International Journal of Orthopaedics Sciences

ISSN: 2395-1958
IJOS 2017; 3(4): 114-117

www.orthopaper.com
Received: 25-08-2017
Accepted: 26-09-2017

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FRAX predictior with and without BMD for assessment of osteoporotic fracture risk in the Himalayan state of India: A comparative study

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DOI: https://doi.org/10.22271/ortho.2017.v3.i4b.19

Abstract
Objective: BMD (bone mineral density) testing facilities are not available in every places in India. We compare the predictive ability of FRAX with BMD and FRAX without BMD for major osteoporotic and hip fracture in Himalayan population.
Materials and methods: a hospital based cross sectional study was conducted on patients attending the outpatient Department of orthopaedics of SGRRIMHS, and others for a period of 2 years from Aug 2015 to July 2017. A total no. of 125 patients (104 F+ 21M) in the age group 40 -90 years were selected randomly for study. Exclusion criteria were age less than 40 and more than 90 years, confirmed cases of osteoporosis, patients on antiresorptive treatment, cases of surgically removed ovary and uterus, bone metastasis. Dual Energy X-ray Absorptiometry (DXA) scans were obtained to assess presence of low BMD. FRAX calculations with and without addition of femoral neck BMD were done in all patients. Statistical Package for Social Sciences (SPSS) version 20 was used for statistical analysis.
Results: Hip fracture probabilities (6.00±10.47% -5.03±10.26%) and MO fracture probabilities (11.34±12.85%~ 11.89±12.87%) were similar with or without inclusion of BMD in FRAX tool respectively.
Conclusion: FRAX may be used to assess for 10 year hip and major osteoporotic fracture probabilities status in the absence of DXA facilities or avoiding unnecessary DXA scanning.

Keywords: bone mineral density, dual-energy X-ray absorptiometry, fracture risk assessment, without BMD, World Health Organization

1. Introduction
Osteoporosis is a systemic skeletal disorder which is nicknamed "silent thief" due to the asymptomatic nature of the disorder until it causes an osteoporotic facture [1, 2]. Osteoporotic fractures are one of the major causes of death in elderly men and women across the world [3]. Fragility fractures associated with osteoporosis are common and cause significant costs, morbidity, and mortality [4].
Hip fractures are the major cause of morbidity and mortality, although reliable epidemiological data are lacking hospital data suggest that hip fractures are common in India
Calcium and vitamin D nutrition plays an important role in determining bone health. Vitamin D Deficiency (VDD) in adults can precipitate or exacerbate osteopenia and osteoporosis and increase the risk of fractures, but question is how to detect and treat such cases and how to predict cases, for treatment or preventive measures, with good and cost effective manner, especially in the rural population of country like INDIA where patients cannot afford “DEXA SCANS” for economic and availability reasons.
The WHO introduced the Fracture Risk Assessment Tool (FRAX) in 2008 for use of estimating the 10-year probability of hip fracture as well as other major osteoporotic fractures (spine, forearm, or humerus) in untreated patients with osteopenia. FRAX calculates fracture probability of individuals from age, body mass index and risk factors comprising prior fragility fracture, parental history of hip fracture, current tobacco smoking, 0veruse of long‐ term oral glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis, and alcohol consumption with or without information on BMD [4].

Therapeutic interventions are recommended if the 10-year risk of fractures is more than 20% for major osteoporotic fractures (MOF) and more than 3% for hip fractures.
The aim of our study was to determine if FRAX calculations without BMD and with BMD would produce comparable predictions for the 10-year probability of hip fracture.

2. Materials and Methods

A hospital based random cross sectional study was conducted on patients attending the Out Patient Department Orthopaedics of SGRRIM&HS, and others for a period of 2 years from Aug 2015 to July 2017. A total number of 125 patients in the age group 40 to 90 years, of both sexes were screened for the study who visited OPD for various orthopaedics problems. We excluded confirmed cases of osteoporosis, patients on antiresorptive treatment, cases of surgically removed ovary and uterus, bone metastasis.

2.1 Measurements

Height and weight were recorded of all patients. Informed written consent has been taken from all participants. Participants were asked for information to be entered in the FRAX tool. These risk factors include history of prior fracture, family history of parental fracture, current smoking, long term glucocorticoids use, rheumatoid arthritis, secondary osteoporosis and alcohol consumption. Hip DEXA were obtained using the lunar DPX DXA system analysis version 13.6 (manufactured by GE healthcare). As per guideline of WHO subjects were categorized based on SD into normal BMD (-1 and above) low BMD (osteopenia, between-1 and <2.5) and osteoporosis (-2.5 and below) [5].

2.2 FRAX Calculation

Fracture risk probability was calculated by entering patients information on the FRAX calculator available online (http://www.sheffield.ac.uk/FRAX/tool) for Asian country India. BMD femoral neck obtained from DEXA scan was entered in the FRAX tool to compute FRAX with BMD fracture probability in terms of risk of major osteoporotic fracture (hip, spine, wrist and humerus) or Hip fracture alone. Thus we obtained FRAX with BMD and FRAX without BMD values for major osteoporotic and hip fracture for all participants.

