Prescreening For Osteoporosis With Forearm Bone Densitometry In Health Examination Population

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Research Article

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Abstract

Background: Early detection and timely prophylaxis can retard the progression of osteoporosis. The purpose of this study was to determine the usefulness of peripheral Dual Energy X-ray Absorptiometry (DXA) for osteoporosis screening. We utilized AKDX-09W-I, a domestic brand instrument to perform peripheral DXA. Briefly, we acquired bone mineral density (BMD) data from manufacturer-supplied density-gradient phantoms and 30 volunteers to investigate its accuracy and precision, then we measured BMD from 150 volunteers using both AKDX (left forearm) and Hologic Discovery Wi (left forearm, left hip and L1 - L4 vertebrae) simultaneously. Correlation analysis of BMD results from two instruments was assessed by simple linear regression, the Receiver Operating Characteristic (ROC) curves and Areas Under the Curves (AUCs) were evaluated for the diagnostic value of left forearm BMD from AKDX in detecting osteoporosis.

Results: In vitro precision errors of AKDX BMD were 0.40%, 0.20%, 0.19%, respectively, on low-, medium-, and high-density phantom; in vivo precision was 1.65%. Positive correlation was observed between AKDX BMD and Hologic BMD at the forearm ($r = 0.670$), L1–L4 ($r = 0.430$), femoral neck ($r = 0.449$), and total hip ($r = 0.559$). With Hologic DXA T-score as the gold standard, the sensitivity of AKDX T-score < -1 for identifying suboptimal bone health was 63.0% and 76.1%, respectively, at the distal one-third radius and at any site, and the specificity was 73.9% and 90.0%, respectively; the AUCs were 0.708 and 0.879. The sensitivity of AKDX T-score ≤ -2.5 for identifying osteoporosis at the distal one-third radius and at any site was 76.9% and 70.4%, respectively, and the specificity was 80.4% and 78.0%, respectively; the AUCs were 0.823 and 0.778.

Conclusions: Peripheral DXA appears to be a reliable tool for prescreening for osteoporosis.

Introduction

Osteoporosis is characterized by low bone mineral density and microarchitectural deterioration of bone tissue and consequent proneness to debilitating fragility fractures. The prevalence of osteoporosis and the incidence of fragility fracture have increased markedly over the last three decades in China.^[1] In 2018, China's first large-scale multicenter epidemiological survey of osteoporosis showed a prevalence of 32.1% in women and 6.0% in men aged >50 years, which translates into an estimated population prevalence of 49.3 million and 10.9 million, respectively.^[2] Osteoporotic fracture is a serious disabling condition with high mortality rate and so imposes a heavy burden on the family, society, and medical resources. According to some estimates, by 2050, there will be an estimated 5.99 million osteoporotic fractures every year in China—a 2.7-fold increase since 2010—that will cost the country \$25.43 billion.^[3]

Osteoporosis is preventable and treatable, but only a small proportion of high-risk individuals are evaluated and treated. The National Osteoporosis Foundation treatment guidelines and the World Health Organization (WHO) recommend assessment of bone mineral density (BMD) by dual-energy x-ray absorptiometry (DXA) as the gold standard for osteoporosis screening.^[4–6] At many centers, hip and spine BMD measured by DXA is used to assess risk of hip fracture and monitor treatment efficacy.^[7, 8] But axial DXA examinations is restricted to a few large centers because the equipment is dependent on imports and the large volume requires a dedicated room; moreover, the high testing cost and the long testing time makes axial DXA unsuitable for use during routine physical examination and for screening of large groups. According to the 2013 International Osteoporosis Foundation (IOF) Asia Pacific Audit report, access to DXA is limited in China, with only 0.46 DXA systems available per million citizens.^[9] Cheaper and more convenient methods of evaluating BMD are needed, and peripheral DXA devices might be the answer.^[10]

BMD measurements at the forearm have been validated for osteoporosis diagnosis and follow-up evaluations.^[11] The incidence of osteoporotic forearm fractures is increasing,^[12, 13] and forearm BMD has been shown to be a better predictor of forearm fracture risk than BMD at other skeletal sites^[14, 15] as it best reflects cortical bone damage. Peripheral DXA is

portable, inexpensive, time saving, and well suited for osteoporosis and fracture screening in large populations. Prescreening with peripheral DXA may even help reduce the number of unnecessary axial DXA measurements being performed in individuals with high BMD and low fracture risk.

