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IMPACT OF THE CHANGE IN THE BONE DENSITOMETER REFERENCE DATABASE ON THE PREVALENCE OF OSTEOPOROSIS AND VERTEBRAL FRACTURES.

Imad Ghozlani[1,2], Aziza Mounach[3], Mirieme Ghazi[2,4], Anass Kherrab[2,4], Radouane Niamane[2,4] , Abdellah El Maghraoui[3].
[1]-Rheumatology Department, 1st Military Medico Surgical Center, Agadir, Morocco.
[2]-Rheumatology Department, Faculty of Medicine and Pharmacy, Cady Ayyad University, Marrakech, Morocco.
[3]-Rheumatology Department, Military Hospital Mohammed V, Mohammed V University, Rabat, Morocco.
[4]-Rheumatology Department, Military Hospital Avicenne, Marrakech, Morocco.

ABSTRACT

Objective: The aim of our study was to evaluate the impact of the change in the bone densitometer reference database on the prevalence of osteoporosis and the identification of vertebral fractures (VFs) in postmenopausal Moroccan women.
Methods: 328 post-menopausal women were recruited. Bone mineral density (BMD) and lateral Vertebral Fracture Assessment (VFA) images were obtained using a bone densitometer. VFs were defined using a combination of Genant semi-quantitative approach and morphometry. The discriminative performance of Morocco, Europe, Middle East and USA reference database to identify osteoporosis and prevalent VFs was assessedby evaluating the areas under the ROC curve (AUC), and calculating sensitivity, specificity, positive, negative predictive value and positive likelihood ratio. A stepwise conditional binary regression analysis was reported in the order to assess the risk of occurrence of vertebral fractures for all bone reference databases.
Results: the mean age was 65±6.5 (50 to 84) years. Vertebral fractures were identified in 84 (25.6%).Using the Moroccan databases, 144 women (43.9%) were identified with osteoporosis at any site. According to the European, Middle Eastern and American reference databases, osteoporosis prevalence at any site was 138 (42%), 137 (41.7%) and 132 (40.2%); respectively (p=0.01).The highest AUC was observed for Moroccan lumbar spine reference database, which had also the best sensitivity and specificity balance (65.5% - 63.8%) and the highest positive predictive value and the positive likelihood ratio (38.5-1.8). The step wise conditional binary regression analysis showed that Moroccan (OR [CI 95%] = 5.8 [1.2 – 27.8]) and, at lower odds, European (OR [CI 95%] = 2.7 [1.3 – 5.7]) databases were independently able to predict prevalent vertebral fractures.
Conclusion: The Moroccan reference database with the elevated prevalence of osteoporosis noted can better identify subjects at highest risk of osteoporotic VFs.

Keywords: reference database, osteoporosis, vertebral fractures.

Corresponding author:
Dr. Imad Ghozlani:
Rheumatology Department, 1st Military Medico Surgical Center, Agadir, Morocco.
Mail : ghozlani123@gmail.com, Tel: +212661590176

INTRODUCTION

Osteoporosis (OP) has become a real public health problem [1-3]. Its prevalence is on the rise because of a considerable increase in life expectancy [4, 5].In Morocco, its prevalence varies between 30.1% and 37.9% [6, 7].Osteoporotic fractures, in particular vertebral fractures, are the most frequent occurrences.They are important to detect because they have been associated with reduced quality of life and an increased risk of future vertebral and non-vertebral fractures[8]. The costs of these fractures are alsohigh for society. Moreover, drugs such as bisphosphonates, strontium ranelate, teriparatideor denosumab areeffective at reducing the risk of further VFs and are so recommendedfor use in this disease[9].Among several techniques for measuring and detecting bone loss [10], Dual-energy X-ray Absorptiometry (DXA) is currently the reference method due to its reproducibility,

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reliability and relatively low cost[11].In clinical practice, Bone mineral density (BMD) measurements are widely used to diagnose and assess osteoporosis and its severity.However, the BMD values (in g/cm²) are not used for diagnosing osteoporosis[12]. Indeed, WHO experts have developed a definition of Osteoporosis based on T-score, which is the difference between measured BMD and the mean value of young adults expressed as standard deviations for a normative population with the same ethnic origin[13]. In this context, a number of studies showed theimportance of establishing measurements for each particular population [6, 14].
Dual-energy X-ray Absorptiometry can also be used for the visualization of vertebral fractures (Figure 1) also known as vertebral fracture assessment (VFA).

