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Fracture Assessment tool of Osteoporotic (FRAX) Fractures with bone Mineral Density (BMD) in Babylon-Iraq

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ABSTRACT

Osteoporosis is the leading cause of the bone weakness of the Skelton and increased risk of the fractures particularly of the spine, hip and wrist and its global health problem. The WHO fracture risk assessment tool, FRAX, is a computer-based algorithm with an input of patient demographics, a "yes" or "no" response indicating the presence or absence of each of seven clinical risk factors for fracture, and femoral neck BMD (when available) to estimate the 10-year probability of major osteoporotic fracture (ie, hip, spine, proximal humerus, and distal forearm). Many risk factors for osteoporotic fractures have been identified, including clinical factors such as age and history of fracture and measured parameters such as body mass index (BMI) and bone mineral density (BMD). The bone DEXA machine start to use in Babylon in Merjan teaching hospital in year (2011) and from that time the number of patients whom examined and screen for osteoporosis were at least (5000) patients. Aim of study was Assessment of FRAX index in Babylon population. A cross sectional study done in Merjan hospital in Babylon-Iraq with FRAX assessment and bone mineral density assessment by DXA for 202 patients of both sex, 90.6 % of patients were female, and the mean age was $[54.56 \pm 13.33]$ years. The Results show that Patients with age between 56-65 had the highest percentage and osteopenia [42.0%] and osteoporosis [44.9%] in comparison with other age group ($p < 0.001^*$), the patients with age older than 65 years had the higher mean of major osteoporosis and hip fractures [11.30% and (5.78), respectively ($p < 0.001^*$), the probabilities of major osteoporosis $> 20\%$ and hip fracture $> 3\%$ were highest among patients with osteoporosis (15.21 ± 10.38) and (7.68 ± 8.31) respectively. There were significant association between 10 years risk of fracture and each age group and BMI level, history of fracture as well as T score grade, 47% of high risk fracture were among patients older than 65 years. We concluded that the study was done to improve the assessment of fracture risk and the treatment consideration by using of clinical risk factors with BMD that mean the treatment and prevention measures should not directed only on the basis of the T score for BMD. This study showed that with increasing the numbers of risk factors like low BMI, history of fracture and the advancing of the age in association with osteoporosis or osteopenia would lead to increasing the risk of hip fracture or major osteoporotic fracture, which better than use of BMD alone, this will help us specially in patients with osteopenia or osteoporosis so the use of FRAX is essential because it provide clear answer about the risk of fracture better than BMD measurement alone.

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INTRODUCTION

Osteoporosis is the leading cause of the bone weakness of the Skelton and increased risk of the fractures particularly of the spine, hip and wrist and its global health problem and because its associated fractures it is important cause of mortality and morbidity that affecting millions of people in the worldwide

The first sign of osteoporosis is a fracture, for this reason osteoporosis is often referred to as silent epidemic, the bone fragility and susceptibility that lead to fracture is the result of low bone mass and micro architectural deterioration of the bone tissue the goal of osteoporosis treatment is fracture risk reduction. Identification of patients at high risk for fracture is facilitated by the World Health Organization (WHO) diagnostic classification system, whereby osteoporosis is diagnosed in the presence of a T-score of -2.5 or less. However, many fragility fractures occur in individuals with a bone mineral density (BMD) T-score that is better than -2.5 (Shuit, 2004).

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The WHO fracture risk assessment tool, FRAX, is a computer-based algorithm with an input of patient demographics, a "yes" or "no" response indicating the presence or absence of each of seven clinical risk factors for fracture, and femoral neck BMD (when available) to estimate the 10-year probability of major osteoporotic fracture (ie, hip, spine, proximal humerus, and distal forearm) and the 10-year probability of hip fracture.

The FRAX algorithm computes the 10-year probability of hip fracture and/or a major osteoporotic fracture (of the spine, hip, forearm, or humerus). The use of the tool improves risk assessment compared with the use of BMD alone.

FRAX is now a component of many national guidelines for the assessment of osteoporosis and international guidelines for postmenopausal osteoporosis and glucocorticoid-induced osteoporosis (Kanis, 2008).

Fragility fractures associated with osteoporosis are common and cause significant costs, morbidity, and mortality. In white populations, approximately 50% of postmenopausal women and 20% of men older than 50 years will experience at least one fragility fracture in their remaining lifetime. Many risk factors for osteoporotic fractures have been identified, including clinical factors such as age and history of fracture and measured parameters such as body mass index (BMI) and bone mineral density (BMD) (Sambrook, 2006)

The important potential application of fracture risk calculators is to identify patients without osteoporosis by BMD criteria who nevertheless are at high risk of fracture and may benefit from closer monitoring and/or treatment. Since most osteoporotic fractures occur in older osteopenic women, (Siris, 2004)

Cost-utility analysis then may be applied to FRAX-derived data, using numerous economic, social, and political assumptions, to determine the magnitude of fracture risk at which it is likely to be cost-effective to initiate pharmacologic therapy to reduce fracture risk. FRAX has been incorporated recently into bone densitometer software and some handheld computer devices, allowing greater access to this tool as an aid in making treatment decisions (Binkly, 2010)

The risk of fracture of elderly women was double with each SD reduction in BMD (Marshall, 1996; Johnell, 2005).