In this study, we used a locally made peripheral DXA device (AKDX-09W-I), with a linear double-energy X-ray sector beam scanning mode, low radiation exposure, and short scanning time (no more than 5 seconds) for measurement of distal forearm BMD. The purpose of the study was to verify the accuracy of the AKDX by comparison with axial DXA (performed with a Hologic DXA system) and to evaluate its effectiveness in screening for osteoporosis.

Results

Demographic Characteristics

A total of 150 participants (38 males, 112 females; mean age, 48.9 ± 15.9 years; age range, 20–84 years) were included in this study. All participants were right-handed. The mean height was 158.8 ± 7.2 cm and the mean weight was 58.5 ± 9.7 kg. The mean BMD at different ROIs varied. Table 1 summarizes the characteristics of the study population.

Table 1
Basic Characteristics of the Participants(n = 150, 38 males and 112 females)

Variables	Mean $\pm$ SD	Range
Age	48.9 ± 15.9	20 ~ 84
Height(cm)	158.8 ± 7.2	145.0 ~ 184.5
Weight(kg)	58.5 ± 9.7	43.8 ~ 101.5
BMI(kg/cm ²)	23.2 ± 3.0	17.7 ~ 30.1
AKDX BMD(g/cm ²)	0.406 ± 0.047	0.284 ~ 0.507
Hologic distal 1/3 of radius BMD(g/cm ²)	0.640 ± 0.087	0.422 ~ 0.842
Hologic spine L1–L4 BMD(g/cm ²)	0.921 ± 0.145	0.560 ~ 1.350
Hologic femoral neck BMD(g/cm ²)	0.735 ± 0.128	-3.3 ~ 4.1
Hologic total hip BMD(g/cm ²)	0.881 ± 0.132	0.56 ~ 1.35
AKDX BMD T score	-1.401 ± 0.672	-3.24 ~ 0.5
Hologic distal 1/3 of radius BMD T score	-1.429 ± 1.195	-4.5 ~ 1.6
Hologic spine L1–L4 BMD T score	-0.584 ± 1.257	-3.7 ~ 3.2
Hologic femoral neck BMD T score	-0.863 ± 1.183	-3.3 ~ 4.1
Hologic total hip BMD T score	-0.155 ± 1.084	-2.8 ~ 3.7
BMI, body mass index; SD, standard deviation; BMD, bone mineral density		

Measurement Precision

Table 2 presents the mean BMDs measured by AKDX and Hologic DXA on the density-gradient phantom and on the forearms of healthy volunteers. There were significant differences between BMD values measured by the two devices. On

the low-, medium-, and high-density forearm phantom, the AKDX BMD precision errors were 0.4%, 0.2%, and 0.19%, respectively; the precision error on the 30 volunteers was 1.65%. The precision errors of Hologic DXA on low-, medium-, and high-density gradient phantom were 0.50%, 0.85%, and 0.82%, respectively; the precision error in the human volunteers was 1.48%.

Table 2
Precision of Measurement–AKDX and Hologic (n = 30)

		BMD Mean Value±SD	<i>p</i> -value	RMS-SD (g/cm ²)	Precision (CV%)
Low	AKDX	0.300±0.001	<i>p</i> <0.01	0.033	0.40
	Hologic	0.432±0.003		0.002	0.50
Medium	AKDX	0.492±0.002	<i>p</i> <0.01	0.003	0.20
	Hologic	0.671±0.006		0.006	0.85
High	AKDX	0.582±0.002	<i>p</i> <0.01	0.003	0.19
	Hologic	0.886±0.007		0.007	0.82
Healthy	AKDX	0.402±0.044	<i>P</i> <0.01	0.019	1.65
volunteers	Hologic	0.633±0.072		0.009	1.48
Low, Medium, and High densities gradient phantom; SD, standard deviation; RMS-SD, root mean square standard deviation; % CV, percent coefficient of variation					

Linear Correlation Coefficients

Table 3 shows the fitted regression equations and the estimated conversion coefficient of slope and intercept with standard error. The Pearson *r* for correlation between BMD measured with peripheral AKDX and Hologic DXA varied from 0.430 to 0.670. The highest correlation between AKDX and Hologic BMDs was observed at ultradistal and distal one-third radius (*r* = 0.670) and the lowest correlation between AKDX forearm BMD and Hologic L1–L4 vertebrae BMD (*r* = 0.430). In addition, there was good correlation between AKDX ultradistal forearm BMD and Hologic DXA total hip BMD (*r* = 0.559).