Figure 1: a VFA image by DXA showing T12 grade 3vertebral fracture.

It is a practical and low-radiation techniquethat visualizes images of good quality to be used to diagnose the presence of osteoporotic vertebral fracturein women and men [15, 16]. A number of methods have been assessed for interpretation of spinal X-rays and diagnosis of vertebral fractures.The Genant semiquantitative method is more objective and reproducible than other qualitative methodsandhas been used as a gold standard in a several osteoporosis works[17, 18].Thus, the aim of our study was to evaluate the impact of the change in the bone densitometer populationreference database on the prevalence of osteoporosis and the identification of vertebral fractures using VFA in postmenopausal Moroccan women.

MATERIALS AND METHODS

Subjects

Three hundred and twenty-eight consecutive postmenopausal women aged 50 years and over who had no previous diagnosis of osteoporosis were recruited in the study from the general population through advertisements and "word of mouth" in local hospitals.General exclusion criteria were non-Caucasian origin, history of diseases, drugs, and other major determinants known to affect bone metabolism.Thus, women with liver or renal disease, endocrine or metabolic abnormalities, and receiving medicine known to influence bone mineralization such as corticosteroids, heparin, anticonvulsants, vitamin D, and bisphosphonates, were excluded. The procedures of the study were in accordance with the Declaration of Helsinki, and local ethics committee approval was obtained for the study. All the participants gave an informed and written consent. Each subject completed a standardized questionnaire designed to document putative risk factors of osteoporosis. History of fractures, lifestyle (alcohol consumption, gymnastics and smoking) and diet (milk, yogurt, cheese) habits were also recorded. Menstrual and reproductive histories were assessed: all patients were menopausal since at least 1 year. Height and weight were measured in our center before DXA measurement.

Bone mineral density measurement

Bone mineral density(BMD)was determined by a Lunar Prodigy VisionDXA system (Lunar Corp., Madison, WI). All BMD measurements were carried out bytwo experienced technicians.Daily quality control was carried out by measurement ofa Lunar phantom.
TheWorldHealth Organization(WHO)classification systemwas applied, defining osteoporosisas T-score ≤-2.5 and osteopenia as -2.5 < T-score <-1. Study participantswere
categorized by the lowest T-score of the L1-4 lumbarspine, femur neck, or total hip using our reference values [6].

Vertebral fracture assessment

VFAwas classified using a combination of Genant semiquantitative(SQ) approach andmorphometry in the following manner: EachVFA imagewas inspected visually by two experienced clinicians (IG and AM whohad a previous training session in VFA), to decide whether it containeda fracture in any of the visualized vertebrae. Each vertebrathatwas judged fracturedthrough visual

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inspection by either one of the investigators,wasmeasured using built-in morphometry and assigned agrade based on Genant SQ scale [17], where grade 1 (mild) fractureis a reduction in vertebral height of 20–25%, grade 2 (moderate) areduction of 26-40%, and grade 3 (severe) a reduction of over 40%.As most epidemiological studies defined fractures as grade 2 andhigher, subjects with no fractures or with grade 1 fractures wereincluded in the non-fracture group, whereas those with grade 2 orhigher fractures were included in the fracture group[15, 19-21].

Statistical analysis

Results are presented as means (S.D.) and categorical variablesare expressed as frequencies.
Prevalence and proportion of subjects with osteoporosis (T-score≤-2.5) according to the different bone densitometer reference database values (Morocco, Middle East, Europe, and USA)was calculated on the lumbar spine, total hip and at any site(defined as lumbar spine or total hip T-score≤-2.5).The impact of other bone references databasein identifying women with vertebral fractures compared to the Moroccan reference curve was assessed by:

- Evaluating their areas under ROC (Receiver Operating Characteristics)curves (AUC), a model with no utility in predicting fracture would have an AUC of 0.50 (i.e., no better than flipping a coin or chance alone); AUC was greater than 0.50 for all models [22].
- Calculating sensitivity, specificity, positive, negative predictive value and positive likelihood ratio for each population reference curve.