From the known relationship between BMD and fracture risk factors and the loss of bone with age it expected that the hip fracture risk will rise four fold and the increase in the risk with age was approximately seven fold greater than be explained by BMD alone (Kanis, 2000; Delaet, 1997)

The screening and diagnosis of osteoporosis start in Babylon at [2008]by use of spiral CT scan and the first study done at Babylon province in year (2009) (Alkazzaz, 2013).

The bone DEXA machine start to use in Babylon in Merjan teaching hospital in year (2011) and from that time the number of patients whom examined and screen for osteoporosis were at least (5000) patients.

Aim of study:

The aim of this study to apply assessment tool for the predication of the risk of fracture in women and men with use of risk factors with use of femoral neck bone mineral density measured by DEXA machine.

Patients and methods:

This cross sectional study and was conducted from January 2013 to December 2014, 202 patients from both genders were included to achieve the aim of the study at Merjan teaching hospital ,all patients were referred to rheumatology unit for bone density measurement by DEXA machine .all people whom enrolled in this study underwent medical history that assessed from their interview to include :name ,age ,gender ,body weight ,height ,address as well as history of chronic disease, rheumatological disorder and history of drug use ,also history of family osteoporosis and personal history of fragility and smoking habit, the female was asked about menopausal state and its duration and female considered postmenopausal if she experienced the last menstrual cycle at least 1 year prior to the history taking time[p38smaha rech].the clinical risk factors utilized were those identified from interview of persons .these include parental history of hip fracture ,exposure to systemic steroid ,a prior history of fragility fracture ,current smoking ,high intake of alcohol[3 or more units daily on average and the presence of rheumatoid arthritis as indicator for secondary osteoporosis. the exclusion criteria were: patient refuse ,pregnant lady, extreme obesity ,patients recently had gastrointestinal contrast or radionuclide and patients with incomplete information .The BMD of both hips were examined by bone densimeter,DEXXUM3 manufactured by Osteosys ,Korea, before the examination the weight and height of patients were measured in light indoor clothing by the use of well calibrated digital weight and height scale measuring device ,BMI was calculated by dividing weight in kilograms by the square of the height in meters, complete blood count ,renal function test and liver function done for whom got systemic disease.

We used FRAX Lebanon because the Lebanese patients of similar characteristics of Iraqi and thus offer the best FRAX tool to be used to measure fracture risk in patients at risk of osteoporosis, which hits one in three women and one in five men worldwide[Lebanon],this country is one of the highest with calculation of FRAX per million of population in the world (Kanis, 2008).

Statistical analysis:

Statistical analysis was carried out using SPSS version 20 .Categorical variables were presented as frequencies and percentages. Continuous variables were presented as mean with either 95% confidence interval [CI].One way analysis of the variance [ANOVA] was used to compare among more than two means .The Pearson's chi-square test [χ^2] test was used to determine the association between categorical variables .A p – value of ≤ 0.05 was considered as statistically significant.

Results:

This study was carried out on to 202 patients ,their mean age was $[54.56 \pm 13.33]$ years old the age of the patients was range between 25 to 75 years old ,90.6 % of patients were female tab.[2]

The patients whom aged between 35-55 years had the significant high mean of BMD than other age groups as shown in fig (Shuit, 2004) while the group of patients with age between 56-65 had the highest percentage and osteopenia[42.0%]and osteoporosis [44.9%]in comparison with other age group[$p < 0.001^*$] [fig2].

The patients with age older than 65 years had the higher mean of major osteoporosis and hip fractures[11.30] and [5.78],respectively [$p < 0.001^*$][fig3].

There were significant mean difference of age ,BMI,BMD ,probability of major osteoporosis and hip fractures by T score grades in patients with osteoporosis aged 60.89 ± 13.11 years while there was significant association between patients with osteopenia and BMI variables as shown in tab ((Shuit, 2004)).

However the probabilities of major osteoporosis $> 20\%$ and hip fracture $> 3\%$ were highest among patients with osteoporosis [15.21 ± 10.38]and [7.68 ± 8.31]respectively as shown in tab (Shuit, 2004).

There were significant association between 10 years risk of fracture and each age group and BMI level ,history of fracture as well as T score grade ,47%of high risk fracture were among patients older than 65years, [64.7%] of patients with high risk fracture had a history of fracture bone ,however [82.4%]of high risk of fracture was among patients with osteoporosis as shown in tab (Kanis, 2008).

