QUS measurements (BUA and SOS) is an even better indicator of bone quality than either BUA or SOS interpreted alone (Xu et al. 2014).

Nevertheless, with the rising number of QUS devices used around the world, a new problem has arisen—the diagnostic criteria for osteoporosis based on ultrasound measurements are not clearly established. Moreover, it is even more important for practitioners to verify the usefulness of QUS parameters in osteoporotic fracture prediction.

Only few studies have determined *T*-score cutoff values that could be used for osteoporosis diagnosis based on QUS measurements. In their meta-analysis, Nayak et al. (2006) reported that at the QUS *T*-score cutoff threshold of -1 standard deviation (SD), sensitivity was 79% and specificity was 58% for identifying individuals with DXA *T*-scores of -2.5SD or less at the hip or lumbar spine. According to other studies, patients with QUS *T*-scores ≥ -1.0SD were assessed to have low risk of abnormal BMD in DXA measurement, and patients with *T*-scores ≤ -1.0SD in QUS were assessed as probably osteopenic or osteoporotic according to DXA criteria (Rozental et al. 2010; Sherchan et al. 2014). In retrospective studies, other researchers have found SI to be a significantly better indicator with which to discriminate women with low bone density or fractures from healthy postmenopausal controls than BUA or SOS analyzed separately (Hadji et al. 1999; Xu et al. 2014).

The main aim of the present study was to assess the conformity between QUS and DXA methods in the group of postmenopausal women enrolled in the Silesia Osteo Active Study. Furthermore, we attempted to determine the *T*-score cutoff values for QUS corresponding to current World Health Organization (WHO) criteria for the diagnosis of osteoporosis based on DXA (a *T*-score for DXA threshold of -2.5SD is applicable). An additional hypothesis was that Achilles Express II examinations most closely match DXA findings based on the percentage of younger postmenopausal women (<65 y of age) found to have osteoporosis, as defined by a DXA *T*-score <-2.5 at the femoral neck. This position was also supported by the manufacturer's data. Thus, separate analyses in age subgroups were planned.

METHODS

Patients

The Silesia Osteo Active Study was performed in a group of 365 postmenopausal Caucasian women aged 55−87 y who responded to the invitation sent to 3000 women randomly selected from population of Zabrze, Poland. The study was performed at the Metabolic Bone Diseases Unit, Department and Clinic of Internal Diseases, Diabetology and Nephrology, of the Medical University of Silesia in Katowice. Based on statistical analysis (the age median value) and because of general practical issues (most developed countries have accepted the chronologic age of 65 y as defining an elderly person—less physically fit), all 351 of the study patients were enrolled into subgroups (subgroup A: <65 y, 176 women; subgroup B, ≥65 y, 175 women).

All patients were interviewed and assessed by medical history. Fourteen women were not excluded from the study on the basis of the following criteria: implant of lumbar spine, 1; total hip arthroplasty, both sides, 2; severe skin ulcerations of foot or crus, 10; massive ankle edema, 1. The study was approved by the ethics committee of the Medical University of Silesia in Katowice. All enrolled women gave their informed written consent.

Ultrasound calcaneus measurements

In all patients, ultrasound examination of the non-dominant calcaneus with the Lunar Achilles Express II (Lunar Co., Madison WI, USA, Fig. 5) was performed according to the manufacturer's instructions. The Achilles is used to measure two parameters, BUA [dB/MHz] and SOS [m/s]. A third parameter, stiffness index (SI), is calculated based on BUA and SOS according to the equation given by the Achilles manufacturer: $SI = (0.67 * BUA + 0.28 * SOS) - 420$. Additionally, the Achilles