Finally, a stepwise conditionalbinary regression analysis and the resulted odds ratios (ORs) with 95%confidence intervals were reported in the order to assess the risk of occurrence of vertebral fractures for all bone reference databases. The level for significance wastaken as p≤0.05. SPSS 15.0was used for statisticalanalysis.

RESULTS

Patient demographics

The basic anthropometric characteristics of the 328 females studied are presented in Table I. In this cohort the mean±S.D. (range) age,weight and BMI were 65±6.5 (50-84] years, 72.0±12.8 (42-125) kgand 29.4±5.0 (17.1-45.8) kg/m²; respectively. Vertebral fractures were identified using VFA in 84 (25.6%).

Table I: Characteristics of the population study (*n* = 328).

	Mean ± S.D.	Range
Age (years)	65 ± 6.5	50-84
Weight (kg)	72 ± 12.8	42-125
Height (m)	1.56 ± 0.1	1.38-1.71
BMI (kg/m2)	29.4 ± 5.0	17.1-45.8
Number of parity	5.4 ± 2.6	0-13
Years since menopause	15.2 ± 8.5	1-38
BMD lumbar spine (g/cm2)	0.921 ± 0.1	0.945-1.384
BMD total hip (g/cm2)	0.860 ± 0.1	0.050-1.197
T-score lumbarspine (S.D.)	-2.0 ± 1.2	-5.2-1.9
T-score total hip (S.D.)	-1.3 ± 0.9	-4.2-1.4
Grade 2/ 3 VFs n (%)	84 (25.6)	-

Osteoporosis prevalence and reference database performance

Figure 2 (*A*, *B* and *C)* shows a strong positive correlationand a good distribution of the Moroccan reference lumbar spine T-score by the European, Middle Eastern and American reference databases. In the overall study group, using Moroccan reference curve, one hundred and forty four women were identified with osteoporosis at any site defined as lumbar spine or total hip T-score≤-2.5 and giving a prevalence of osteoporosis at 43.9% (Table II). Accordingto the reference curves of Europe, Middle East and USA,osteoporosis prevalence at any site was 138 (42%), 137 (41.7%) and 132 (40.2%);respectively (p=0.01).

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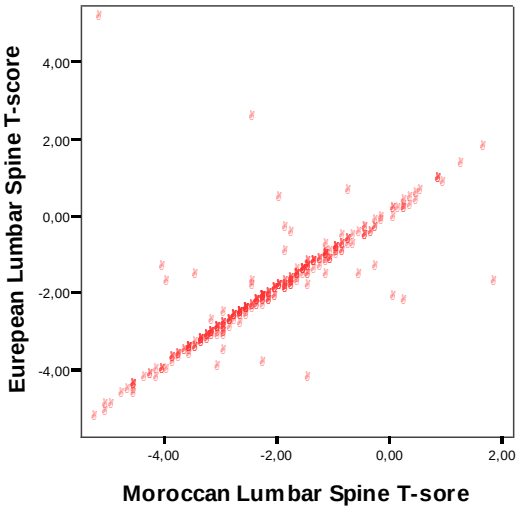
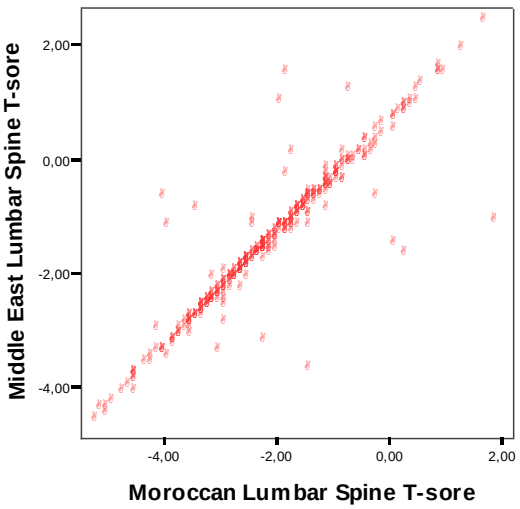
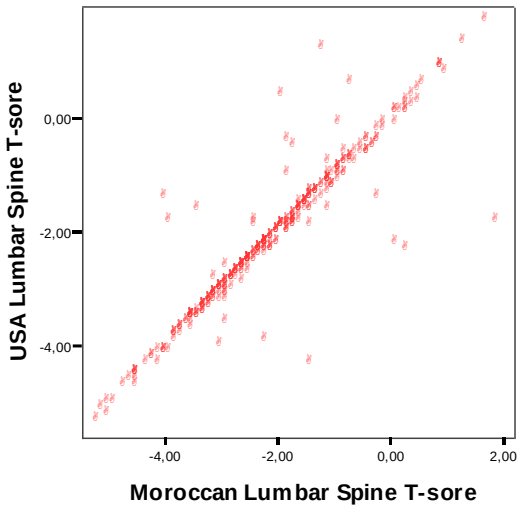


