TEN YEARS FRACTURE RISK ESTIMATION AMONG WOMEN ABOVE 45 YEARS IN MADINA, SAUDI ARABIA

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Abstract

Background*: Osteoporosis is a bone disease characterized by low bone mass and microarchitectural deterioration of bone tissue. Fracture Risk Assessment Tool (FRAX) is a risk assessment tool that calculates a patient's ten years probability of fracture.*

Objective*: To assess the prevalence of osteoporosis and estimate the 10 year- probability of osteoporotic fractures among women above 45 years in Madina, Saudi Arabia.*

Materials and Methods*: This cross-sectional study was carried out on 370 women. Bone mineral density (BMD) was measured by dual-energy X-ray absorptiometry (DEXA scan) at Taibah Early Diagnostic Center, Madina, KSA between 2016 and early 2017. A diagnosis of osteoporosis was made according to World Health Organization (WHO) criteria. The ten years fracture risk for major osteoporotic and hip fracture was calculated online using Fracture Risk Assessment Tool (FRAX).*

Results*: The mean age of the women was 57.3 ± 7.8. Of the participants, 33.8% were osteoporotic, and 45.7%. were osteopenic. The mean 10-year probability of a major osteoporotic or hip fracture was 3.1% and 0.43%, respectively. For women aged ≥ 70 years, the prevalence of osteoporosis was 74.3% and osteopenia 22.9%, and the mean 10-year probability of a major osteoporotic or hip fracture was 2.9% and 28.6%, respectively. In total, approximately 0.3% of women were at high risk of a major osteoporotic fracture (risk ≥ 20%) and 4.9% were at high risk of a hip fracture (risk ≥ 3%). Furthermore, one in seven osteoporotic women was at high risk of a hip fracture at 10 years.*

Conclusion*: Although osteoporosis is common among women above 45 years, the risk of osteoporotic fracture is only of concern among older women. Preventive measures to avoid fracture among elderly women is a priority.*

Key words: *Osteoporosis, Osteopenia, Fracture, FRAX, Saudi Arabia.*

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INTRODUCTION:
Osteoporosis is a bone disease characterized by low bone mass and microarchitectural deterioration of bone tissue. It is caused by an imbalance between bone resorption and bone formation (increasing bone resorption or decreasing bone formation), which may happen due to ageing, estrogen deficiency, calcium or vitamin D deficiencies. (1) Out of every two women aged over 50 years, one of them will develop an osteoporosis-related fracture in her lifetime. (2)

An epidemiological analytic study done in 2012 among Saudi population aged 50 - 79 years old showed that the prevalence of osteoporosis and osteopenia were 34% and 36.6% respectively. The incidence of osteoporotic related fractures of vertebral bone was 20% - 24%. (3) The incidence of hip fracture is suspected to increase by 240% in women by 2050, in the world, compared to rates in 1990.(4)

Fracture Risk Assessment Tool (FRAX) is a risk assessment tool that calculates a patient's ten-years probability of fracture. It is a useful tool to aid clinical decision making about the use of pharmacologic therapies in patients with low bone mass.(5) FRAX uses bone densitometer measurements (DEXA scan) along with other risk factors for osteoporosis for fracture risk estimation which include age, ethnicity, body mass index (BMI), a prior fragility fracture, parental history of hip fracture, current tobacco smoking, ever long-term use of glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and alcohol consumption of 3 or more units daily.(5)

In 2013, a study conducted In Al Hassa, Saudi Arabia to estimate the 10-years probability of osteoporosis related fractures and identifying those in need of osteoporosis treatment among Saudi adults attending primary care centers using FRAX® score. Of those aged ≥ 60 years, 14.4 and 18.4% scored probabilities for major and hip fractures respectively suggesting osteoporosis treatment.(6)

In Palestine a study showed that the 10-years probability of major osteoporotic fractures (MOF) was significantly associated with increase age, female gender, multiparity, previous fracture, rheumatoid arthritis, and administration of corticosteroid. The median 10-year probability of MOF and hip fracture (HF) based on BMD were 3.7 (2.43-6.18)%, and 0.30 (0.10- 0.68)% respectively.(7) Evidence showed that many women who developed a fragility fracture were not diagnosed and treated probably for osteoporosis. (8,9)

The aim of this study is to estimate the ten-years fracture risk among women above 45 years old in Madina, Saudi Arabia.