Table 1. Characteristics of the study population

	Mean ± standard deviation		
	All patients	Subgroup A	Subgroup B
Age (y)	65.15 ± 6.9	59.52 ± 2.9	70.8 ± 4.79
Weight (kg)	73.80 ± 12.98	73.97 ± 13.1	73.64 ± 12.89
Height (m)	1.58 ± 0.06	1.59 ± 0.05	1.57 ± 0.05
Body mass index (kg/m^2)	29.6 ± 5.02	29.3 ± 5.19	29.9 ± 4.83
Years since menopause	15.74 ± 8.87	9.69 ± 4.98	21.82 ± 7.68
BMD at the femoral neck (g/cm^2)	0.737 ± 0.114	0.760 ± 0.119	0.713 ± 0.104
T-Score at femoral neck	−1.01 ± 1.03	−0.80 ± 1.07	−1.21 ± 0.96
BMD at lumbar spine (g/cm^2)	0.853 ± 0.145	0.859 ± 0.190	0.832 ± 0.182
T-Score at lumbar spine	−1.74 ± 1.32	−1.62 ± 1.34	−1.86 ± 1.30
QUS BUA (dB/MHz)	110.53 ± 11.40	112.72 ± 11.94	108.32 ± 10.40
QUS speed of sound (m/s)	1536.88 ± 31.13	1545.00 ± 30.81	1528.71 ± 29.35
QUS stiffness index (%)	83.93 ± 14.99	87.65 ± 15.24	80.19 ± 13.79
QUS *T*-score	−1.00 ± 0.94	−0.77 ± 0.95	−1.24 ± 0.86

BMD = bone mineral density; BUA = broadband ultrasound attenuation; QUS = quantitative ultrasound; SI = stiffness index.

Express II also generates *T*-scores for individual SI values that are comparable to those obtained by DXA. The precision, expressed as the coefficient of variation (CV%) of SI measurements, was 0.6% based on repeated measurements (performed twice) in 25 randomly selected patients. After the first examination, the lower leg was removed from the device. If the temperature of the fluid (99.9% isopropyl alcohol) measured on both membranes as TC 1 and TC 2 was proper, the second examination was performed after 90−120 s. The SI results were calculated to assess precision errors. All measurements were performed by one operator.

Densitometry

Dual-energy X-ray absorptiometry measurements were performed using the Hologic Explorer (Hologic Inc., Waltham, MA, USA; software version: 13.0:3). Bone mineral density (areal BMD, g/cm^2), *T*-score and *Z*-score of the lumbar spine (LS, L1−L4) and non-dominant femoral neck (FN) were measured. All analyses were performed by one experienced technician. On the basis of repeated measurements of 25 women, the precision (CV%) of DXA measurements at the FN and LS was 2.03% and 1.6%, respectively.

Statistical analysis

Statistical analysis was performed using the Statistical Analysis System (SAS). Spearmans's correlation coefficient (*r*) was used to examine the association between calcaneal QUS and DXA of hip and lumbar spine measurements. To assess the ability of QUS to identify patients with osteoporosis diagnosed by DXA, receiver operating characteristic (ROC) analysis was performed. ROC curves and areas under the curve were estimated for FN DXA and lumbar spine DXA and QUS *T*-scores for the whole study group, subgroup A and subgroup B. On the basis of the ROC curves and Youden's index, the sensitivity and specificity of QUS *T*-score cutoff values for each skeletal site and age group were obtained. In all statistical analyses, $p < 0.05$ was considered to indicate significance.

RESULTS

The clinical characteristics of the whole study group and subgroups, as well as the descriptive statistics of QUS and DXA measurement results, are summarized in Table 1.

Table 2 outlines the skeletal status of all patients interpreted according to DXA diagnostic guidelines recommended by WHO. According to DXA measurements,

Table 2. Skeletal status based on dual X-ray absorptiometry and quantitative ultrasound measurements of all patients

Site	Status	Whole group	Subgroup A	Subgroup B
Femoral neck	Normal	152 (43.30%)	92 (26.21%)	60 (17.09%)
	Osteopenia	177 (50.43%)	77 (21.94%)	100 (28.49%)
	Osteoporosis	22 (6.27%)	7 (2.99%)	15 (4.27%)
Lumbar spine	Normal	104 (29.63%)	56 (15.95%)	48 (13.67%)
	Osteopenia	130 (37.04%)	65 (18.52%)	65 (18.52%)
	Osteoporosis	117 (33.33%)	55 (15.67%)	62 (17.66%)
QUS at calcaneus	Normal	151 (43.02%)	95 (27.06%)	56 (15.95%)
	Osteopenia + osteoporosis	200 (56.98%)	81 (23.08%)	119 (33.90%)

QUS = quantitative ultrasound.