A: scatter-plots of Moroccanlumbar spine T-score against European.



B: scatter-plots of Moroccanlumbar spine T-score against Middle East.



C: scatter-plots of Moroccanlumbar spine T-score against USA.

Figure 2 A, *B* and *C*: distribution of Moroccan reference lumbar spine T-score by the European, Middle East and USA referencedatabase.

Table II: Prevalence of osteoporosis (OP) usingdifferent population bone densitometer reference databases.

	Morocco	Europe	Middle East	USA	*p*
OP lumbarspine n (%)	135 (41.2)	134 (40.8)	132 (40.2)	131 (39.9)	0.01
OP total hip n (%)	43 (13.1)	28 (8.5)	31 (9.4)	26 (7.9)	0.004
OP any site n (%)	144 (43.9)	138 (42)	137 (41.7)	132 (40.2)	0.01

OP at any site= OP at lumbar spine or OP at total hip.

The AUCs are reported in Table III and depicted in Figure 3. The highest AUC was observed forMoroccan lumbar spine reference database (0.687).The European lumbar spine reference database had the second largest AUC(0.674) followed by the Middle Eastern (0.670) and finally by the American lumbar spine reference curve (0.667).

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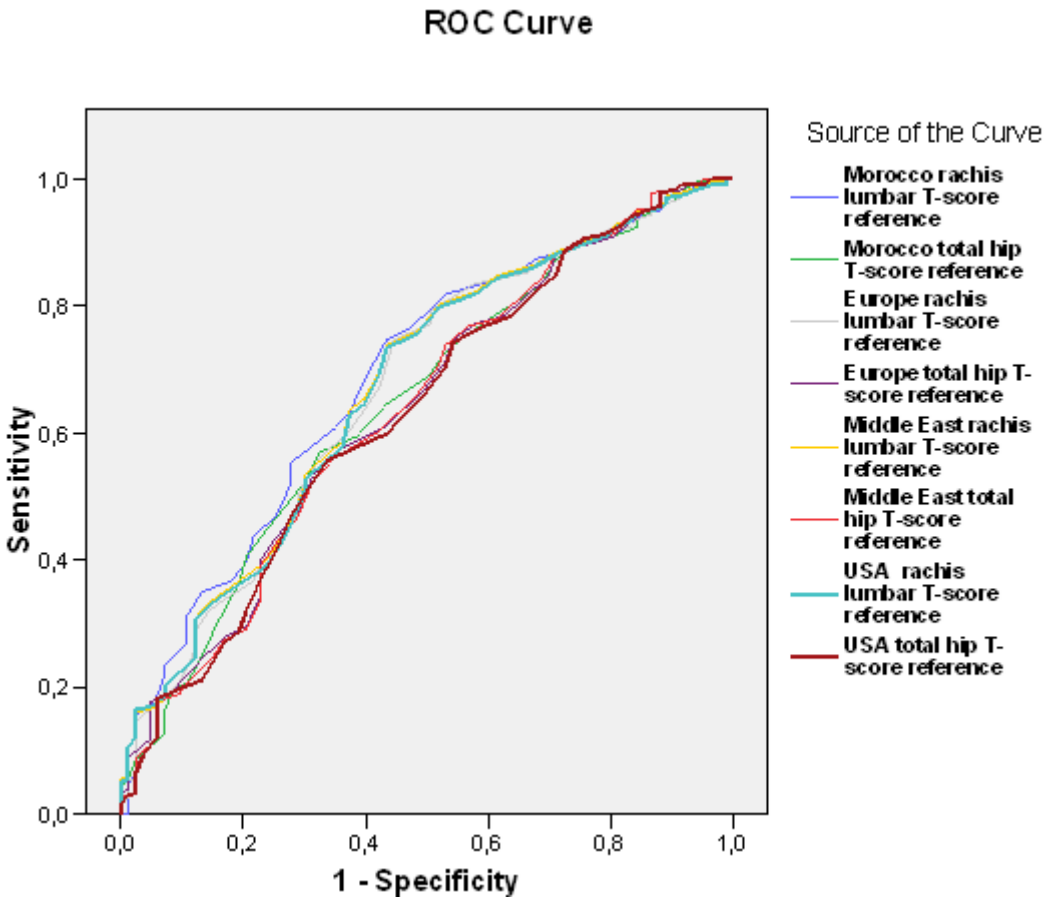

