

**SCREENING FOR OSTEOPOROSIS - A MISSED OPPORTUNITY?**

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**Background:** Osteoporosis is a common skeletal disease characterized by low bone mineral density (BMD) predisposing an individual to fragility fractures. Osteoporosis can be diagnosed with dual-energy x-ray absorptiometry (DXA). Pharmacotherapy for osteoporosis reduces the incidence of fragility fractures. Osteoporosis is clinically silent unless complicated by fracture; therefore, it is generally overlooked, particularly in an underserved population. The National Osteoporosis Foundation (NOF) recommends BMD-measurement in all women and men older than 65 years and 70 years respectively. The main objective of our study was to assess rates of osteoporosis screening in eligible patients in our resident run ambulatory clinic. In addition, charts were reviewed to determine whether the osteoporosis risk factors were assessed in these patients. Moreover, osteoporosis screening was compared to screening rates of other common diseases, such as colon, breast, cervix and prostate cancer.

**Methods:** Medical records of women over 65 and men over 70 years were reviewed and analyzed as to whether BMD-testing with DXA and osteoporosis risk factor assessment were performed. Rates of colonoscopies, mammographies, PAP smears and PSA-measurements were also collected.

**Results:** A total of 53 women and 27 men of 2063 patients were over 65 and 70 years respectively. Twenty one women (39.6%) and one man (3.7%) were referred for BMD-testing. Osteoporosis was diagnosed per DXA scan in seven patients (one man and six women); treatment was started in all cases. Family history of fragility fracture was obtained in four cases (7.5%) of women and in no men. Sixteen women (30.2%) and five men (18.5%) had 25(OH)-Vitamin D level drawn. When indicated, screening colonoscopy was performed in 28.3% of women and 67.8% of men. PAP smear was obtained in 60.4% and mammography was performed in 71.7% of those eligible. 59.3% of male subjects were screened for prostate cancer with PSA.

**Conclusion:** This study reveals that only a minority of patients was sent for BMD measurement. This was particularly striking in males, where only 3.7% were screened for osteoporosis. Osteoporosis risk factors were rarely obtained. Screening rates for colon, breast, cervix and prostate cancer were much higher. We conclude that there is a lack of awareness of osteoporosis and its potential sequelae and an insufficient screening system utilized by the resident physicians examined in this study.

**USE OF THE FRAX TOOL: A NEW APPROACH TO THE DIAGNOSIS AND RISK ASSESSMENT OF OSTEOPOROSIS IN A GREEK RURAL AREA**

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**BACKGROUND:** Osteoporosis is recognized as a major Health Problem worldwide.

NOF recommends a comprehensive approach to the diagnosis and management of osteoporosis to establish the individual patients fracture risk with the use of medical history and examination together with BMD measurement, incorporated in the use of FRAX tool, released by WHO in February 2008.

The aim of this pilot study is the beginning of a cooperation between the district Hospital of Molaoi (GREEK NHS) with a pharmaceutical company, which provided the proper equipment and personnel from Athens, that is 285 km away. This cooperation will explore the management of osteoporosis in women of this region over 40, using the FRAX tool.

**METHODS:** We used the FRAX tool for a total of 200 women ,aged 40 and over, with and without BMD measurement of the heel. This densitometer is fully equivalent to central DXA assessment of the hip.

**RESULTS:** We have found that 55 out of 151 women (42,3%) ,aged 40-65 years, have a 10 year major osteoporotic fracture probability (<10YP>) over 6%, although 139 out of 151 had none to two risk factors of the FRAX tool. This is much higher than the UK percentage (6-20%) for the age of fifty ,set by Kanis et al, (6-9 % threshold- eligibility for BMD testing). After BMD measurement, 66 persons (43,7%) had still a <10YP> over 6%. This applies to , even for ages from 40-49, because 20 out of 53 (37,7%) had , after BMD measurement, their <10YP> over 6%.