Table 3. Correlation analysis between QUS measurements and DXA at the spine and femoral neck in the whole group, subgroup A and subgroup B

Group	Correlation	Stiffness index
Whole group	Lumbar spine BMD	$r = 0.52$ $p < 0.0001$
	Femoral neck BMD	$r = 0.51$ $p < 0.0001$
Subgroup A	Lumbar spine BMD	$r = 0.56$ $p < 0.0001$
	Femoral neck BMD	$r = 0.60$ $p < 0.0001$
Subgroup B	Lumbar spine BMD	$r = 0.46$ $p < 0.0001$
	Femoral neck BMD	$r = 0.33$ $p < 0.0001$

BMD = bone mineral density; DXA = dual X-ray absorptiometry; QUS = quantitative ultrasound.

osteoporosis (*T*-score ≤ -2.5SD) was diagnosed in 6.3% and 33.3% of all study patients according to FN and LS scans, respectively. Based on T-score for SI (QUS measurements) results, 57% of patients were at high risk of osteopenia or osteoporosis (*T*-score ≤ -1.0SD) and 43% of patients were at low risk of abnormal bone mineral density (*T*-score > -1.0SD).

Table 3 lists the Spearman correlation coefficients between DXA results (FN and LS BMD) and QUS SI in all patients (Fig. 4) and subgroups A and B. There is a significant correlation between all DXA measurements and SI in the whole study group and subgroups. In subgroup A, there was a moderate correlation between FN BMD and SI ($r = 0.60$, $p < .0001$) and LS BMD and SI ($r = 0.56$, $p < 0.0001$). In subgroup B, there was a moderate correlation between LS BMD and SI ($r = 0.46$, $p < 0.0001$, no significant difference compared with coefficient of correlation in subgroup A) and a weak correlation between FN BMD and SI ($r = 0.33$, $p < 0.0001$, significantly lower coefficient of correlation compared with subgroup A, $p < 0.01$).

The ROC analysis was performed using an FN DXA or LS DXA *T*-score < -2.5SD as standard according to WHO guidelines (Figs. 1a−c, 2a−c). The sensitivity and specificity of calcaneal QUS *T*-scores were set based on Youden's index and are listed in Tables 4 and 5.

For FN DXA in the whole study group and in subgroup A, the QUS *T*-score cutoff value corresponding to a FN DXA *T*-score < -2.5SD was -1.63SD. However, in subgroup A, the sensitivity and specificity were higher (86% and 85%) compared with those obtained in the whole group (77% and 78%). In subgroup B, the QUS *T*-score cutoff value was -1.70SD, and the sensitivity and specificity were 73% and 74%. Detailed data are outlined in Table 4.

Table 5 provides analogous results for QUS versus LS DXA. One can observe that there were larger differences between age subgroups in QUS *T*-score cutoff values based on LS DXA than in those based on FN DXA analysis. In subgroup A, the QUS *T*-score cutoff value corresponding to a LS DXA *T*-score < -2.5SD was -1.22SD, with a sensitivity of 65% and specificity of 82%. In the whole group and subgroup B, the QUS *T*-score cutoff values were –-1.50SD and -1.51SD, respectively. The sensitivity and specificity were 58% and 82% (all patients) and 66% and 73% (subgroup B).

On the basis of ROC analysis of QUS versus FN DXA, the areas under curves (AUCs) ranged from 0.74 in subgroup B to 0.87 in subgroup A. In analysis of QUS versus LS DXA, AUCs ranged from 0.70 in subgroup B to 0.79 in subgroup A. However, further analysis with the χ^2-test did not reveal statistically significant differences between the two subgroups for AUCs at the FN ($p = 0.11$) and LS ($p = 0.11$) (Fig. 3a,b).