Figure 3: Receiver Operating Characteristic (ROC) curves for prediction of vertebral fractures using different reference database T-scores.

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Table III: Area Under Curve (AUC) of Receiver Operating Characteristics (ROC) for the prediction of grade 2/3 vertebral fractures usingdifferent reference databases.

	Reference database	AUC	*p*
Lumbar Spine T-score	Moroccan	0.686 (0.619-0.751)	<0.0001
	Europe	0.674 (0.606-0.742)	<0.0001
	Middle East	0.670 (0.602-0.737)	<0.0001
	USA	0.667 (0.599-0.736)	<0.0001
Total Hip T-score	Moroccan	0.647 (0.578-0.715)	<0.0001
	Europe	0.636 (0.565-0.706)	<0.0001
	Middle East	0.631 (0.561-0.702)	<0.0001
	USA	0.635 (0.570-0.709)	<0.0001

Table IV shows the sensitivity, specificity, PPV, NPV, and positive LR of different reference databases for the prediction of grade 2/3 vertebral fractures.The Moroccan database hadthe best sensitivity and specificity balance (65.5% - 63.8%) and thehighest positive predictive value(38.5) and positive likelihood ratio (1.8).

Table IV: Sensitivity, specificity, positive predictive value, negative predictive values andpositive likelihood ratioofdifferent reference databasesfor the prediction of grade 2/3 vertebral fractures.

	Se (%)	Sp (%)	PPV (%)	NPV (%)	PLR
Morocco	65.5	63.8	38.5	84.2	1.8
Europe	61.4	64.2	37.2	82.2	1.7
Middle East	61.4	63.8	37	82.7	1.6
USA	60.4	63.3	37	85	1.6

Se: sensitivity, Sp: specificity, PPV: positive predictive value, NPV: negative predictive value, PLR: positive likelihood ratio.

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As shown in Table 5, a stepwise conditional binary regression analysis and the resulted odds ratios with 95% confidence intervals were reported for osteoporosis using all bone reference databases. The Moroccan (OR [CI 95%] = 5.8 [1.2 – 27.8]) and, at a lower odds, theEuropean (OR [CI 95%] = 2.7 [1.3 – 5.7]) reference databases wereindependentlyable to predict prevalent vertebral fractures.

Table V: ORs for different osteoporosis reference database measurements associated with grade 2/3 vertebral fractures.

	OR	95% CI	*p*
Morocco	5.8	1.2-27.8	0.027
Europe	2.7	1.3-5.7	0.007
Middle East	2.7	0.6-4.6	NS
USA	2.4	0.2-4.5	NS

OR: odds ratios, CI: confidence interval.