For women over 65, we have found 29 out of 49 to be eligible for treatment after a DEXA measurement. Also 41 out of 49 had none to two risk factors. We have found that 28 out of 49 (57,1%) had a <10YP> over 14%, still higher than the UK percentage for this age (14-27%). In total 36 out of 200 (18%) were found eligible for treatment, according to the N.O.F. guidelines, lower than the U.K. percentage of 23-46%, depending on age.

Our results are depicted on the following table:

Characteristics

Values(mean)

Range

Age : 40-79 57,44

BMI(kg/m2): 20,0-47,0 28,81

AGE	<10YP> without BMD	<10YP> with BMD	T <-2,5	-1<T<-2,5 @ 10yhip>3%	major ost p >20%	FRAX TOOL CALCULATED RISK FACTORS						
						NONE	ONE	TWO	>TWO			
40-49 (n=53)	14 (26.4%)	20 (37.7%)				0	0	0	15 (28.3%)	21 (39.6%)	9 (16.9%)	4 (7.5%)
50-65 (n=98)	41 (41.8%)	46 (46.9%)				1 (0.01%)	4 (4.1%)	2 (2.0%)	20 (20.4%)	44 (44.8%)	30 (30.6%)	8 (8.1%)
>65 (n=49)	10yp>14 24 (48.9%)	10yp>14 28 (57.1%)				11 (22.4%)	17 (34.7%)	1 (0.02%)	11 (22.4%)	16 (32.6%)	14 (28.5%)	8 (16.3%)
TOTAL (n=200)					12 (6%)	21 (10.5%)	3 (1.5%)		46 (23%)	81 (40.5%)	53 (26.5%)	20 (10%)

**CONCLUSION:** Central DXA assessment of the hip or spine is currently the “gold standard” ,but in our study the heel densitometer proved to be a good screening tool for further evaluation and follow up with DEXA.

This pilot study demonstrates the possible heavy burden of osteoporosis in the region outlining the need for further studies and intervention under the age of 50, although this the usual age cut-off limit for NOF and European screening guidelines.

**IMPROVEMENT OF TREATMENT DECISIONS IN EPILEPTIC PATIENTS BY PERFORMING LATERAL VERTEBRAL ASSESSMENT (LVA)**

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**Purpose:** The WHO fracture risk algorithm (FRAX™) is a tool developed to assist clinicians in making treatment decisions for patients at risk for developing osteoporotic fragility fractures.

The National Osteoporosis Foundation suggests that patients with a vertebral fracture or with a low bone mass and a FRAX™ calculated 10-year probability of fracture  $\geq 3\%$  for hip fracture or  $\geq 20\%$  for major osteoporotic fracture are at a high risk and should be considered for treatment. The FRAX™ algorithm is validated based on femoral neck bone mass as determined by bone mass densitometry (BMD) by dual-energy X-ray absorptiometry (DXA). The FRAX™ is considered to be most useful in patients with low hip bone mass and of less predictive value in patients with relatively normal BMD at the hip and low BMD at the spine. Epileptic patients have a 50% higher risk for developing osteoporotic fractures compared to non-epileptic patients.

Newer generations of DXA instruments, allow lateral vertebral assessment (LVA) and vertebral fracture assessment (VFA). Presence of compression vertebral fractures is considered to be a strong predictor of future vertebral and non-vertebral fractures.

The purpose of this study is to report our experience comparing the FRAX™ calculator and VFA findings in a cohort of epileptic patients.

**Method:** Chronic epileptic male subjects (more than two years of disease) taking antiepileptic drugs for at least two years were recruited from a VA primary care and neurology clinics. Recruited subjects underwent BMD evaluation with a GE LUNAR densitometer or a GE IDXA densitometer. Sites scanned included P-A L1-L4, morphometric studies of LVA and VFA from T7 to T12 and L1 to L4, bilateral hips, in addition to the non-dominant forearm. Height and weight were assessed in all subjects. The lowest femoral neck BMD and data collected from an Osteoporosis Risk Factor questionnaire were used to calculate the FRAX™ scores for each patient.