METHODOLOGY:
Study design and Study setting and Study period:
This is a cross-sectional analytic study that was done in Taibah Early Diagnostic Center in Al-Madina City between the period of January 2017 until January 2018.

Sampling:
The sample size was 384, calculated using OpenEpi statistical website with confidence interval 95%. Inclusion criteria included women above 45 years who live in Al-Madina and underwent DEXA scan at Taibah Early Diagnostic Center during January 2016 to January 2018. Exclusion criteria included women who are below 45 years old.

Data collection:
The data were collected by a questionnaire in English language filled by interviewers. First, the researchers gathered the contact details of the patients who fitted the inclusion criteria from the center. Then we contacted the patients and asked them about the risk factors of osteoporosis which are: smoking status, history of parents hip fracture, history of previous fracture, history of glucocorticoids use, rheumatoid arthritis, alcohol use and having any disease that leads to secondary osteoporosis. After that, the following data have been taken from the system: height, weight, bone mineral density, T score and Z score for lumbar spine L1-L4 and right and left femoral neck. All of these data used for FRAX calculation using Abu Dhabi version.

Statistical analysis:
The collected Data were entered using Microsoft Excel and analyzed using the statistical package for social scientists (SPSS) software version 21, United States of America. SPSS has been used to generate graphs and tables. Statistical methods included descriptive analysis, such as numbers, percentages and frequencies. Quantitative data were expressed as mean and standard deviation (SD). Qualitative data were expressed as numbers and percentages. The mean and proportion of the 10-year probability of a major osteoporotic or hip fracture using FRAX tool with and without BMD.

The discriminating ability of the FRAX tool to identify people at increased risk of fracture after a 10-year period was assessed using the area under the curve (AUC) of receiver operating characteristic (ROC) curves.

Ethical consideration:
The ethical approval was obtained from the research ethical committee at Taibah University and also another approval was obtained from Taibah Early Diagnostic Center. Informed consent was taken from the patient participating in the study after explaining the aim of the study and their privacy was assured.

RESULTS:
In this study, we analyzed 370 Saudi women aged between 45 and 83 years with a mean age of 57.3 ± 7.8.
The demographic data for the participants are presented in Table 1.

Variable	Pencent
Mean age	57.37
Percentage of age groups (%) 45-50 51-55 56-60 61-65 66-70 71 and above	19.5 27.8 22.4 14.3 7.6 8.4
Mean height (cm)	154
Mean Weight (Kg)	75.1
Mean BMI	31.64
Smoking %	3.0
Alcohol use %	0
Fragility fracture %	14.6
Parent hip fracture %	5.4
Glucocorticoids use %	5.7

Table 1: Demographic data for the participants.

