Introduction

Osteoporosis develops with decreasing (or low) bone mass, structural deterioration of bone tissue, and increasing bone fragility. Initially it is asymptomatic but may later on lead to easy fractures, back pain, loss of height, spinal deformities, and a stooping posture. These are inevitable with aging. The risk rate of these incidences increases exponentially with age. Such risks can be assessed with a bone mineral density (BMD) test using a dual-energy X-ray absorptiometry (DXA), but this procedure is expensive. The main challenge in relation to the cost rationale is to develop appropriate public health approaches to bone health.

ABSTRACT

Background: Bone health is an important requirement for healthy aging. Osteoporosis is an important cause of both mortality and morbidity among older adults. If we can predict the risk of future osteoporosis by cost-effective methods, we can prevent it up to certain level and plan intervention accordingly. That's why the present study aims to estimate the likelihood of osteoporosis in patients attending the outpatient department (OPD) in a selected community health center (CHC). Methods: A cross-sectional study was conducted in a CNC in Siwan, Bihar, India. An equal number of male and female patients were recruited by quota sampling. A semi-structured proforma was prepared for data collection using the Fracture Risk Assessment (FRAX) tool without performing a bone mineral density (BMD) test in order to assess major osteoporotic fractures and risk for hip fractures with other requisite information. Results: The collected data were organized using Microsoft Excel and analyzed using the statistical software SPSS Statistics 20. As data were gleaned and put under different categories, a statistical analysis based on the Chi-square test was carried out, and an ROC (receiver operating characteristic) curve was also drawn for statistical inference of the data gathered. The main findings of our analyses include the following: Approximately 15% males and 30% females in the study sample had a higher risk of osteoporosis and about 9% males and 36% females had a higher risk of hip fracture. Overall, the findings showed a statistically significant association (p < 0.05) between the gender of the participants and the FRAX risk scores for osteoporosis and hip fracture. Conclusion: Previously osteoporosis was thought of as a disease that affected only women; nevertheless, emerging findings show that osteoporosis is not unusual in men. The FRAX tool can be used as a screening tool before going for a BMD test.

Keywords: Fracture and osteoporosis, FRAX, future risk prediction, BMD, OPD, CHC, ROC, AUC, menopause

Cross-sectional osteoporotic risk prediction with the FRAX without BMD in male and female patients attending OPD in a community health center of Bihar

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Access this article online

Quick Response Code:

Website: www.jfmpc.com

DOI: 10.4103/jfmpc.jfmpc_1165_21

How to cite this article: Bhujade R, Srivastava A, Chinchodkar KN, Pathak P, Ibrahim T. Cross-sectional osteoporotic risk prediction with the FRAX without BMD in male and female patients attending OPD in a community health center of Bihar. J Family Med Prim Care 2022;11:2345-50.
Expensive diagnostic tools and treatment interventions should target those with a higher risk for developing bone disorders. By adding the Fracture Risk Assessment (FRAX) tool without BMD in common wellness screenings, we can help community make better-informed decisions about health conditions specifically at the primary level of care. The present study was designed to foretell the risk of osteoporosis by using clinical factors only.

**Methodology**

After taking approval from the Institutional Ethical Committee, the present study was carried out in a community health center (CHC) of Bihar. Patients in the age range of 40–90 years attending the outpatient department (OPD) were included in the study, whereas patients who did not give consent or were already having clinical symptoms of osteoporosis were excluded from the study. By quota sampling we have recruited 250 men and 250 women as participants in the present study. For assessing the risk of osteoporosis, we used the FRAX proforma without BMD. FRAX provides a quantitative estimation of the risk of fractures based on robust data for a substantial number of males and females in an ethnically and geographically different population. It contains multiple independent risk factors that are used to optimize the prediction of osteoporotic fracture. Although risk stratification can be ameliorated by considering clinical risk factors in combination with BMD, in a resource-limited country like India, it is not economically viable for every individual to opt for BMD in order to determine their bone health. This was the reason we used FRAX without BMD to predict the future risks for osteoporotic fractures. Overall, we found a 10-year probability of osteoporotic fractures to occur among both in males and females. Data analysis was carried out using the statistical analysis software, SPSS Statistics 20.

**Results and Observations**

Table 1 shows that an equal number of male and female participants were recruited and most (74%) of them were from urban areas. As much as 29% of the women in our study had reached menopause. In the weight category, only 32% participants were in the normal weight category and about 59% of the participants were in the obese or overweight category.