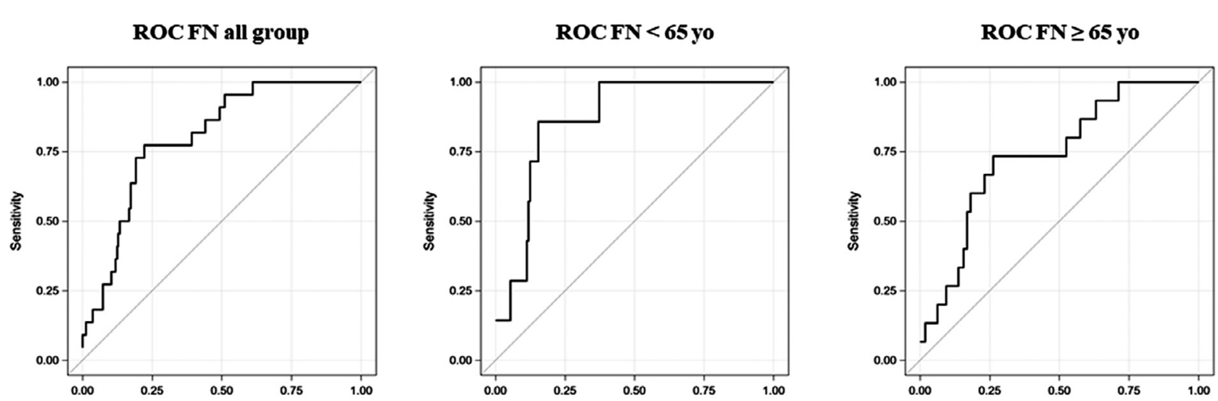

Fig. 1. Receiver operating characteristic curves (ROC) for dual X-ray absorptiometry at the femoral neck (FN) versus quantitative ultrasound at the heel (a) in the whole group, (b) in subgroup A (<65 y of age) and (c) in subgroup B (≥65 y of age).

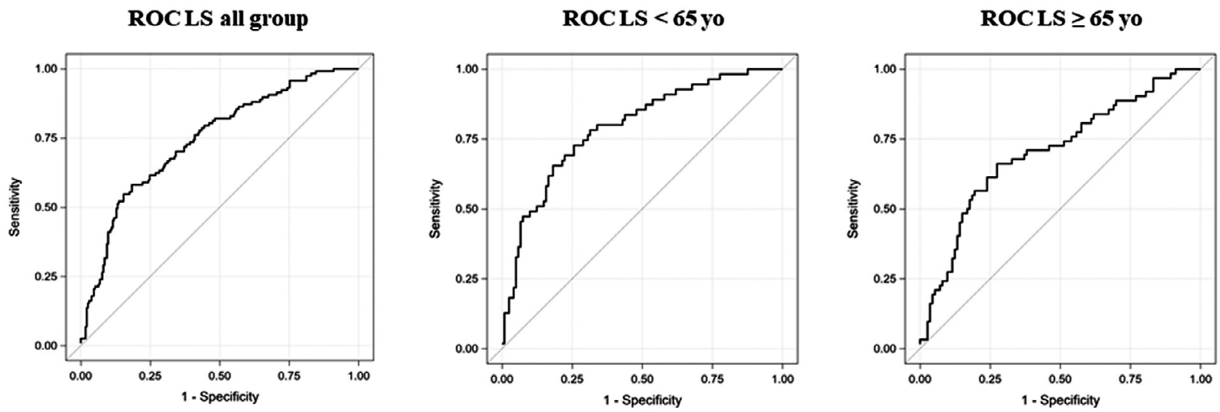

Fig. 2. Receiver operating characteristic curves (ROC) for dual X-ray absorptiometry at the lumbar spine (LS) versus quantitative ultrasound at the heel (a) in the whole group, (b) in subgroup A (<65 y of age) and (c) in subgroup B (≥65 y of age).