The mean BMD of the spine was 0.897± 0.16 g/cm2 and the mean femoral BMD was 0.840± 0.14 g/cm2. BMD decreased as the age increased as shown in Fig. 1. Of the participants, 36.7% were osteoporotic (8.4% of them had severe osteoporosis), and 44.6% were osteopenic. The prevalence of osteoporosis increased significantly with age as shown in Fig 2.
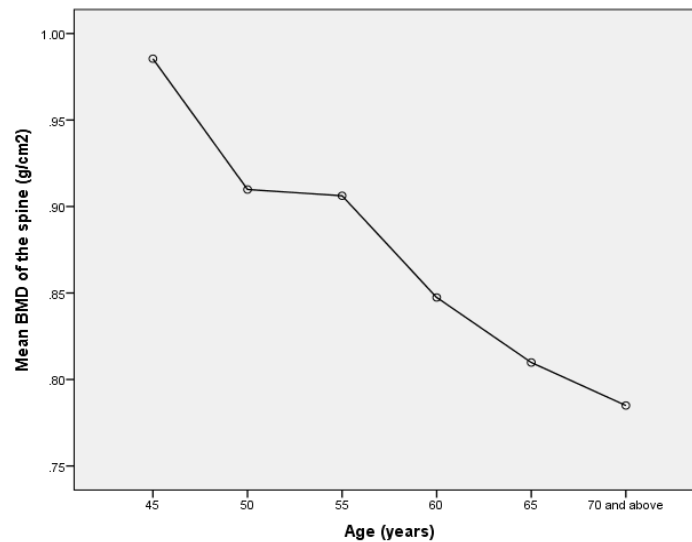
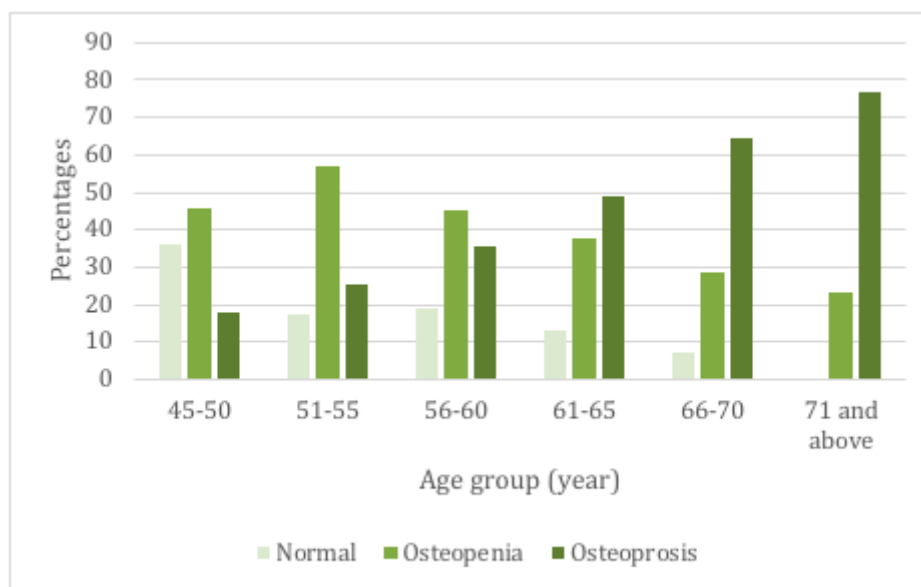Fig 1: Mean spinal bone mineral density by age.

Fig 2: Proportion of osteopenia and osteoporosis by age groups.

Fig 2: Proportion of osteopenia and osteoporosis by age groups.

The mean and proportion of the 10-years probability of a major osteoporotic or hip fracture using FRAX tool with and without BMD are presented in table 2.

FRAX	Group	Mean± SD	P-value	Percentage (%)	P-value
Major osteoporotic fracture	Without BMD	3.62±3.081	0.089	0.5	0.94
	With BMD	3.27±2.537		0.3	
Hip fracture	Without BMD	0.97±1.677	0.000	8.1	0.00
	With BMD	0.58±1.213		4.3	

Table 2: Mean and proportion of the 10-year probability of a major osteoporotic or hip fracture with and without BMD among the participants.

For women aged >70 years, the prevalence of osteoporosis was 76.7% and osteopenia 23.3%, and 3.3% of them were at high risk of a major osteoporotic fracture (both with BMD or without BMD) (risk ≤ 20%(and 43.3% were at high risk of a hip fracture (risk ≤ 3%( )with including BMD to the FRAX %23.3). The cutoff level of

