Original Research Article

Prevalence of fracture risk among middle-aged and elderly population of Gujarat, India: an observational study

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ABSTRACT

Background: This study was conducted to estimate the prevalence of fracture risk among middle-aged and elderly population of Gujarat and to find out the prevalence of the clinical risk factors (CRF) and its significance with risk of fracture. To compare the risk of fracture among men and women.
Methods: An observational study included 500 participants both men and women, in age group of 40-80 years. Participants were assessed with the fracture risk assessment tool (FRAX) without BMD to evaluate the 10-year probability of risk of Major osteoporotic fracture (MOF) and Hip fracture (HF). India-specific age-dependent thresholds were used to categorize the participants into safety zone and treatment zone followed by statistical analysis. Level of significance was kept at 5%.
Results: Total 500 participants, 56.8% males and 43.2% females with mean age 56.3±9.7 years. As per the estimated prevalence, 22% participants were in treatment zone and 78% were in safety zone for HF risk and for major osteoporotic fracture risk, 24% participants were in treatment zone and 76% were in safety zone. In 18.6% participants the hip fracture risk was ≥3% and in 2% participants the major osteoporotic fracture risk was ≥20%. Women had more fracture risk compare to men, for HF [t (464.6)=-3.04, p=0.002] and for MOF [t (441.3)=-5.13, p<0.001]. Significant difference in fracture risk was found with presence of CRF except with smoking and alcohol use.
Conclusions: FRAX can be used to identify the 10-year probability of fracture risk. The prevalence showed fewer participants in treatment zone and more in safety zone. Women had higher fracture probabilities than men.

Keywords: Clinical risk factors, Fracture risk, FRAX, Osteoporosis, Gujarat, Prevalence

INTRODUCTION

Osteoporosis is a disease in which the bone density gets reduced which leads to increased fracture risk with aging. In most of the cases, people are not aware of the possibility of getting a future fracture due to the silent nature of osteoporosis.[1] Reduced bone strength and quality with increasing age can lead to fragility fractures.[2] These fractures can occur with a minor trauma. Common factors associated with the risk of fragility fractures include age, gender, previous fracture, family history of osteoporosis, use of glucocorticoids, tobacco, alcohol etc.[3]

It was estimated that the number of people with osteoporosis in India was around 26 million in year 2003 which was then around 50 million in year 2013.[4,5] Also, hip fractures occur in earlier age like in sixties in Indians compared to western countries.[6] An earlier study of postmenopausal women in India found that on average, 34% of osteoporotic women were in their middle age and the rate of hip fractures was more in women compare to

men.[7] Bone mineral density (BMD) is commonly used for the diagnosis of osteoporosis and related fracture risk but bone mineral density provides only one element of bone strength. Hence, there is a need to use the clinical risk factors (CRF) with or without BMD to predict the fracture risk more accurately.[8]

Many studies have been done to identify the clinical risk factors that could be used to identify the risk of fracture. Fracture risk assessment tool (FRAX) combines the clinical risk factors with or without BMD to measure fracture risk. It is an easily accessible tool.[9,10] Assessment of bone mineral density is an important factor to know the fracture risk and most of the guidelines have used BMD thresholds for recommendation of treatment. On the other hand, many other risk factors for fracture have been recognized in addition to that provided by BMD.[11]

FRAX is a diagnostic tool used to evaluate the 10-year probability of bone fracture risk. FRAX is a scientifically validated and is designed for primary care. It calculates 10-year probability of hip fracture (HF) and a major osteoporotic fracture (MOF) in individuals from age (40-90), body mass index and clinical risk factors including prior fracture, parental history of hip fracture, current tobacco smoking, ever use of glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and alcohol consumption.[12] The bone mineral density for the femoral neck can be optionally entered.