Table 4. Sensitivity and specificity of calcaneal QUS *T*-score according to Youden's index for DXA FN and QUS *T*-scores for the whole group and subgroups A and B

	Sensitivity	Specificity	*J* (Youden)	*T*-Score cutoff (SD)
Whole group	0.7727	0.77812	0.55084	−1.63
Subgroup A	0.85714	0.84615	0.70330	−1.63
Subgroup B	0.73333	0.73750	0.47083	−1.70

DXA = dual X-ray absorptiometry; FN = femoral neck; QUS = quantitative ultrasound; SD = standard deviation.

Table 5. Sensitivity and specificity of calcaneal QUS *T*-score according to Youden's index for DXA at the lumbar spine and QUS *T*-score for the whole group and subgroups A and B

	Sensitivity	Specificity	*J* (Youden)	*T*-Score cutoff (SD)
Whole group	0.58120	0.81624	0.39744	-1.50
Subgroup A	0.65455	0.81818	0.47273	-1.22
Subgroup B	0.66129	0.72566	0.38695	-1.51

DXA = dual X-ray absorptiometry; LS = lumbar spine; QUS = quantitative ultrasound; SD = standard deviation.

DISCUSSION

The most significant finding from the present study was the establishment of *T*-score cutoff values for QUS SI compared with diagnostic thresholds based on BMD from DXA in the cohort examined. An additional outcome of the study was the confirmation that calcaneal measurements may be used as an alternative diagnostic tool in osteoporosis screening.

This study re-affirmed the role of calcaneal QUS as an alternative method to DXA in diagnosis of osteoporosis and allowed us to suggest new *T*-score thresholds differing with age group and corresponding to specific skeletal sites in DXA measurement. The authors state that QUS can be used as an optional diagnostic tool to identify patients with low bone mineral density who may benefit from additional assessment with DXA. From a practical point of view, this is very important because compared with DXA, QUS is a less expensive, easily accessible exam with possibly carried out with a portable device, providing an opportunity to screen many people in a relatively short time.

We performed ROC analysis of *T*-score QUS measurements and DXA of the LS and FN to assess T-score cutoff values to identify women at risk of osteoporosis in different age subgroups and sites. At the same time, sensitivity and specificity were calculated for different *T*-score cutoff values according to Youden's index.

The AUCs ranged from 0.70 to 0.87 and were higher for the relationship between FN DXA and QUS *T*-score than that for LS DXA versus QUS *T*-score. Our results are similar to those of Steiner et al. (2019), who assessed heel QUS to identify women with DXA *T*-scores ≤ −2.5SD at the FN (AUC = 0.824) and DXA *T*-scores ≤−2.5 SD at the LS (AUC = 0.704). Additionally, Steiner et al. (2019) highlighted that there was a high AUC (0.956) for measurements of the right calcaneus and right hip in the group of patients between 50 and 65 y of age, which is important because of the