**Results:** 130 patients were studied; mean age of the group was  $63 \pm 13$  years. Based upon DXA results (P-A spine, hip, forearm), 26 patients were classified as osteoporotic, 61 osteopenic, and 43 had normal BMD. By FRAX™ 57 patients (44%) were considered to be at high risk for a major osteoporotic fracture for either hip or any other osteoporotic fracture (forearm, vertebral, humerus). Incidental vertebral compression fractures were found in 48 patients (37%), of these there were 20 patients (15%) who by performing LVA were found to have compression fractures but scored at a low risk on the 10-year FRAX™ calculator.

**Conclusion:** Incorporation of LVA and VFA as part of a comprehensive BMD evaluation by DXA scan in chronic seizure patients on antiepileptic drugs may improve fracture risk stratification and treatment recommendations.

**CHARACTERISTICS OF A POPULATION WITH BMD DEFINED OSTEOPOROSIS BUT LOW FRACTURE RISK**

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**Purpose of Study:** To examine the characteristics of patients with osteoporosis (T-score  $\leq -2.5$ ) who cannot be identified by FRAX as high fracture risk patients.

**Methods Used:** A retrospective chart review was performed on consecutive DXA scans collecting data on patients age 50 and older with a BMD indicating osteoporosis (T-score  $\leq -2.5$  at any site). Individuals were separated into high FRAX (group A) and low FRAX (group B) groups, where high FRAX was  $>3\%$  hip or  $>20\%$  major osteoporotic 10 yr fracture risk and low FRAX included patients with  $\leq 3\%$  hip and  $\leq 20\%$  major osteoporotic 10 yr fracture risk. FRAX was calculated without BMD included in the FRAX calculation.

**Summary of Results:** Data on 134 consecutive patients were analyzed. Group A had 73 patients: age 74 yrs, 81% Caucasian, 97% female. Group B had 61 patients: age 63 yrs, 46% Caucasian, 54% African American, 92% female. Group B had a higher hip (p  $<0.001$ ), lower spine BMD (not significant, p=0.188), higher BMI (29.0 vs 25.1, p=0.001), were younger (p  $<0.001$ ) and more likely to be African American (p  $<0.001$ ). Presence of self fracture (Odds Ratio=0.44 p= $<0.001$ ) but not parental hip fracture (Odds Ratio=0.51, p=0.205) increased the likelihood of being in Group A.

**Conclusions:** In this study, 46% of patients with BMD-defined osteoporosis had a low fracture risk by FRAX. In our population these patients were younger, predominantly African American, and had a higher BMI and hip BMD. Spine BMD was lower presumably due to the younger age reflecting less degenerative spine changes. NOF 2008 guidelines recommend initiating treatment for patients age 50 and older with osteoporosis (T-score  $\leq -2.5$ ) regardless their FRAX. If FRAX is a better predictor of fracture risk than BMD alone, then NOF 2008 osteoporosis treatment guidelines including treatment of osteoporosis based on T-score alone may need further modification. Modification may include restriction of treatment in younger, high BMI and non-Caucasian patients.

**MEDICAL HOME CARE MODEL IMPROVES QUALITY AND EFFICACY OF BONE CARE OF OUR PATIENTS AT SCPMG/RIVERSIDE MEDICAL CENTER**

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**CONTEXT:** Osteoporosis is a common and costly disease that is associated with high morbidity and mortality. Given the availability of efficacious anti-fracture medication, screening with BMD testing for osteoporosis is recommended in women aged  $\geq 65$  years and in men aged  $\geq 70$  year. Recently, it is also recommended that clinicians consider using Fracture Risk Assessment tool to evaluate absolute fracture risk to determine appropriate osteoporosis therapies. Our Electronic Medical Record integrated Medical Home care Model has made it possible for our Primary Care Physician to implement this recommendation promptly and effectively.

**CARE MODEL:** The "Healthy Bones" part of our Medical Home Care Model is a highly integrated and innovative process of capturing high risk members, and identifying those who may have the disease. This multidisciplinary team consists of the departments of Endocrinology, Orthopedics, Preventive Medicine, Radiology, Internal Medicine, Family Practice, and out reach and in reach programs. In conjunction with this, the department of Endocrinology has launched a walk-in clinic consisting of a supervising Endocrinologist, a Physician Assistant (PA), a Licensed Vocational Nurse (LVN), and a Project Manager to implement the bone care plan. The clinic actively assigns walk-in and out reached patients into the different management groups, initiates appropriate treatment, and then refers them to related care providers for follow up and/or further evaluation.