2.3 Statistical Analysis

SPSS (version 20, IBM SPSS statistics for windows) was used for analysis of and all data. Descriptive statistics were used to report mean, standard deviation, standard error of deviation, percentage and range. Statistical significance was set at $p<0.01$. After running the normality test on data, Pearson correlation was applied. Correlation between risk probabilities obtained for Major Osteoporotic fracture and Hip fracture by the FRAX without BMD and FRAX with BMD was compared, thereafter correlation results were graphically represented by scatter plots.

3. Results

Total 125 patients with an average age of 59.72±11.11 (range 40 to 90 years) were included in the study consisted of 21 males (M) and 104 females (F). Mean BMD T score at the femoral neck was -1.27±1.05. According to femoral neck BMD 18 (14.4%) patients (3 M, 15 F) had osteoporosis, 60 patients (48%), (11 M, 49 F) had osteopenia and rest 47 (37.6%) patients (7 M, 40 F) had normal BMD.
Major Osteoporotic (MO) fracture probability without BMD 11.34±12.85% and with BMD 5.03±10.26% were calculated. Demographic baseline characteristics shown in table 1.
Mean Hip fracture probability was lower than the MO fracture probability. Hip fractures probabilities (6.00±10.47% -5.03±10.26%) and MO fractures probabilities (11.34±12.85%~ 11.89±12.87%) were similar with or without inclusion of BMD in FRAX tool respectively. There is significant positive relationship between all fracture probabilities (shown in table 2)
There was considerable agreement between them on applying Pearson's correlation. The correlation coefficient was r = .832 for major osteoporotic probabilities with or without BMD and r =.726 for hip fracture probabilities respectively.
The scatter plots show strong positive correlation between the FRAX without BMD and FRAX with BMD values for both probabilities.

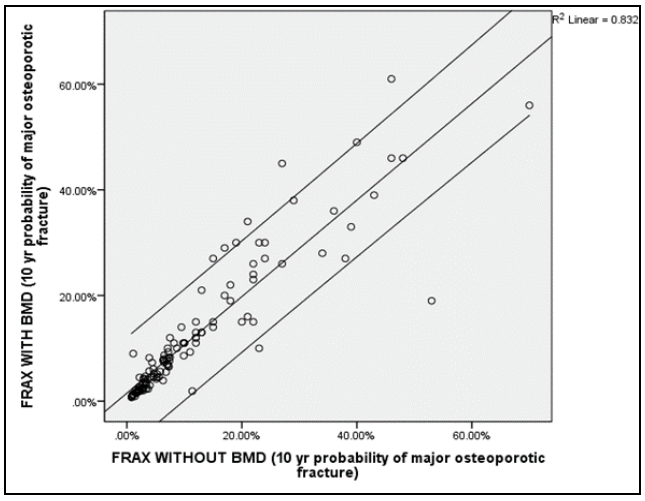
Table 1: demographic baseline characteristics of all 125 patients

	Age (yrs.)	Wt. (pound)	Ht (inches	FRAX with BMD (10 yrs. probability of MO fracture)	Femoral neck BMD	T score (neck of femur)	FRAX with BMD (10 yrs. Probability of hip fracture)	FRAX without BMD (10 yrs. probability of MO fracture)	FRAX without BMD(10 yrs. Probability of hip fracture)
Mean	59.74	140.54	62.01	11.89%	.98	-1.27	6.00%	11.34%	5.03%
Std. Error of Mean	.992	2.474	.279	1.15%	.011	.09	0.93%	1.15%	0.91%
Median	60.00	143.00	62.00	7.30%	1.00	-1.0	1.70%	6.50%	0.70%
Std. Deviation	11.087	27.554	3.115	12.87%	.126	1.05	10.47%	12.85%	10.26%
Variance	122.92	759.21	9.702	165.78	.016	1.10	109.75	165.24	105.36
Range	50	149	19	60.30%	1	5	58.00%	69.20%	70%
Minimum	40	71	52	0.70%	0	-4	0.00%	0.80%	0%
Maximum	90	220	71	61.00%	1	1	58.00%	70.00%	70%

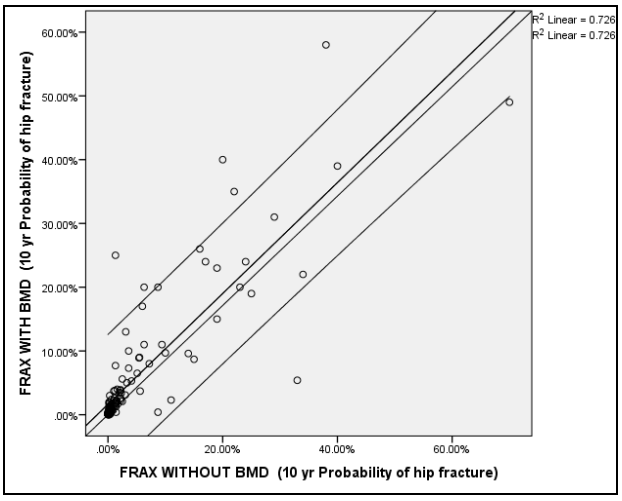
Table 2: Pearson correlation of FRAX fracture probabilities between FRAX with BMD and FRAX without BMD.