Table 3
Linear correlation coefficients(*r*) of the dual-energy X-ray absorptiometry (DXA) measurements with AKDX to Hologic

Region (BMD, g/cm ²)	R	Slope	Intercept	S.E.E. (g/cm ²)
distal 1/3 of radius	0.670	0.400	0.150	0.041
Spine L1–L4	0.430	0.170	0.250	0.012
Femoral neck	0.449	0.180	0.280	0.011
Total hip	0.559	0.220	0.210	0.011
R: Correlation coefficient; S.E.E: Standard errors of the estimate				

Roc Analysis

The performance of AKDX was assessed through ROC analysis, with Hologic DXA as the reference (Figure 1A-D). Among 150 participants, a total of 77 postmenopausal women and men over the age of 50 were recruited. According to WHO diagnostic criteria, a BMD T-score ≤ -2.5 indicates osteoporosis, while a T-score between -1 and -2.5 indicates osteopenia. [16] The sensitivity of AKDX T-score <-1 for identifying suboptimal bone health (Hologic DXA T-score <-1) at the distal one-third radius of the non-dominant forearm and at any site (i.e., distal one-third radius, L1–L4 vertebrae, femoral neck, and total hip) was 63.0% and 76.1%, respectively, and the specificity was 73.9% and 90.0%, respectively; the AUCs were 0.708 and 0.879 (Table 4). The sensitivity of AKDX T-score ≤ -2.5 for identifying osteoporosis (Hologic DXA T-score ≤ -2.5) at the distal one-third radius and at any site were 76.9% and 70.4%, respectively, and the specificity was 80.4% and 78.0%, respectively; the AUCs were 0.823 and 0.778 (Table 5).

Table 4
The performance of AKDX in identifying subjects with suboptimal bone health (Hologic DXA T-score <-1)

	Sen.(%)	Spe.(%)	AUC	95% CI	<i>p-value</i>
distal 1/3 of radius	0.630	0.739	0.708	0.573 ~ 0.843	0.004
Any site	0.761	0.900	0.879	0.792 ~ 0.967	0.000
Significant <i>p-values</i> are italicized. AUC, area under curve; CI, confidence interval; Sen., sensitivity; Spe., specificity; Any site, any site of the distal 1/3 of radius of left forearm, spine L1 - L4, femoral neck, total hip.					

Table 5
The performance of AKDX in identifying subjects with osteoporosis (Hologic DXA T-score ≤ -2.5)

	Sen.(%)	Spe.(%)	AUC	95% CI	<i>p-value</i>
distal 1/3 of radius	0.769	0.804	0.823	0.732 ~ 0.915	0.000
Any site	0.704	0.780	0.778	0.677 ~ 0.880	0.000
Significant <i>p-values</i> are italicized. AUC, area under curve; CI, confidence interval; Sen., sensitivity; Spe., specificity. Any site, any site of the distal 1/3 of radius of left forearm, spine L1 - L4, femoral neck, total hip.					

Discussion

In this study, the precision of AKDX was verified on the density-gradient phantom provided by the manufacturer and by two repeated measurements of BMD in healthy volunteers. The usefulness of peripheral AKDX for prescreening for osteoporosis was assessed by comparison with axial Hologic DXA. The locally made peripheral AKDX machine was found to be a feasible and precise modality for osteoporosis prescreening.

Assessment of precision errors in BMD is a prerequisite, without knowing the precision of BMD measurement, it is not possible to accurately assess changes that occur over time. Precision refers to the reproducibility of results when quantitative measurements are repeated. [17] According to the methodology recommended by the International Society for Clinical Densitometry (ISCD), [4] precision is evaluated by repeated measurement on the manufacturer-supplied phantom (in vitro) or on a patient (in vivo), and is expressed as the percentage coefficient of variation. Precision errors of bone densitometry techniques are remarkably low, much lower than that of many other quantitative measurements used in clinical medicine. In our study, the density phantom CVs were all below 1%, the vivo CV were below 2%, referring to the Table 1. The reported CVs of most DXA instruments are about 0.5–1% in vitro and 1–2% in vivo. [18] In previous reports, the CVs have been 0.5–3% for central DXA and 1% for peripheral DXA. [18–20] DXA measurements at the radius or ulna showed precision errors in vivo of 0.5–1.9%. [21–22] Our results for precision of peripheral DXA is of the same order as that of other clinically accepted densitometry techniques, the range of change is acceptable. The precision of BMD

measurement must be maintained at the highest level so that biological changes can be detected as early as possible. Our study shows that the AKDX instrument has sufficient precision for screening for osteoporosis.