**RESULT:** Our care model has increased osteoporosis screening and treatment by 70 percent. This will reduce the risk of subsequent fracture significantly. This clinic provides patients the services of same-day evaluation and treatment following their BMD testing. Since the implementation of the clinic in February 2009, forty-seven percent of the abnormal t-score patients have been provided same-day evaluation and treatment. Of the remaining patients, forty-nine percent have been referred to Preventive Medicine and four percent to Endocrinology for further evaluation and treatment.

**CONCLUSION:** Our experience indicates that our Medical Home Care Model is accessible, comprehensive, integrated, patient-centered, safe, scientifically valid, accountable and satisfying to both patients and their physician.

**THE TEN YEAR PROBABILITY OF HIP FRACTURE IN THAI POPULATION BY WHO FRACTURE RISK ASSESSMENT TOOL**

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**Background:** The WHO Collaboration Center has identified a clinical risk factors which are including sex, age, body mass index, history of previous fracture etc, that call the FRAX<sup>®</sup> tool. The FRAX<sup>®</sup> algorithms give the 10-year probability of fracture. The output is a 10-year probability of hip fracture and major osteoporotic fracture to predict probability of fracture. It is considerable use to health care professionals, particularly in places where there are few DXA machines. But this tool limit number of country is not represented of references. The aim to determine the FRAX<sup>®</sup> tool (10-year probability of hip fracture) in Thai peoples ages over 50 years who have fragile fracture around hip as a diagnosis test.

**Methods:** The retrospective study was conducted during 2006 - 2008 by chart review and interview. 263 patients over the age of fifty with fragile fracture around hip were recruited compare with aged match control group, 270 patients. 10-year probability of hip fracture was evaluated by using the FRAX<sup>®</sup> WHO Fracture Risk Assessment Tool (available at <http://www.shef.ac.uk/FRAX/index.htm>). We used age, sex BMI and 7 clinical risk factors without bone mineral density (BMD) due to limited healthcare resources. The output was based on China model. The probability of hip fracture more than three percents should be assumed as patients fracture and needed to intervention.

**Results:** The populations in both groups were similar in age and gender ratio. At the cut point, probability of hip fracture was more than three percents, in these groups showed 171 in 263 patients and 114 in 270 control groups. The sensitivity was 0.65. The specificity was 0.58. Positive predictive value (PV+) was 0.60. The Negative predictive value (PV-) was 0.63. And Likelihood ratio LR (+ve) was 1.54, LR (-ve) was 0.61

**Conclusion:** WHO fracture risk assessment tool used 10-year probability of hip fracture at cut point 3% was ineffective and had limitation to predict fracture in Thai peoples. Because of low sensitivity and specificity, this tool may not suitable for the screening method for population with risk for fragility fracture. Further cohort study, vary in cut point decision and country-specific calculation tools especially in Thai model were needed to confirm this study.

**FRAX CONTRIBUTION TO THE MANAGEMENT OF PATIENTS WITH FRACTURE RISK. RESULTS FROM THE FIRST 19 MONTHS SINCE ITS IMPLEMENTATION IN OUR CLINICAL PRACTICE**

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**Introduction:** Using the WHO DXA-based T-score diagnostic criteria of osteoporosis to initiate treatment lacks sufficient sensitivity and specificity. FRAX was designed to identify patients with osteopenia and high fracture risk. Shortly after its introduction, it was suggested that FRAX should be used to “screen” patients for DXA. Nineteen months after its implementation in our clinical practice we evaluated the impact of FRAX on patient management.

**Material and methods:** The study population comprised all Caucasian post-menopausal women (n=541) in our case series. The mean age of the participants was  $62.5 \pm 8.9$  years and their mean BMI was  $27.6 \pm 4.6$  kg/m<sup>2</sup>.