Table 2 shows that an almost equal number (77%) of male and female participants had a high risk of osteoporosis and hip fracture.

Table 3 shows the association between the FRAX score for the risk of osteoporosis and hip fracture and participants’ gender was found to be statistically significant at $P < 0.05$. A binomial logistic regression analysis using variables such as age, gender, menopause, and BMI in the study population was carried out to determine the presence of the high risk of hip fracture and osteoporosis. Approximately 15% males and 30% females had a higher risk of osteoporosis, and about 9% males and 36% females had a higher risk of hip fracture.

The above [Table 4] shows based on the Nagelkerke $R^2$ that the values of the dependent variables—risk of fracture hip and risk of osteoporosis—differed by 71% and 54%, respectively.

The first part of this table shows how many cases were correctly anticipated; a total of 375 and 82 cases were observed to be in the “no” and “yes” (of being “at risk”) categories, respectively, and were correctly predicted to be in the “no” and “yes” categories,
respectively. Whereas 12 cases were observed to be in the “no” category but predicted as “yes,” as many as 31 cases were observed to be in the “yes” category only initially but were later predicted to be in the “no” category.

Under the column head “percent correct,” the percentages of cases that are correctly predicted for high risk of hip fracture and high risk of osteoporosis were 91.4% and 89.2%, respectively.

Table 5 shows that age was a statistically significant predictor ($p < 0.05$), but gender, BMI, and menopause were not ($p > 0.05$). For age $p$ value is $< 0.05$ and for others its $> 0.05$. This indicates increasing age is associated with an increased high risk of hip fracture as compared to other independent variables. In the case of osteoporosis, age and BMI were statistically significant ($p < 0.05$), but gender and menopause were not ($p > 0.05$). This indicates increasing age and BMI are associated with an increased high risk of osteoporosis as compared to other independent variables.

Table 6 shows 113 cases were identified as high risk (positive result) and 387 cases identified as “not high risk” (negative result) in the case of hip fracture, whereas for osteoporosis, 112 cases were categorized “high risk” (positive) and 388 cases categorized as “not high risk” (negative).

Figure 1 and 2 shows The receiver operating characteristic (ROC) curve can be seen squeezed at the top left corner of the plot, which is a model with high sensitivity and high specificity. On the other hand, a curve close to diagonal line indicates a model with low sensitivity and low specificity.

Table 7 shows clearly that for the age variable the area under the ROC curve (AUC) is 0.928, which is extremely high. This model can also predict whether or not patient will develop the risk of hip fracture in future based on the variables gender and BMI, for which the AUC values are, respectively, 0.69 and 0.61. Given these low values, we can conclude that these are not good predictors of the risk for hip fracture in future.

Similarly, for the variable age it can be seen clearly that AUC is 0.87, which is extremely high. Again in this case the model yielded smaller AUC values for the variables gender and BMI, at 0.60 and 0.49, respectively, in predicting whether or not a patient will be at risk for osteoporosis in future. Hence, these are not good predictors of the risk of osteoporosis in future.

Table 8 shows 91 cases were under the high-risk category (positive result) and 159 cases were in the “not high risk” category (negative result) for the risk of hip fracture, whereas for osteoporosis 74 cases were categorized as positive and 176 cases as negative.

Figure 3 and 4 shows In both curves ($N = 250$), the line of plot hugs the bottom right corner, which means the model doesn't predict the risk for hip fracture as well the risk for osteoporosis based on the menopause variable.

### Table 4: Observed and predicted high risk of hip fracture and osteoporosis

| Hip fracture                  | Predicted high risk | Percent correct | Nagelkerke R² |
|------------------------------|---------------------|-----------------|---------------|
| Observed High risk of hip fracture | No 375 Yes 12 | 96.9 | 0.713 |
| Yes 31 | 82 | 72.6 | |
| Overall percent | | 91.4 | |

| Osteoporosis                  | No 375 Yes 13 | 96.6 | 0.549 |
|------------------------------|----------------|-------|-------|
| Observed High risk of osteoporosis | No 41 Yes 71 | 63.4 | |
| Yes 41 | 71 | 89.2 | |
| Cut-off value 0.500 | | | |