This study successfully validated BMD measured by portable peripheral AKDX against Hologic DXA for use in adult physical examination population. Pearson correlation analysis demonstrated that AKDX forearm BMD was significantly correlated to Hologic BMD at distal one-third of radius, total hip, femoral neck, and L1–L4; the strongest correlation was with Hologic BMD at distal one-third of radius. This finding is consistent with previous studies in young children and adults that have demonstrated agreement between peripheral DXA BMD and Hologic DXA forearm BMD.^[23–24] Better comparability of forearm densitometry would require, in particular, standardization of the ROIs to be used. It should be noted that the ratio of cortical to trabecular bone mass increases from the proximal to the distal forearm,^[25] so mismatch of ROIs could result in different rates of loss or gain. Thus, when individuals in a clinical trial are being followed up over time, change of device should be avoided.

This study evaluated the ability of peripheral AKDX to identify osteoporosis and low bone mass was assessed. In evaluating the peripheral device, we first used the T-score derived from the database supplied by the manufacturer, which is standard practice for health care professionals using these devices. As recommended by the World Health Organization, osteoporosis was defined as a T-score ≤ -2.5 , while a T-score between -1 and -2.5 indicates osteopenia. ROC curves are a useful way of evaluating the value of BMD measurement.^[26] In the present study, the area under the curve and the sensitivity and specificity of AKDX (AKDX T-score < -1) for identifying subjects with suboptimal bone health (i.e., Hologic DXA T-score < -1) was found to be fair. The sensitivity and AUC of AKDX for detecting osteoporosis (Hologic DXA T-score ≤ -2.5) in forearm were better than for detecting suboptimal bone health.

BMD measured by peripheral bone densitometry has been shown to be a reliable predictor of fracture risk. Studies using various peripheral bone densitometry instruments have consistently shown that low BMD in the forearm, finger, or heel is associated with high probability of fracture in the lumbar spine, hip, forearm, or ribs within 1 year in postmenopausal white women.^[14] Other studies have shown that peripheral BMD together with a thorough clinical evaluation can provide a reliable osteoporosis risk profile and can therefore be used for diagnosis of osteoporosis when central DXA is not available.^[27]

This study has several limitations. First, all measurements reported in this study were obtained from AKDX-09W-I and Hologic DXA scanners; our findings cannot necessarily be extrapolated to scanners from other manufacturers, as the ROIs could be slightly different for those machines. Second, because of the limited number of participants in this study, we did not attempt subgroup analyses based upon patient characteristics such as age and sex. To find the best cutoff value for identifying osteopenia and osteoporosis and to validate effectiveness of peripheral DXA, larger samples would be required. Nevertheless, the information from this study can serve as a guide for future studies using AKDX for screening of bone health.

Conclusions

Peripheral BMD measurement with the AKDX-09W-I appears to be a feasible and reliable method for prescreening for osteoporosis diagnosis. Because of its portability, low cost, and ease of use, the AKDX is particularly well suited for osteoporosis screening in rural areas or in patients who are home bound. Aspects that should be investigated in future research include clinical significance and cost–benefit analysis of peripheral DXA screening.

Methods

Participants

The study participants were selected from among individuals coming to the Health Management Center of Second Xiangya Hospital, Central South University, Hunan province, China, for routine health examination between February and April 2021. Participation in the study was voluntary. The exclusion criteria were 1) under the age of 20, 2) has a history of left forearm, left hip and lumbar fracture, or 3) pregnancy. A total of 150 individuals (38 males and 112 females) met the eligibility criteria. At enrollment, a structured questionnaire was used to collect data on sex, age, age at menopause, medical history, and handedness (ascertained by asking which hand the subject preferred to use for the majority of tasks). Height and weight were recorded and the BMI was calculated as weight (in kilograms) divided by the height (in meters) squared.

All participants signed an informed consent form prior to enrollment. The study protocol was approved by the Ethics Committee of Second Xiangya Hospital.