Discussion:

This study was done to improve the assessment of fracture risk and the treatment consideration by using of clinical risk factors with BMD that mean the treatment and prevention measures should not directed not only on the basis of the T score for BMD.

The FRAX is used now for the assessment of individuals to identify those who would candidate for pharmacological therapy while previously the majority of clinical guidelines for the management of osteoporosis have been made recommendation for the intervention based on the T-score for BMD (Kanis, 2008). The recent data that relates high fracture probability with FRAX to densitometric osteoporosis may have important clinical implications in Asia where, except in a few countries, access to bone densitometers is limited.

The FRAX model has been calibrated based on fracture and mortality data for China, Hong Kong, Japan, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Jordan and Lebanon, and is a work in progress. Unfortunately, there is a lack of epidemiological data from other Asian countries to enable wider calibration. Although using available FRAX models in countries without fracture data may not be suitable, it may be possible to extrapolate fracture risk in neighbouring countries with similar ethnicities and levels of development (Koh, 2012)

In our study we found that with increasing the age the probability of major and hip fractures specially after age of 65 years ,this finding was similar to study done by J Kanisetal at2002 in which there was increased in 10 years probabilities of hip and spine with age and T score (Kanis, 2002)

The fracture probability was not affect by the sex of our patients ,which was similar the finding of J Kanis study, thus the effect of age is independent risk on BMD and intervention not depend on T score only.

The importance of age risk on the probability of fractures was important finding in many studies where at age of 50 years the 10 –years hip fractures is approximately 2% in women but at age of 80 years it is 12%for the same T-score while for major osteoporotic fractures ,the 10-year probability is approximately 11% in women at age of 50 years with T score -2.5 increased to 26% at age of 80 years with same T score (Kanis, 2001; Hui, 1998).

This study showed that with increasing the numbers of risk factors like low BMI ,history of fracture and the advancing of the age in association with osteoporosis or osteopenia would lead to increasing the risk of hip fracture or major osteoporotic fracture, which better than use of BMD alone , this will help us specially in patients with osteopenia because it is transitional state so the use of FRAX is essential because it provide clear answer about the risk of fracture for each patients (Kavroudakis, 2012), these result were similar to study published at 2009 in which BMD tests alone selected women at higher risk of hip fracture than the use of clinical risk factors and the combined use of BMD and clinical risk factors identified fewer women above the threshold but with higher risk of hip fracture and consequently a lower number needed to treat and better to use the combination of both when available than one alone in all age groups of low BMD patients (Johansson, 2009).

Conclusion:

The use of FRAX is important tool to detect patients with osteoporosis with high risk when use in combination with BMD measurement ,but also can use alone in area where the DXA machine not available in hospital in Iraqi towns that for early detection of patients at risk and treat them because free available on line and it easy to use.

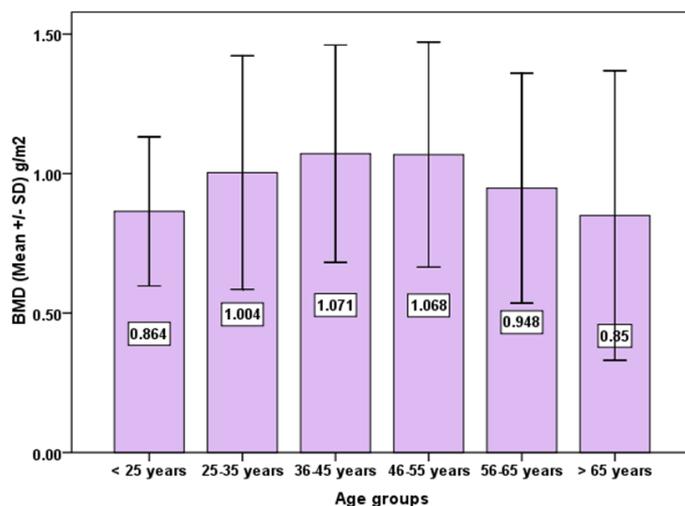


Fig. 1: BMD mean differences by patients' age groups.