### Table 5: Variables in the equation

| Variable                | B     | SE    | Wald   | df | Sig. |
|-------------------------|-------|-------|--------|----|------|
| High risk of hip fracture |       |       |        |    |      |
| Age_new                 | 0.315 | 0.039 | 64.317 | 1  | 0.00 |
| Gender_MF (1)           | 1.103 | 0.792 | 1.939  | 1  | 0.164|
| BMI_category            | 4.448 |       | 0.217  |    |      |
| BMI_category (1)        | -1.072| 0.736 | 2.123  | 1  | 0.145|
| BMI_category (2)        | -1.058| 0.772 | 1.881  | 1  | 0.17 |
| BMI_category (3)        | -1.813| 0.873 | 4.307  | 1  | 0.038|
| Meno_category           | 1.499 |       | 0.221  |    |      |
| Meno_category (1)       | 0.851 | 0.695 | 1.499  | 1  | 0.221|
| Constant                | -19.045| 2.271| 70.352 | 1  | 0.000|
| High risk of osteoporosis |       |       |        |    |      |
| Age_new                 | 0.2   | 0.024 | 68.548 | 1  | 0.000|
| Gender_MF (1)           | -0.558| 0.793 | 0.496  | 1  | 0.481|
| BMI_category            | 15.744|       | 0.001  |    |      |
| BMI_category (1)        | -1.159| 0.488 | 5.636  | 1  | 0.018|
| BMI_category (2)        | -2.127| 0.564 | 14.204 | 1  | 0.000|
| BMI_category (3)        | -2.069| 0.639 | 10.474 | 1  | 0.001|
| Meno_category           | 3.487 |       | 0.062  |    |      |
| Meno_category (1)       | 1.474 | 0.789 | 3.487  | 1  | 0.062|
| Constant                | -11.261| 1.314| 73.401 | 1  | 0.000|

| Variable(s) entered in step 1: Age_new, Gender_MF, BMI_category, Meno_category. |

### Table 6: Receiver operating characteristic (ROC) curve

| Risk of hip fracture (n=500) | Risk of osteoporosis (n=500) |
|-------------------------------|-----------------------------|
| Positive*                    | 113                         | 112  |
| Negative                     | 387                         | 388  |

*The positive actual state is high risk.

Table 9 shows clearly that for the variable menopause the AUC values are 0.119 and 0.224, respectively, for the risk of hip fracture and the risk of osteoporosis; these again are extremely low values. Therefore, this model doesn't predict the risk of hip fracture and risk of osteoporosis in relation to the variable menopause.

### Discussion

Opting for costly diagnostic tests in low-risk patients is waste of time and effort and resources. Screening of diseases is an...
important part of primary care, and by screening we can detect diseases at an early stage where it is still curable. FRAX also can be used in the primary level of care as a medical surveillance tool. Using FRAX, we can predict with reasonable accuracy whether or not subjects will develop health risks in future and, based on the findings, follow up with appropriate diagnostic tests and interventions. This is the reason the present study was planned to predict based only on clinical factors the risk of osteoporosis in patients attending the outpatient department.

Goldshtein I (2018) et al. found a major risk for osteoporotic fracture at 13.5% and hip fracture at 2.9% in their study population; see also Ensrud EK (2009) et al.\textsuperscript{10} and Siris ES (2010).\textsuperscript{11} A 2001 study concluded that BMI is a major risk factor for osteoporosis, which agrees with our study findings; however, this study targeted only post-menopausal women and our study included males as well, and females both in the pre-menopausal and post-menopausal stages. Other study\textsuperscript{12} concluded that age, use of corticosteroids, and BMD T score of femoral neck were significantly associated with high risk for fracture. Naguyen ND et al.\textsuperscript{13} concluded that the rate of risk of hip fracture was 8.5% for women and 4% for men. Risk of vertebral fracture was 18%
Table 7: Area under the ROC curve (AUC) for predicting the risk of hip fracture and the risk of osteoporosis (n=500)

| Variable(s) | AUC for the risk of hip fracture | AUC for the risk of osteoporosis |
|------------|---------------------------------|---------------------------------|
| Age        | 0.928                           | 0.874                           |
| Gender     | 0.697                           | 0.604                           |
| BMI        | 0.612                           | 0.485                           |

Table 8: Receiver operating characteristic (ROC) curve

| Risk of hip fracture (n=250) | Risk of osteoporosis (n=250) |
|-----------------------------|-------------------------------|
| Positive*                  | 91                            | 74                            |
| Negative                   | 159                           | 176                           |

*The positive actual state is high risk.