FRAX major osteoporotic fracture risk estimated without BMD for identifying osteoporosis at the femoral neck was 4.45%. The sensitivity, specificity and AUC were 33.1%, 80.0% and 0.615. The cutoff level of FRAX hip fracture risk estimated without BMD for identifying osteoporosis at the femoral neck was 1.15%. The sensitivity, specificity and AUC were 33.1%, 83.3% and 0.623 (Fig 3).
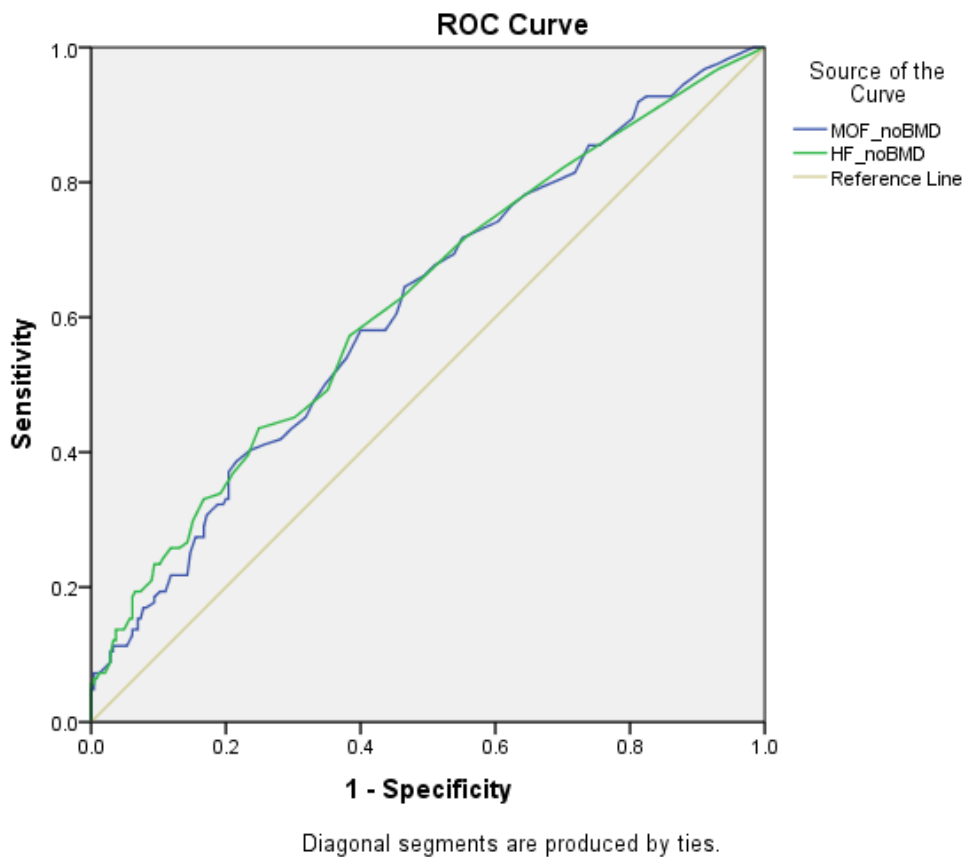

Diagonal segments are produced by ties.

Fig 3: Usefulness of FRAX major osteoporotic and hip fractures risk for diagnosis of osteoporosis. The curve represents the receiver-operating-characteristic (ROC) curve for detecting osteoporosis.

DISCUSSION:

No disease has attracted attention in the last 2 decades all over the world, such as osteoporosis. (10) 200 million women are affected by osteoporosis and it is a major cause of morbidity and mortality worldwide. (11) In this study, 36.7% of the participants were osteoporotic (8.4% of them had severe osteoporosis), and 44.6% were osteopenic. Similar result has been reported in systematic review study done in KSA, 2012 on 5160 healthy women 50 to 79 years of age (mean, SD: 56.8 [2.7]), showed that 34.0% (8.5%) were osteoporotic and 36.6% (6.6%) were osteopenic. (3) A higher percentage has reported in Taiwan, showed that out of 63 patients 36 (57.1%) were osteoporotic and 19 (30.1%) were osteopenic. (12) In contrast, Japanese study done on women aged 40 to 70 years showed a lower prevalence of osteoporosis 17.5% and osteopenia 15% (13). Al-Shoumer in Kuwait reported 20.2% and 12.5% of osteoporotic BMD of the spine and femur neck among postmenopausal women, respectively,

whereas osteopenic BMD of the spine and femur neck was 35.4% and 42.8%. (14)
The incidence of osteoporotic fragility fractures in a study done in the Eastern region of Saudi Arabia among 1,300,336 women aged 55 or above was 7528. Where the prevalence was 42% and 38.6% at neck of femur and intertrochanteric fractures respectively. (15)

Age is considered as a significant risk factor for osteoporosis. In our study the prevalence of osteoporosis and osteopenia was significantly increasing with age. For women who were 70 years old or above, osteoporosis and osteopenia prevalence was 76.7% and 23.3% respectively. Similar result was reported in Spanish study showed a higher rate of fractures in the group over 65 years old (16). This is higher than a study in Taiwan which exhibited prevalence of osteoporosis for females in the same age (≥70 years old) about 62.9% (17). In a Chinese study 35.8% of females ≥65 years old only had osteoporosis (18). Another

study in Bulgaria showed that 16.8% of women ≥50 years old had osteoporosis and 46.5% had low BMD of femoral neck (19).