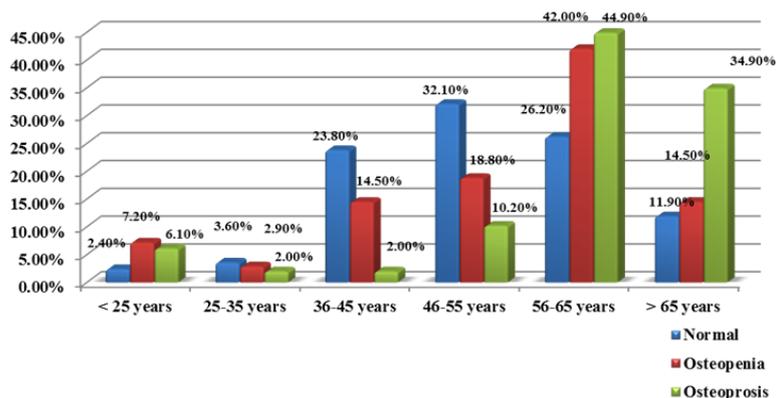


Fig. 2: Proportion of osteopenia and osteoporosis according to dual energy X-ray absorptiometry by age groups

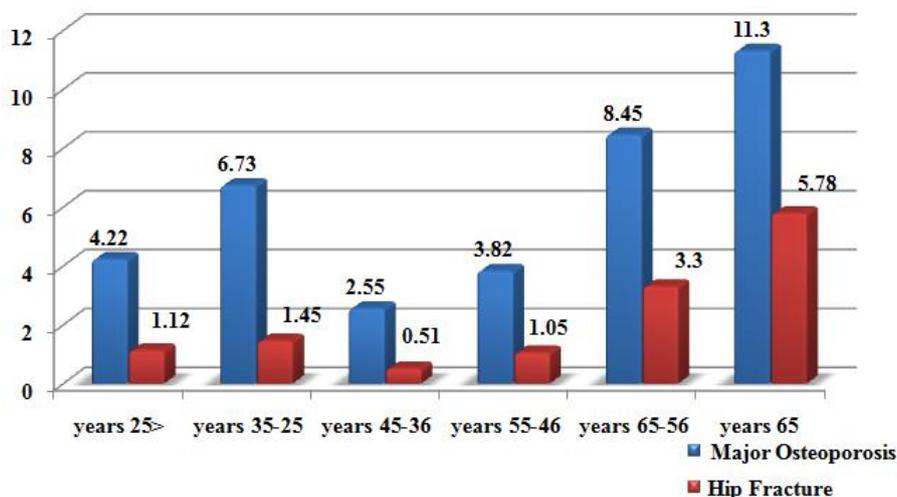


Fig. 3: Mean 10-year probability of osteoporotic fracture by age groups.

Table 1: Mean Differences of Age, BMI, BMD, Probabilities of Major Osteoporosis > 20% and Hip Fracture > 3% by T Score Grades

Variable	T Score	Mean± SD	F	P value
Age	Normal	51.71± 11.52	8.20	<0.001*
	Osteopenia	53.53±14.19		
	Osteoporosis	60.89±13.11		
BMI	Normal	33.45±6.09	23.38	<0.001*
	Osteopenia	29.77±6.27		
	Osteoporosis	26.47±4.30		
BMD	Normal	1.14±0.13	242.51	<0.001*
	Osteopenia	0.90±0.07		
	Osteoporosis	0.73±0.07		
Probability of Major Osteoporosis > 20%	Normal	2.84±4.69	61.46	<0.001*
	Osteopenia	5.56±3.63		
	Osteoporosis	15.21±10.38		
Probability of Hip Fracture > 3%	Normal	0.93±3.22	38.26	<0.001*
	Osteopenia	1.19±0.96		
	Osteoporosis	7.68±8.31		

Table 2: Association of 10 Years Risk of Fracture by Study Variables.

Variable	10 Years Risk of Fracture		χ^2	P Values
	High risk (%)	Low risk (%)		
Age Groups (years)			9.941	0.048 ^{ab}
< 25 years	0 (0.0)	10 (5.4)		
25-35 years	0 (0.0)	6 (3.2)		
36-45 years	1 (5.9)	30 (16.2)		
46-55 years	1 (5.9)	44 (23.8)		
56-65 years	7 (41.2)	66 (35.7)		
> 65 years	8 (47.0)	29 (15.7)		
Sex			0.210	0.647
Male	1 (5.9)	17 (9.2)		
Female	16 (94.1)	168 (90.8)		
BMI			9.227	<0.019 ^{ab}
Underweight < 18.5 kg/m ²	1 (5.9)	2 (1.1)		
Normal weight 18.5-24.9 kg/m ²	6 (35.3)	31 (16.8)		
Overweight 25-29.9 kg/m ²	6 (35.3)	50 (27.0)		
Obese ≥ 30 kg/m ²	4 (23.5)	102 (55.1)		
History of fracture bone			11.390	0.001*
Yes	11 (64.7)	16 (8.6)		
No	6 (35.3)	169 (91.4)		
Family history of fracture bone			0.375	1.000 ^a
Yes	0 (0.0)	4 (2.2)		
No	17 (100.0)	181 (97.8)		
T. Score			34.141	<0.001*
Normal	2 (11.8)	82 (44.3)		
Osteopenia	1 (5.9)	68 (36.8)		
Osteoporosis	14 (82.4)	35 (18.9)		

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