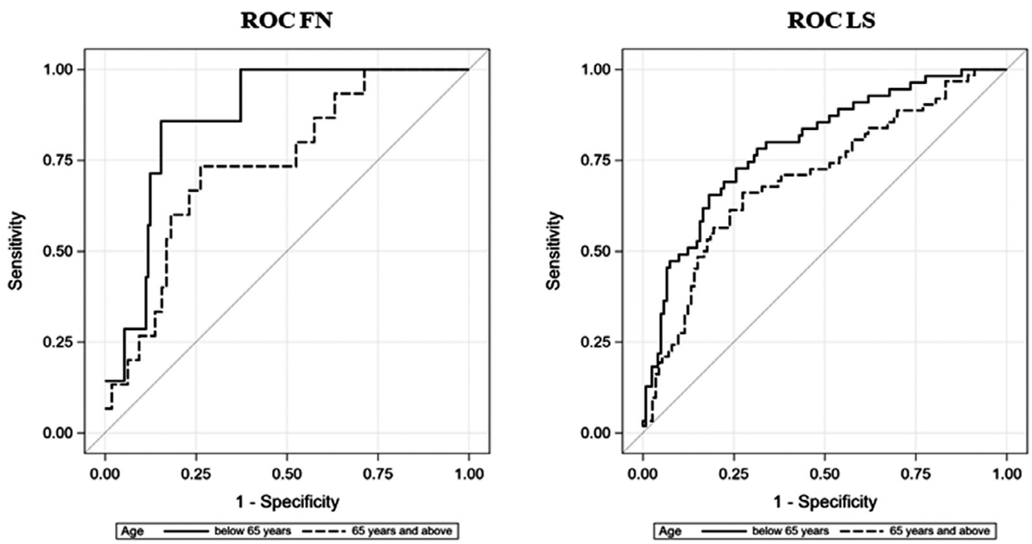

Fig. 3. Receiver operating characteristic curves (ROC) for dual X-ray absorptiometry at the femoral neck (FN) and lumbar spine (LS) versus quantitative ultrasound at the heel (a) in subgroup A (<65 y of age) and (b) in subgroup B (≥65 y of age).

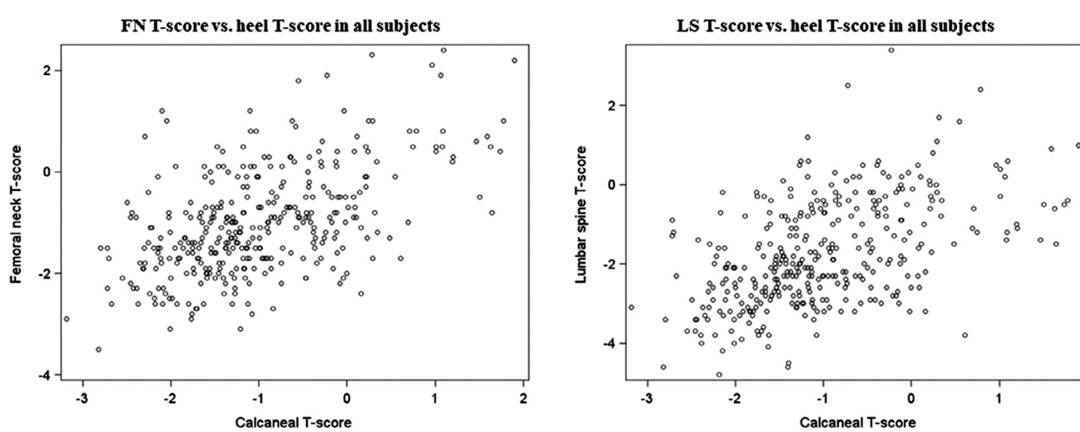

Fig. 4. Correlations (a) between femoral neck (FN) and calcaneus (heel) *T*-scores and (b) between lumbar spine (LS) and calcaneus (heel) *T*-scores for the whole group.

potential for using a QUS device to prescreen proximal femur fractures in this age group. This is consistent with the Achilles Express II user manual, which gives a high negative predictive value of 97% for 50- to 59-y-old Caucasian women (Krieg at al. 2008). The study of Steiner et al. (2019) gave a QUS *T*-score cutoff value of −1.45SD, which is comparable to that in our study (−1.63SD in all study groups for FN DXA and −1.50SD for LS DXA).

The highest sensitivity and specificity rates (86% and 85%) were obtained for FN DXA in the subgroup under 65 y. In the group of all study participants, sensitivity and specificity were 77% and 78% for FN DXA and 58% and 82% for LS DXA. Our results indicate that adequate cutoff values for different age subgroups and each site may increase the accuracy of the proper classification of osteopenia and osteoporosis. Comparable data have been obtained by other authors investigating postmenopausal women. In the study performed in 221 postmenopausal women by Boonen et al. (2005) with a QUS *T*-score cutoff value of −1.66SD, 67.6% of patients with osteoporosis (sensitivity) and 70.4% of women without osteoporosis (specificity) were identified. In a different study, Larijani et al. (2005) investigated a cohort of 420 postmenopausal women with the Achilles QUS device (*T*-score threshold = −1.0SD) and reported a sensitivity of 84% and specificity of 50% at the FN and a sensitivity of 83.9% and specificity of 51% at the LS.