Table 9: Area under the ROC curve (AUC) for predicting the risk of hip fracture and risk of osteoporosis (n=250)

| Variable     | AUC for the risk of hip fracture | AUC for the risk of osteoporosis |
|--------------|---------------------------------|---------------------------------|
| Menopause    | 0.199                           | 0.224                           |

for women and 11% for men. Szoltyk AN et al(7) concluded that most of the Polish women living in care facilities are at a medium risk of low-energy fracture. Gadam RK (2013) et al(8) concluded that FRAX alone is an effective screening tool for predicting the risk of osteoporotic fracture. Dagan NAA (2017) et al. found that the AUC values for hip fracture prediction were 82.7% for QFracture, 81.5% for FRAX, and 77.8% for Garvan. For major osteoporotic fractures, AUCs were 71.2% for QFracture and 71.4% for FRAX. Premaor M (2013) et al. concluded that ROC analysis revealed no significant variation between obese and non-obese women in fracture prediction by FRAX, with or without BMD. Tamaki J et al. (2011) concluded that AUC value for FRAX® with BMD for predicting major osteoporotic fractures was similar to that of a logistic model with BMD for age and body weight (0.69 vs. 0.71, respectively; P = 0.198); the AUC of FRAX with BMD for predicting hip fractures was similar to that of a model based on age and BMD (0.88 vs. 0.89, respectively; P = 0.164). They concluded that AUCs of FRAX with no BMD for predicting major osteoporotic and hip fractures were identical to those with BMD (0.69 vs. 0.67, respectively; P = 0.121; 0.88 vs. 0.86, respectively; P = 0.445). Unnanuntana A et al. (2010) also conducted a study with similar objectives.

Ranjan R et al. (2020) concluded that the prevalence of osteoporosis at spine was 45% and at femoral neck was 32.6%. The performance of all three categories for FRAX® (without BMD), FRAX® (with BMD), and FRAX® (with BMD and TBS) (major osteoporotic fracture [MOF]) and FRAX® (hip fracture [HF]) were good (AUCs were 0.798, 0.806, and 0.800, respectively, for MOF) at a cut-off score of ≥9, and, at a cut-off of ≥2.5 for HF, it was 0.818, 0.775, and 0.770, respectively. At these cut-offs, sensitivities were 77%–89%, and specificities were 55%–72% for predicting prevalent vertebral fractures. Ribot C et al. (1992) and Kung AWC et al. (2007) found eight independent clinical risk factors, including age >65 years, history of fracture, and BMI <10, were significant predictors of osteoporotic fracture. Kanis JA et al. (2008) concluded that in the absence of BMD, hip fracture probability in women with a fixed BMI (25 kg/m (2)) ranged from 0.2% at the age of 50 years without CRFs to 22% at the age of 80 years with a parental history of hip fracture (approximately a 100-fold range). In men, the probability was lower, as was the range (0.1%–11% in the examples above). For a major osteoporotic fracture, the probability ranged from 3.5% to 31% in women, and from 2.8% to 15% in men in the example above. The results of this study added to a growing body of evidence that FRAX is an effective adjunct in the identification and management of osteoporosis in primary care. Early recognition and treatment of osteoporosis can prevent or reduce complication, improve quality of life, and reduce the health care costs.

Key points—FRAX can be used as screening tool for osteoporosis, and, if results fall in the action threshold, we can then go for a higher-level or advanced diagnostic test and we can consider the patient for intervention.

Key takeaway—By a simple screening test we can detect the disease in an early stage where it can still be cured. The results of this screening test can be used as a guide to decide further course of action if results warrant the need to go beyond the screening test, and FRAX is the most practical and cost-effective tool to use to further diagnose for the disease and provide appropriate interventions. The FRAX tool based on clinical features can also meet the needs in primary care.

Novelty of the study—This study concluded that osteoporosis is not uncommon in men, which is in contrast to the general understanding that women are commonly at a greater risk of developing osteoporosis than men are.

Conclusion

Screening is a cornerstone of primary care, as it can be used for a presumptive identification of an unrecognized illness. By adding FRAX without BMD in common wellness screenings, we can help the community make better-informed decisions about their health condition especially at the primary level of care. It can be used as selective screening tool to detect osteoporosis early enough to treat it most effectively. Although osteoporosis was found to occur more commonly in women, our study findings showed a significantly higher likelihood of osteoporosis occurring in men as well.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and
due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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