FRAX estimations were based on the Spanish reference population as no equivalent data are available for the Portuguese population. The FRAX algorithm identified risk factors in 178 (38%) women, mainly a history of a previous fracture (12.6%) and a family history of fracture (11.6%). Multiple risk factors were present in 8.4% of women.

**Results:** A total of 199 (43%) participants were regarded as normal according to the WHO diagnostic classification, with 98 (21%) being diagnosed with osteoporosis and 168 (36%) with low bone mass. The majority of the osteoporosis diagnoses (84%) were based on spine analysis. Among the 59 women with a history of a previous fracture consistent with an osteoporotic etiology, only 21 (36%) had osteoporosis on DXA.

Forty-nine women had a FRAX 10-year probability of hip fracture  $\geq 3\%$ , with all but 10 having osteoporosis or a previous fracture. Six patients had a FRAX 10-year probability of major osteoporosis related fracture  $\geq 20\%$ . All were included in the  $\geq 3$  probability group.

In all, 146 patients (31%) were candidates for treatment. Among patients without a previous fracture, if the FRAX 10-year probability of hip fracture  $\geq 3\%$  was used as the selection criteria for further evaluation with DXA, 53 patients with osteoporosis (54% of all osteoporosis diagnoses) would have been missed.

**Conclusions:** In our study population, the majority of indications for treatment were based on the WHO category (defined by DXA) and history of previous fracture. FRAX 10-year probability of hip fracture  $\geq 3\%$  identified an additional 6.8% of women with low bone mass. FRAX should not be used to exclude patients from DXA analysis because 54% of osteoporosis diagnoses could be missed. The relatively young age distribution and high average BMI may explain the findings.

**FRACTURE RISK EVALUATION THROUGH FRAX<sup>®</sup> MODEL USING BMI ONLY IS SIGNIFICANTLY UNDERESTIMATED COMPARING TO THE USE OF FEMORAL NECK BMD**

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**Background:** FRAX<sup>®</sup> model offers the possibility to use either femoral neck BMD or BMI alone to evaluate fracture risk. Our aim was to evaluate the impact of using femoral neck BMD or BMI only on the fracture risk assessment based on this model.

**Materials:** We use a retrospective analysis of medical records of 280 patients (262 women and 18 men, mean age of 63.4 years) who received treatment in National Program for Osteoporosis in Elias Hospital and C.I. Parhon Institute in Bucharest in 2008. Patients were selected based on the availability of femoral neck BMD and the lack of previous antiosteoporotic treatment. We calculated major osteoporotic fracture risk based on femoral neck BMD respective based on BMI alone for every patient. Same analysis was done for hip fracture risk. For treatment recommendation a cut off point of 20% was used for major osteoporotic fracture and 3% for hip fracture.

**Results:** We found a significantly lower ( $p < 0.001$ ) risk fracture when we used BMI alone for both major osteoporotic fracture (mean 9.7 vs. 11.4) and hip fracture (mean 3.6 vs 4.8) risk evaluations. Using BMI alone comparing to femoral neck BMD to calculate major osteoporotic fracture risk, 17 patients (6%) were excluded from treatment recommendation and 2 (0.7%) were included. In the same manner, in the hip fracture risk evaluation, using BMI alone excluded 61 (21.8%) patients from treatment and 8 (2.8%) were included.

**Conclusion:** Use of BMI alone significantly underestimated fracture risk for both major osteoporotic and hip fracture. Treatment recommendation based on hip fracture risk assessment was changed in almost 25% of the patients when using BMI alone, mostly through exclusion from treatment (21.8%). It suggests that, for hip fracture risk assessment based on BMI alone could exclude from treatment a significant number of high risk patients.

**ASSESSING FRACTURE RISK WITH DXA: COMPARING 2008 TO 1998 NOF GUIDELINES - THE INFLUENCE OF FRAX**

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**BACKGROUND:** In February 2008, the NOF published new guidelines for fracture risk assessment. We sought to evaluate how these guidelines performed versus the previous 1998 guidelines.