In the study described here, a moderate correlation between applied DXA and QUS measures was obtained. Our results are similar to those of other published studies

Fig. 5. Achilles Express II bone ultrasonometer.

indicating a moderate correlation ($r = 0.4-0.7$) between QUS and BMD at the LS and FN (Faulkner et al. 1994; Tromp et al. 1999). Among the parameters measured with QUS, BUA is believed to be strongly related to bone mineral content (BMC) and weakly related to connective tissue properties, whereas SOS is strongly related to BMC and weakly related to bone microarchitecture (Leib et al. 2004; Baroncelli 2008). Based on a meta−analysis of three prospective studies performed by Moayyeri et al. (2012), we know that SI, BUA and SOS are significantly associated with fracture risk. Furthermore, it has been reported that SI had a high hazard ratio for fracture prediction (2.26, 95% CI: 1.71−2.99) per *T*-score decrease of 1.0SD in stiffness. Other data indicate that the risk of fracture is increased 1.5- to 2.5-fold for each 1.0SD decrease in *T*-score derived by QUS measurement and that it is comparable to the values for hip and lumbar DXA (Marshall et al. 1996; Stone et al. 2003; Moayyeri et al. 2009).

Although DXA is considered the “gold standard” for osteoporosis diagnosis, there are also well-documented differences between regions of interests within this technique: in approximately 40% of patients undergoing spinal and femoral DXA the diagnosis will differ in one or more WHO diagnostic classes (Woodson 2000; Moayyeri et al. 2005; El Maghraoui et al. 2007). There might be several reasons for this phenomenon: physiologic (resulting from the skeleton’s adaptive reaction), pathophysiologic (secondary to a disease, vertebral osteophytosis, osteochondrosis, hip osteoarthritis, even arterial calcifications), anatomic, artifactual (synthetic substances interfering with density measurement) and technical (*i.e.,* improper positioning). In contrast, the ISCD recommends QUS scanning for osteoporosis diagnosis at only one site, namely, the calcaneal region, which has mostly trabecular architecture (Shuhart et al. 2019). It seems that this body site is free of some pathophysiologic disturbances; it is also easier to avoid artifacts such as metal zippers and coins as might occur in lumbar scans. Nevertheless, calcaneal bone properties are modified by mechanical strain owing to weight bearing. Still, heel QUS reflects both bone quantity (bone mineral density, bone mass) and quality (microarchitecture, strength) (Chin and Ima-Nirwana 2013).

Our study has some limitations. The number of patients who responded the invitation was small, and the rural population was not included. However, the patients studied were randomly selected from the local population and may be considered as a representative female sample. Still, the number of patients was small compared with the large studies that have been performed with DXA.

The analysis performed revealed that the QUS *T*-score results referred to FN DXA were more strongly correlated and had higher sensitivity and specificity in the subgroup of younger women (<65 y) than older women (≥65 y). However, ROC analysis did not reveal statistically significant differences in AUCs between age subgroups.

From a practical point of view, it is important that a less expensive, non-invasive examination method such as QUS is also more available method than DXA in many regions, making it possible to examine larger numbers of postmenopausal women in a short time. According to our results, based on the sensitivity and specificity of different designated *T*-score cutoff values, QUS can be used in postmenopausal women with further validation of suggested diagnostic thresholds.

In conclusion, the present study confirmed that QUS measurements at the calcaneus may provide information comparable to that obtained with DXA examinations at the FN and LS in postmenopausal women. Further research is necessary to validate the clinical utility of QUS at the calcaneus for screening purposes in osteoporosis diagnosis in postmenopausal women and to verify the appropriate *T*-score thresholds of high risk of osteoporosis in different age groups.

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