DISCUSSION

This study shows that Moroccan database with the highest AUC, sensitivity, PPV, PLR and resulted odds ratio, can independently predict prevalent asymptomatic osteoporotic vertebral fracturesin postmenopausal women recruitedfrom general population. In our cohort, the prevalence of osteoporosis was excessively important.The relatively high average age of our study group may account for this result. Compared to the European, Middle Eastern andAmerican reference curves, the proportion of subjects with a BMD-based diagnosis of osteoporosis at any site (lumbar spine ortotal hipT-score ≤-2.5) was higher when using Moroccan population-specific database.It has been well demonstrated that there are ethnic and racial differences in BMD and T-score values[23].In this context, several studies have evaluated BMD in Arab and western populations[6, 24-27].A Lebanese study [24]evaluating reference bone mineral density curves found BMD values taken at the lumbar spine to be around5-6% lower than American/European values for elderly subjects over 60 years. Total hip BMD values were 2-3% lower in the postmenopausal years.In Tunisia, bone loss is 5% higher in the lumbar spine and 1.1% in the total hip than in Italy[28].

In our work, even in a comparable socio-cultural context,the use of Moroccan database gave a higher prevalence of osteoporosis than using Middle Easternreference curve(43.9% *vs*.41.7%). In this regard, a relevant osteoporosis inter-Arab comparative study showed thatspine BMD of Moroccan women were lower than the Kuwaitis, but higher than the Saudi and Lebanese females[6]. The Saudi women weighed heavier than the Kuwaiti women of all ages[29]. Indeed, thinner women tend to have less bone mass and a greater risk for osteoporosis and fractures than heavier ones[30]. However, increasing parity might be expected to protect against bone loss because of pregnancy related increases, intestinal calcium absorption and cumulative estrogen exposure and a later age at menopause [31, 32], although other studies have reported either no correlation between parity and BMD[33] or a negative correlation[34].In a previous study, the Moroccan reference curve for the lumbar spine and total hip was significantly different from the Caucasian normative data reported by the manufacturer, and this has a significant impact on subject with osteoporosis classification according to the WHO criteria and consequently with prevalent vertebral fractures [6]. However, these results did not agree with those of a Lebanese study proving a better performance of the universal database to predict VFs [35].The use of the Moroccan database could overestimate the prevalence of osteoporosis, which has economic repercussions through the inappropriate use of treatment [36]. However, an underestimation of this prevalence may have morbid consequences with all the socioeconomic impact generated by the occurrence of an osteoporotic fracture [37].

In our study, The AUC was significantly greater for Moroccan Lumbar Spine T-score reference database (AUC =0.686) than other AUC T-scores and successfully identified most women with vertebral fracture with the best sensitivity and specificity balance, and the higher PPV,NPV and PLR.Overall, the use of theEuropean, Middle Eastern or American specific database does not improve the diagnostic performance of DXA for prevalent vertebral fractures.This is to suggest that choosing a Moroccan specific database instead of the others population reference curves will translate into a calculated T-score that merely reflects the difference between Moroccan and foreign population-specific peaks. Thus, even if the Moroccan followed by the European database can predict respectively more than five and twotimesthe presence of vertebral fractures, and which can be explained by geographical proximity, that result does not relatively account for the complex relationship between bone density and vertebral fracture risk. Certainly, patients with osteoporosis are at increased risk for fractures especially vertebral[38], but there are other factors associated with the fracture riskincluding age, body mass index, history of traumatic peripheral fracture, years since menopause, number of parity,current smoking, bone micro architecture and genetic variants [8, 39-42].

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As in most studies, our study has limitations. For example, the subjects in our sample were either referred or came in spontaneously for osteoporosis evaluations, and may differ in some ways from the general population. Also, our cohort may not be adequately representative of the whole Moroccan population. However, because the recruited population is a balanced mixture of the various regions constitutive of the country, we believe that the impact on the prevalence estimation is limited.Further Moroccan ethnic studies needed to help better control of the expected epidemiological features.

CONCLUSION

We showed, in a cohort of Moroccan postmenopausalwomen recruited from the general population,that the Moroccan reference database with theelevated prevalence of osteoporosiscan better identify subjects athighest risk of prevalent asymptomatic osteoporoticVFs. This result suggests itsusefulness in selecting women for VFA indication.

Disclosure statement

All the authors state that there is no conflict of interest related to this manuscript.

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