FRAX identifies individuals with fracture risk more efficiently than BMD.[13] Different countries use different criteria to categorize the fracture risk by FRAX and set their treatment plans accordingly. The current National Osteoporosis Foundation (NOF), USA recommend treatment of patients with FRAX scores of ≥3% for hip fracture and ≥20% for major osteoporotic fracture.[14] The National Osteoporosis Group Guidelines (NOGG), UK uses age specific treatment plans. They have implemented FRAX to assess postmenopausal women and men aged ≥50 years initially with FRAX without BMD and accordingly they categorize the patients into safety zone, intermediate zone and treatment zone.[15] According to the India specific charts of FRAX the participants can be categorized into safety zone and treatment zone. The present guidelines in India for post-menopausal women developed by Prof. John A. Kanis and supported by the Indian menopause society, recommend age specific interventions as per the fracture probabilities by FRAX.[16]

In India the access to densitometry is very low and limited. However, an India-specific FRAX model is available which can be used without BMD. It is an easy to administer tool to identify the absolute fracture risk but despite of its availability the use of FRAX is very low in India. As far as the authors know, in this research work, India specific FRAX was used for the first time to identify the 10-year probability of fracture risk in Gujarat, India. The aims of this study were to estimate the prevalence of 10-year probability of fracture risk among middle-aged and elderly population of Gujarat and to find out the prevalence of the clinical risk factors and its significance with risk of fracture. The study also aimed to compare the fracture risk among men and women.

METHODS

Ethics committee approval was obtained from the ethics committee for this study. The web-based country specific licensed FRAX individual entry version 4.0.as well as the FRAX mobile application version 4.1.0. were collected. The sample size formula used was, $n_0=Z^2p(1- p)/e^2$ where Z=1.96 at 95% CI, p=0.5 is the estimated proportion of population, e=0.05, is the desired level of precision or the margin of error. With the convenience sampling method 500 participants including both the gender and age range from 40-80 years were randomly selected for this observational study. The study duration was March to December 2017. The study population was selected from the outdoor patients (OPD) of hospital and residents of Gujarat. All participants were explained about the study and written informed consent was obtained from each participant for this study.

Inclusion criteria

Participants in the age group of 40-80 years, both males and females who could participate in this study independently were included.

Exclusion criteria

The participants already diagnosed with osteoporosis and on anti-osteoporotic medication were excluded before introducing the questionnaire. Also, participants with any cognitive or neurological affection, any acute injury, illness or surgery, inability to stand were excluded.

To begin, the basic evaluation of the participants was done followed by the fracture risk assessment by FRAX. For that, the weight (kg) and height (cm) were recorded and entered into the FRAX to get the calculation of BMI.

All the questions related to clinical risk factors as per the FRAX were asked to the participants and the information obtained was answered in the form of "Yes" or "No". The questions asked included, country, age, gender, previous fracture, parent hip fracture, current smoking, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis and high alcohol consumption. The BMD was not added in any of the calculation. The outcome of FRAX included the BMI and the 10-year fracture risk probability for hip fracture (HF%) and major osteoporotic fracture (MOF%).

The value of 10-year probability of hip and major osteoporotic fracture risk was plotted on the India-specific FRAX charts and the participants were categorized into safety zone and treatment zone. As per the assessment guidelines based on the 10-year

probability of hip fracture and major osteoporotic fracture (%) for India, there are two zones including red treatment zone and green safety zone and in between there is a sigmoid curve which denotes the fracture threshold which in turn may be considered as an intervention threshold. Individuals with probabilities of a major osteoporotic fracture and/or hip fracture at the fracture threshold were considered in treatment zone as per the guidelines. The prevalence was estimated on the basis of the zone of individual participant.

The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 20 and Microsoft excel. The prevalence of all clinical risk factors included in the FRAX and the 10-year probability of risk of HF and MOF was estimated. Levene's test followed by independent t-test was used to analyze the difference in the 10-year fracture risk probability between men and women and also the difference in fracture risk was analyzed considering the presence of the clinical risk factors. Level of significance was kept at 5%.

RESULTS

There were total 500 participants including 56.8% males and 43.2% females in this study. The mean age of the participants was 56.3±9.7 years with the range of 40-80 years. The mean BMI (kg/m^2) was 25.63±4 with minimum 16.2 and maximum 43.3. The BMI was categorized as <18.5: underweight, 18.5-24.9: normal weight, 25-29.9: overweight and ≥30: obese and accordingly there were 1.2% underweight, 46.2% normal weight, 38.6% overweight and 14% obese participants.