Of our sample 3.3% had high risk for major osteoporotic fracture (MOF) and 43.3% had high risk of hip fracture (HF). In Bulgarian study the mean 10-years probability of MOF was 13.4 ± 9.2% and the mean HF was 2.8 ± 5.2% (19). In a French study that was conducted on 494 postmenopausal women, probabilities for MOF and HF was 3.9 ± 2% and 0.8 ± 0.9% respectively (20). A different study that was done in Poland during 2012 concluded that the MOF for their sample was 79.1% and the risk for HF was 79.5% which is the highest among all the other studies (21). According to Spanish study that measured the FRAX among patients with and without fractures showed a significant difference ($p < 0.001$). In patient with fracture, mean FRAX of MOF without femoral neck (FN) T-score was 6.44% (6.94 SD) and 8.25 (9.19 SD) with FN T-score and HF was 2.38 (5.20 SD) and 3.59 (7.39 SD) respectively. While in patients without fracture, MOF without FN T-score was 3.35 (2.81 SD) and 3.73 (3.48 SD) with FN T-score and HF was 0.74 (1.40 SD) and 0.86 (1.94 SD), respectively (16).

In the present study, the cutoff level of FRAX MOF risk estimated without BMD for identifying osteoporosis at the femoral neck was 4.45%. The sensitivity, specificity and AUC were 33.1%, 80.0% and 0.615. The cutoff level of FRAX HF risk estimated without BMD for identifying osteoporosis at the femoral neck was 1.15%. The sensitivity, specificity and AUC were 33.1%, 83.3% and 0.623 respectively.

A study that was done in Japan over 2009 until 2010 to investigate the efficacy of FRAX tool in specific health checkups compared to periodic osteoporosis screening. The cutoff level for osteoporosis treatment initiation according to ROC curve was 8 % for men and 10.5 % for women (22). Also, another cohort Japanese study that followed a group of women concluded that measuring FRAX with and without femoral neck BMD does not show significant difference as the AUC of FRAX with femoral neck BMD for MOF is 0.69 and for estimation of femoral neck fracture is 0.88. AUC of FRAX without femoral neck BMD for MOF is 0.67 and HF is 0.86 both of which are higher than our study results (0.615 vs. 0.67 and 0.623 vs. 0.86 respectively) (23). The AUC, sensitivity and specificity of FRAX tool in Japanese women are 0.789, 82% and 63% respectively with cutoff value for major osteoporotic fracture 7.2%. (13). FRAX tool has shown a good modality for detecting patients with high risk of fragility fractures. As in hip fracture

FRAX without BMD was higher than FRAX with BMD (0.97±1.677 vs. 0.58±1.213) (P-value= 0.000). In agreement, a Spanish study showed a similar significant result for risk for hip fracture ($p < 0.001$). It was best detected by FRAX without BMD [AUC = 0.883, 95 % CI 0.827–0.938], in comparison with FRAX including FN T-score [AUC = 0.857, 95 % CI 0.773–0.941] and FN BMD alone [AUC = 0.814, 95 % CI 0.712–0.916] (16).

CONCLUSION:
Although osteoporosis is common among women above 45 years, the risk of osteoporotic fracture is only of concern among older women. Preventive measures to avoid fracture among elderly women is a priority.

List of abbreviations
FRAX: Fracture Risk Assessment Tool
DEXA: dual-energy X-ray absorptiometry
WHO: World Health Organization
MOF: Major Osteoporotic Fracture
HF: Hip Fracture
BMD: Bone Mineral Density
ROC: Receiver Operating Characteristic
AUC: Area Under the Curve
FN: Femoral Neck

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