Forearm Phantom And Bmd Measurements

The AKDX forearm phantom was manufacturer-supplied and made of 99% high-purity aluminum in the shape of the radius and ulna. The three-gradient phantom represents low, medium, and high densities with actual BMD values of 0.299 g/cm², 0.494 g/cm², and 0.585 g/cm², respectively. To verify in vitro and in vivo precision the phantom and the left forearms of 30 healthy volunteers (aged 20–77 years) were scanned twice (with repositioning) on the AKDX and the Hologic DXA systems, these 30 volunteers drawn from the selected 150. There was no significant drift or shift in calibration in the 30 subjects during the study period. Subsequently, the 150 study participants were scanned on each of the two machines. Scans were performed and analyzed by the same well-trained operator according to guidelines provided by the manufacturer.

For AKDX BMD, the complete left forearm was scanned. The AKDX region of interest (ROI) is an area corresponding to the Hologic DXA ultradistal ROI but also covers part of the Hologic DXA mid-distal ROI. The AKDX calibration was checked daily on the aluminum forearm phantom before each scanning session. For Hologic DXA, the complete left forearm, L1–L4, femur and total hip were scanned. The left forearm length (distance between the tips of the olecranon and styloid processes) was first measured. The forearm DXA scan defines three ROIs: distal one-third radius, mid-distal, and ultradistal. The Hologic calibration was checked daily using the Hologic calibration phantom and the aluminum spine phantom before each scanning session.

Statistical Analysis

Statistical analysis was performed using SPSS 24.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as the means ± standard deviations. The International Society for Clinical Densitometry (ISCD) DXA Machine Cross-Calibration Tool (www.ISCD.org) was used to examine the relationship between mean BMD measured on the two machines and to determine the percentage coefficient of variation (CV). Pearson correlation coefficients were calculated to quantify the relationship between AKDX and Hologic BMD. Linear regression analyses were performed for AKDX and Hologic DXA. The ability of the AKDX to detect osteoporosis was assessed by determining the area under the receiver operating characteristic (ROC) curve. For ROC analysis, the reference value for presence of osteoporosis was as per World Health organization (WHO) criteria, i.e., T-score ≤ -2.5 either at the distal one-third radius of the nondominant forearm, any site of the distal one-third radius of the left forearm, L1–L4 vertebrae, femoral neck, or total hip. P < 0.05 was considered statistically significant.

Abbreviations

DXA: Dual Energy X-ray Absorptiometry() BMD: Bone mineral density ROC: Receiver Operating Characteristic AUCs: Areas Under the Curves IOF: International Osteoporosis Foundation ISCD: International Society for Clinical Densitometry ROI: Region of interest CV: Coefficient of variation

Declarations

Ethical approval and consent to participate

All participants signed an informed consent form prior to enrollment. The study protocol was approved by the Ethics Committee of Second Xiangya Hospital. All research procedures in this study were in accordance with the ethical standards of institutions and with the 1964 Helsinki declaration and its subsequent amendments.

Consent for publication

Not applicable

Availability of data and materials statements

The datasets generated and/or analysed during the current study are not publicly available due to volunteers and patients' privacy but are available from the corresponding author on reasonable request

Competing interests

All authors declares that they have no competing interests

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Author Contributions Statement

C.Y. analyzed and interpreted the experimental data and drafted the manuscript. N.D., Y.F., Y.G. and L.X. collected the experimental data and contributed to the manuscript. Y.Y., X.Z. and Z.S. critically revised the manuscript and were involved in the planning of the research. Z.S. provided financial support and critically revised the manuscript. All authors read and approved the final manuscript.

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Figures

Figure 1

Receiver operating characteristic curves of AKDX in identifying the risk of osteoporosis with reference to Hologic DXA.

(A, B) Receiver operator characteristic curves on the performance of AKDX (AKDX T score ≤ -1) in identifying subjects at risk of suboptimal bone health (Hologic DXA T score ≤ -1), (A)AKDX forearm distal VS Hologic distal 1/3 of radius, (B)AKDX forearm distal VS Hologic any site.(C, D)Receiver operator characteristic curves on the performance of AKDX (AKDX T score ≤ -2.5) in identifying subjects at risk of suboptimal bone health (Hologic DXA T score ≤ -2.5), (C)AKDX forearm distal VS Hologic distal 1/3 of radius, (D)AKDX forearm distal VS Hologic any site. Any site: distal one-third radius, L1–L4 vertebrae, femoral neck and total hip.