The mean FRAX HF% was 1.58±2.6 with minimum 0 and maximum 25. The mean FRAX MOF% was 4.74±4.9 with minimum 0.7 and maximum 30. The 10-year probability of fracture risk was <3% in 81.4% participants and ≥3 % in 18.6% participants for HF. Furthermore, the 10-year probability of fracture risk was <20% in 98% participants and ≥20% in 2% participants for MOF. Table 1 shows the descriptive characteristics of the participants. Figure 1 shows prevalence of clinical risk factors among participants.

Table 1: Descriptive characteristics of participants.

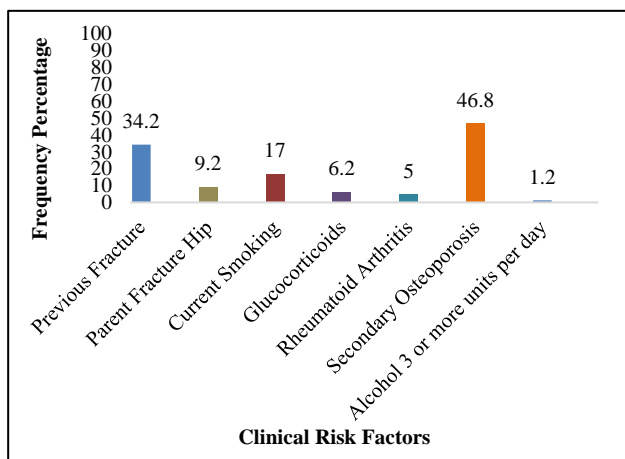| Variables		Age (years)	Height (cm)	Weight (kg)	BMI (kg/m^2)	FRAX HF (percentage)	FRAX MOF (percentage)
Mean		56.3	162.0	67.3	25.6	1.6	4.8
Standard error of mean		0.4	0.3	0.5	0.2	0.1	0.2
95% confidence interval for mean	Lower bound	55.5	161.4	66.3	25.3	1.4	4.3
	Upper bound	57.2	162.7	68.3	25.9	1.8	5.2
Median		55	162	67	25.3	0.6	2.9
Variance		94.6	59.1	123	16.3	6.7	24.4
Std. deviation		9.7	7.7	11.1	4.0	2.6	4.9

Figure 1: Prevalence of clinical risk factors.

As per the assessment guidelines based on the 10-year probability of hip fracture and major osteoporotic fracture (%) for India, there are two zones including red treatment zone and green safety zone and in between there is a sigmoid curve which denotes the "fracture threshold" in postmenopausal women from India, which in turn may be

considered as an intervention threshold. According to it the participants were categorized into treatment zone and safety zone and the prevalence was estimated as per the zone.
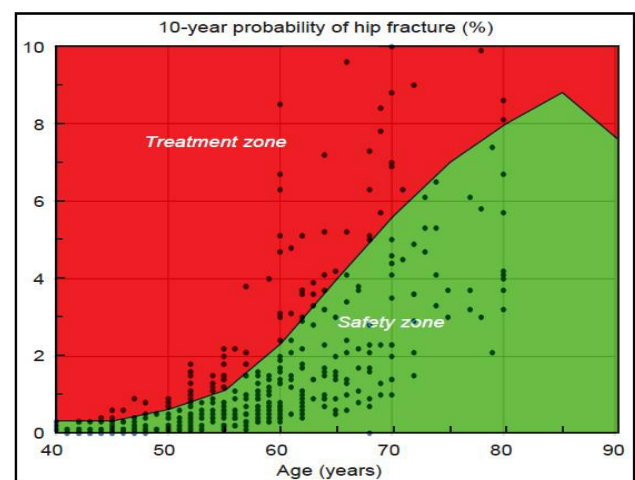

Figure 2: Participants with age-specific 10-year probability of hip fracture and zone.
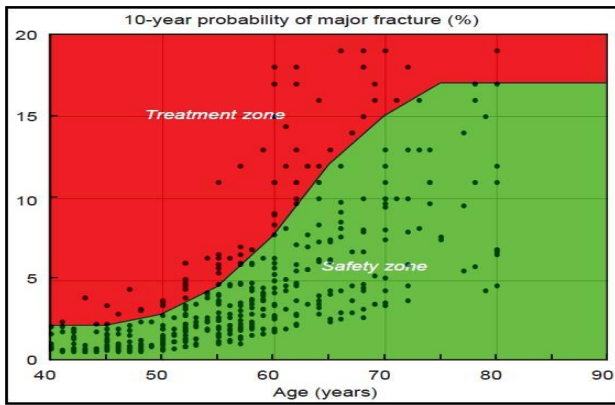
Figure 3: Participants with age-specific 10-year probability of major osteoporotic fracture and zone.