		Frax with BMD (10yrs probability of major osteo- porotic fracture)	Frax without BMD (10 yrs. prob ability of major osteoporotic fracture)	Frax with BMD(10 yrs. Probability of hip fracture)	Frax without BMD (10 yrs. Probability of hip fracture)
Frax with BMD (10 yrs. probability of major osteoporotic fracture)	Pearson Correlation	1	.912**	.925**	.815**
	Sig. (2-tailed)		.000	.000	.000
	N	125	125	125	125
Frax without BMD (10 yrs. probability of major osteoporotic fracture)	Pearson Correlation	.912**	1	.830**	.924**
	Sig. (2-tailed)	.000		.000	.000
	N	125	125	125	125
Frax with BMD (10 yrs. Probability of hip fracture)	Pearson Correlation	.925**	.830**	1	.852**
	Sig. (2-tailed)	.000	.000		.000
	N	125	125	125	125
Frax without BMD (10 yrs. Probability of hip fracture)	Pearson Correlation	.815**	.924**	.852**	1
	Sig. (2-tailed)	.000	.000	.000	
	N	125	125	125	125
**. Correlation is significant at the 0.01 level (2-tailed).					

Scatter plot graph of agreement between FRAX estimated 10-year fracture probabilities with and without the inclusion of BMD results (1) major osteoporotic fracture (2) hip fracture



Graph 1



Graph 2

4. Discussion

The aim of our study was to evaluate the impact Femoral Neck (BMD values on

The Frax calculation in population of Himalayan state of India.

The Frax tool is recommended for use in patients with osteopenia to identify those at high risk for osteoporotic fracture so they can be treated with FDA-approved agents [6].

Treatment is recommended if the 10-year risk is ≥20% for Major osteoporotic fracture and ≥3% for hip fractures in patients with osteopenia [7].

Because BMD data may not always be available, for various reasons, it was important to determine if *FRAX* alone (without BMD) is an accurate prediction tool for fracture incidences likely to happen in future time.

The World Health Organization (WHO)–sponsored tool, FRAX, is a country-specific calculator that incorporates 10 readily available clinical risk factors for fracture and can be used with or without BMD.

an alternative, and would be an efficient, effective, economic and easily affordable predictive tool, especially poor countries like India, to determine a patient's risk for hip fracture if FRAX without BMD provides results comparable to frax with BMD.

Our results suggest that predictions of FRAX without BMD are comparable to those of *FRAX with BMD (p≥0.01)*. Our results show comparable performance of the FRAX calculator without BMD and FRAX with BMD. This is similar to results reported. who conducted a cross sectional study on Pakistani females done by Madeeha Sadiq [8]. There are several lines of evidence that suggest that responses to treatment are independent of BMD [9]. Researches conducted in the United States and Turkey have reported comparable results for FRAX calculations with and without BMD [10, 11]. *Ramesh*

Keerthi Gadam et al, (1) in their study, also concluded that *FRAX* produced predictions that were identical to those of *FRAX-BMD* in most cases. Younger age is more indicative of an identical prediction [12].

Therefore, use of the FRAX tool without BMD will identify most subjects for treatment and may be a more predictive tool than DXA alone. We advocate use of DXA for monitoring treatment after diagnosis is made with the FRAX tool.

5. Conclusion

Our present study shows that-

FRAX alone is an effective screening tool for predicting the risk of osteoporotic fracture, even without calculating BMD, with costly methods like DEXA.

This is especially relevant can give potential impact on healthcare costs, especially economically compromised countries

In rural settings where DXA scanning is unavailable, FRAX could play an important role, as the tool, and is easily accessible.

In cases of limited finances, FRAX is a good and comparable alternative for predicting osteoporosis risk.

If by future studies, identical or comparable results are obtained (with larger groups of studies) this method will prove to be a great tool not only for screening, diagnosing or managing the ostoepenic /osteoporotic patients, but will also be a great help to prevent and manage the future cases of fracture in the peoples of economically compromised countries.

We recommend further studies on this subject, with larger population groups, in the hands of future scientists for comparison and conformations, so that better understanding of the subject and better results are obtained.

That can be a great service to the peoples in the third world, living with compromised and limited assets and low economic condition.

It must be emphasized that the calculated ten-year fracture probability is only a guideline for treatment decisions. Specific treatment decisions should be individualized. Some clinical risk factors, such as the use of glucocorticoids, have been considered indications for treatment by themselves. The American College of Rheumatology has recommended that patients receive prophylactic bisphosphonate therapy when they undergo treatment with ≥5 mg/day of prednisolone for three months or more and their T-score is less than −1.0[42]. Thus, in this circumstance, treatment should be considered even if the ten-year fracture probability calculated with FRAX is <3% for a hip fracture or <20% for a major osteoporosis-related fracture [13].

6. Acknowledgments: We thank all of the participants who made this study possible, as well as our staff who were instrumental in this study.

7. Disclosure Summary: The authors have nothing to disclose.

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