**METHODS:** Between April 15, 2009 - July 15, 2009, 300 untreated, postmenopausal women having first DXA performed were identified. Using the current system, we calculated percentage of High Risk studies and whether risk was designated by T-score, FRAX, or both. Similarly, we interpreted same studies with 1998 guidelines, calculating percentage of High Risk studies and whether risk was designated by T-score or both T-score plus risk factors. Additionally, we compared the percentage of DXA scans classified High Risk with current guidelines but Low Risk with 1998 guidelines and also the percentage of DXA scans classified Low Risk with current guidelines but High Risk with 1998 guidelines. Finally, we determined potential cost savings using the current guidelines.

**RESULTS:** Using current guidelines, 29 % of DXA scans were High Risk, with 11% classified by T-score, 47% classified by FRAX, and 41% classified by both criteria. Using 1998 guidelines, 37 % of DXA scans were High Risk, with 80% classified by T-score and 20% classified by T-score plus risk factors. Five percent of DXA scans were classified High Risk by 2008 criteria but Low Risk with 1998 criteria (Table 1). In all these scans, FRAX methodology was the reason for High-Risk classification. These patients ranged from 70-90 years old. Conversely, 12% of DXA scans were Low Risk by 2008 criteria but High Risk by 1998 criteria. These were younger patients with age ranges 51-72 years old.

**CONCLUSIONS:** Using the 2008 guidelines, 29% of patients were classified High Risk vs. 37 % by 1998 guidelines. FRAX was especially useful in identifying High Risk patients in our older population. The 2008 criteria were less likely to assign High Risk to younger postmenopausal woman. Given the performance of the two guidelines in our 300 patients and based on average wholesale price of generic alendronate (\$960/ year, 2007 estimate), the estimated savings in our 300 patients was \$22,080/year. These savings have significant healthcare cost implications.

Table 1 - Change in classification identified from FRAX methodology or change in guidelines

<b>Low risk (1998 criteria)</b> ↓ <b>High risk (2008 criteria)</b>	<b>High risk (1998 criteria)</b> ↓ <b>Low risk (2008 criteria)</b>
14/300 patients - 5%( identified by FRAX)	36/300 patients-12%
Age 70-90	Age 51-72

**IS A 10-YEAR MAJOR OSTEOPOROTIC FRACTURE RISK ASSESSMENT AN EFFECTIVE COMPLEMENT TO A DENSITOMETRY EVALUATION**

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The WHO 10-year Fracture Risk Assessment is now being applied by many densitometrists with the hope that a 10-year Femur Neck Fracture Risk or a 10-year Major Osteoporotic Fracture Risk Assessment might significantly complement the clinical review of the Femur Neck T-score Assessment. The current study examined if the clinical risk profile and Femur Neck T-score generated different results in the 10-year Femur Neck and 10-year Major Osteoporotic Fracture Risk Assessment.

A population of 150 subjects\_75 male and 75 female-between 45 and 94 years of age underwent a review of their clinical history and a DXA examination of the hip. Results were processed by the Norland Illuminatus Fracture Risk Assessment Software to compute the 10-year Femur Neck Fracture Risk and the 10-year Major Osteoporotic Fracture Risk Assessment.

As expected, T-score was significantly related to both 10-year Femur Neck and Major Osteoporotic Fracture Risk in both male and female subjects (r value about 0.67) and 10-year Femur Neck Fracture Risk was very closely related to 10-year Major Osteoporotic Fracture Risk (r value about 0.95) suggesting a strong influence from the clinical history. When treatment thresholds were set at a Femur Neck T-score  $<-2.5$  a total of 71 subjects were identified as candidates. Adding the threshold of a 10-year Femur Neck Fracture Risk  $>3.0\%$  we found an additional 55 subjects qualified as treatment candidates. Finally, adding a 10-year Major Osteoporotic Fracture Risk  $>20.0\%$  added only six new subjects as treatment candidates.

The data indicate that the 10-year Femur Neck Fracture Risk Assessment significantly adds to the number of treatment candidates while the 10-year Major Osteoporotic Fracture Risk Assessment adds very few additional treatment candidates. We suggest the primary focus of the clinical assessment should be with the Femur Neck T-score and 10-year Femur Neck Fracture Risk Assessment.