Scatters in Figures 2 and 3 shows the participants falling in treatment zone and safety zone. The sigmoid curve denotes the "fracture threshold" which in turn may be considered as an intervention threshold. The India specific base charts were used with the kind permission of Prof. John A. Kanis.[9]

Scatters in Figures 2 and 3 shows the participants falling in treatment zone and safety zone for 10-year probability of HF% and MOF% respectively. The estimated prevalence of fracture risk as per the zone is shown in Figure 4 and 5 for 10-year probability of HF% and MOF% respectively.
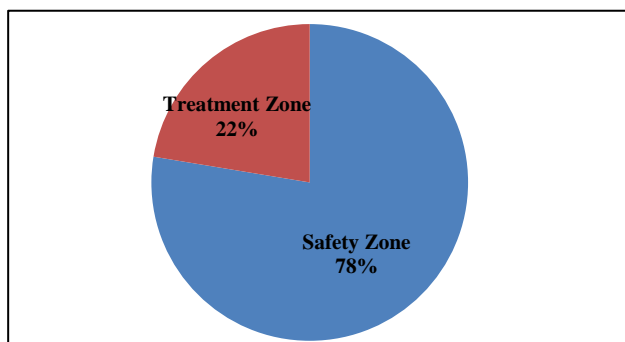

Figure 4: Prevalence of 10-year probability of hip fracture risk by FRAX with age-specific intervention thresholds.
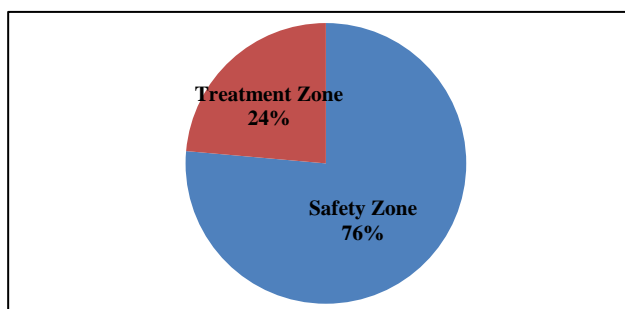

Figure 5: Prevalence of 10-year probability of major osteoporotic fracture risk by FRAX with age-specific intervention thresholds.

When comparing the means gender wise, the mean FRAX HF% was 1.13 ± 1.76 and FRAX MOF% was 3.60 ± 2.98 in men where as in women the mean FRAX HF% was 1.80 ± 3.10 and FRAX MOF% was 5.67 ± 5.86, the difference was significant for the risk of fracture where women had more probability of fracture risk compare to men for FRAX HF [t (464.6)=-3.04, p=0.002 and for FRAX MOF [t (441.3)=-5.13, p<0.001].

A significant difference in the risk of fracture (p<0.001) was found among participants having presence of the clinical risk factor. Participants who had presence of previous fracture, parent hip fracture, rheumatoid arthritis, ever use of glucocorticoids and secondary osteoporosis had higher 10-year probability of risk of HF and MOF compared to those who had absence of that clinical risk factor. However, no significant difference was found in HF risk with the presence of parent hip fracture (p>0.05). Also, the difference in fracture risk was not significant among participants with current smoking and use of alcohol (p>0.05).

DISCUSSION

The purpose of the present study was to provide a primary assessment and to estimate the 10-year probability of HF and MOF using FRAX in middle aged and elderly men and women of Gujarat, India. According to it, age specific intervention threshold for FRAX showed a greater number of participants in safety zone and a smaller number of participants in treatment zone. There were 22% participants for hip fracture risk and 24% participants for major osteoporotic fracture risk in treatment zone. They need to go for the required pharmacological interventions. Moreover, there were 78% participants for hip fracture risk and 76% participants for major osteoporotic fracture risk, in safety zone. Preventive strategies should be provided to these participants in the form of exercises and life style modifications.

Studies categorizing the participants with age-specific intervention thresholds for FRAX were not found for India. However, few studies categorized the participants on the basis of fixed thresholds. As per the present study results, the 10-year probability of HF was ≥3% in 19% participants and the 10-year probability of MOF was ≥20% in 2% participants. In another previous study at New Delhi, India, the number of individuals with >20% MOF risk was 0.04% and the number of individuals with HF risk >3% was 20.89%.[18] The lowest 10-year probabilities of major osteoporotic fracture in both men and women were found in Tunisia, Ecuador, Philippines and China, with the highest rates in Denmark, Sweden, Norway, Switzerland and Caucasian population of USA. Fracture probabilities were about 23% higher in women than men.[19]

In this study significant difference was found in the 10-year probability of fracture risk in participants with

presence of clinical risk factors such as previous fracture, parent hip fracture, ever use of glucocorticoids, rheumatoid arthritis and secondary osteoporosis means participants with presence of mentioned clinical risk factors had higher probabilities of fracture risk. However, no significant difference was found in HF risk with the presence of parent hip fracture. Also, current smoking and high alcohol consumption were not statistically significant risk factors which might be due to less number of participants with these risk factors. Also, there was significant difference in fracture risk between men and women with more probabilities of fracture risk in women. Choi et al found that female sex, older age, lower BMI, longer disease duration, and glucocorticoid dose were associated with a higher probability of osteoporotic fractures however current smoking and high alcohol consumption were not significant factors. Also, the results suggested that no use of glucocorticoid is important for the prevention of osteoporotic fractures.[20] Hillier et al mentioned in their study that prior fracture after the age of 50 and low bone mass in women are very good and simple predictors of fracture risk. They also suggested that for primary prevention of fractures, FRAX can be used in predicting fracture risk mainly for hip fracture.[21] Moreover, the Brazilian model identified a parental history of hip fracture as the strongest risk factor, particularly in the elderly. According to it the long-term use of glucocorticoids, rheumatoid arthritis and a prior fragility fracture were associated with moderate increments in probability.[22] The 10-year absolute probability of any major osteoporotic and hip fracture in the presence of a single risk factor increased with advancing age in both sexes, being higher in women than in men.

Perry et al emphasized on the use of FRAX and recommended that physical therapist should prioritize bone health and fracture prevention by exercises and physical activities.[23] Clinically, physical therapist can use the FRAX without BMD to predict the 10-year probability of risk of fracture (HF and MOF) among middle and elderly aged population. The patients who have moderate to low fracture risk or safety zone should be given preventive strategies and life style modifications and referral should be made for the patients who fall in high risk or treatment zone and require medication. Also, specific exercise program should be designed to minimize the risk of osteoporotic fracture for all individuals. Moreover, age, gender and clinical risk factors present, play a very important role in identification of patients at risk so they should be evaluated as routine practice. One of the strong points of this study was the large sample size with no missing data. There were few limitations too. The comparison of fracture risk between pre and post-menopausal women was not done. The FRAX without BMD was used for this study; hence the significance of using BMD in FRAX was not determined. However, previous studies have concluded that FRAX with or without BMD effectively predicted the risk of osteoporotic fractures.[24] The risk factors other than FRAX were not included for prediction of fracture risk.

CONCLUSION

In conclusion, this study showed that FRAX without BMD can be used as a screening tool to assess the 10-year probability of fracture risk (HF and MOF).There were less number of participants with high risk of fracture and fell in treatment zone while most of the participants had moderate to low risk of fracture and fell in safety zone. Also, the fracture probabilities were more in women compare to men. There was significant increase in risk of fracture with presence of clinical risk factors except with smoking and alcohol use. Thus, FRAX can be used to predict 10-year probability of fracture risk to identify patients who may benefit from early intervention. Its integration in primary assessment can facilitate treatment decisions and enhancing its utilization in daily practice may help to plan preventive strategies. Future research may find out the association between predicted risks of fracture with the actual fracture occurrence.

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