

Original Research Article

Screening for absolute fracture risk using FRAX tool in men and women within 40-90 years in urban population of Puducherry, India

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ABSTRACT

Background: Osteoporosis is presently considered as one of the major non-communicable world health hazards. It predominantly affects post-menopausal women, elderly men and women. The aim of the study was to assess fracture risk among men and women within 40-90 years in urban population of Puducherry, India and detect the most prevalent risk factors for fractures.

Methods: This is a cross-sectional study done over a period of two months (July - August 2015) involving a sample size of 500 participants, 250 in each gender. Using the FRAX (Fracture Risk Assessment) tool the major osteoporotic fracture risk percentage (MOFR) and hip fracture risk (HFR) were obtained without femoral neck bone mineral density. Chi-square test was applied to test association and $p < 0.05$ considered statistically significant.

Results: The mean age of males (57.2 ± 12.7 years) was higher than females (52.5 ± 2.6 years). Out of 500 participants, 18 and 95 participants were found to satisfy the criteria of $\geq 20\%$ MOFR and $\geq 3\%$ HFR respectively. The average MOFR was 4.5 ± 6.7 and 4.0 ± 4.6 for women and men respectively. The mean HFR was 1.8 ± 4.0 and 1.8 ± 3.3 for women and men respectively. The requirement of treatment did not differ significantly between gender (44 females versus 51 males). Eight male participants and 9 female participants were advised for further evaluation with a DEXA scan.

Conclusions: The FRAX tool provides an aid to enhance patient assessment by the integration of clinical risk factors especially as an osteoporosis screening tool with/without the combination of bone mineral density. It is an effective tool, particularly in developing countries like India, where most of the patients cannot afford expensive investigations like DEXA. People with high risk can be subjected to further evaluation and management, thereby reducing the health resources.

Keywords: FRAX, BMD, Osteoporosis, Risk assessment tools, Hip fracture

INTRODUCTION

Advancement in health care sector has resulted in increase of the aging population. This has led to increase in the proportion of patients with osteopenia and osteoporosis in both developed and developing countries like India. Osteoporosis is presently considered as one of

the major non-communicable world health problem. Throughout the world, osteoporosis is said to cause more than 8.9 million fractures yearly, resulting in an osteoporotic fracture every 3 seconds.^{1,2} It predominantly affects post-menopausal women, elderly men and women. It is calculated that the residual lifetime risk of experiencing an osteoporotic fracture in men over the age

of 50 is up to 27%, higher than the lifetime risk of developing prostate cancer of 11.3%.³ An elderly woman has a 2.8% risk of death related to hip fracture during her remaining lifetime, equivalent to her risk of death from breast cancer and 4 times higher than that from endometrial cancer.^{4,5} Osteoporosis is considered a silent disease because bone loss occurs without symptoms or signs. Approximately two-thirds of vertebral fractures are asymptomatic and go unnoticed. Most common clinical manifestation of osteoporosis is a pathological bone fracture; typically at the spine, hip, proximal femur, wrist or humerus. It has been reported that the combined lifetime risk for hip, forearm and vertebral fractures coming to clinical attention is around 40%, similar to the risk for cardiovascular disease.^{6,7} Early prevention of an osteoporotic fracture is much better than cure.

A simple screening tool called the Fracture Risk Assessment tool (FRAX), created by WHO in 2008, estimates the risk for major osteoporotic and hip fracture within the next 10 years.⁶ It uses a medical interview and the body mass index (BMI) to calculate fracture risk without measuring bone mineral density (BMD). Aim of the present study is to find out the absolute fracture risk using FRAX tool in men and women between the age of 40-90 years in Puducherry and classify into two groups (treatment required and treatment not required) based on data collected. Also to observe the effect of various variables like age, gender, previous fractures, smoking, glucocorticoids and rheumatoid arthritis on the treatment required group.

METHODS

This cross-sectional study was carried out in the urban areas of Puducherry over a period of two months (July - August 2015). Home visits were made so as to meet people between the age group of 40-90 years. After explaining the objectives and methodology of the study in their own language, a written consent was taken in the participant's native language prior to the data collection. Their participation was entirely voluntary. Permission and acceptance were obtained from the Institutional Scientific Research Committee and Institutional Ethics Committee (IEC: RC/14/149).

A total of 500 men and women between the ages of 40-90 years from urban areas of Puducherry like Muthialpet were screened for the study. This was a voluntary door to door survey. Individuals with kidney failure, liver impairment, Cushing's disease, leukaemia, thalassemia, metastatic bone disease and individuals on drugs like lithium, barbiturates and antacids containing aluminium were excluded from the study.

Brief procedure

For the purpose of the study, participants were asked questions from the questionnaire approved by WHO, which was entered in the FRAX Tool. The FRAX tool

assessed the probability risk of a fracture in the next 10 years. Probability was calculated from parameters such as age, sex, body mass index and dichotomized risk factors comprising prior fragility fracture, tobacco smoking, use of long-term of oral glucocorticoids, and rheumatoid arthritis. The collected data and the risk of Osteoporosis and Hip fracture as calculated using FRAX software was entered in excel sheet. According to the 2008 National Osteoporosis Foundation recommendations, treatment of osteoporosis should be considered for:

- 1) Patients with a history of hip or vertebral fracture.
- 2) Patients with a T-score of -2.5 or lower at the femoral neck or spine, and
- 3) Patients who have a T-score of between -1.0 and -2.5 at the femoral neck or spine and a ten-year hip fracture risk of $\geq 3\%$ or a ten-year risk of a major osteoporosis-related fracture of $\geq 20\%$ as assessed with the FRAX tool.^{8,9}

However, participants of this study were classified into two groups: treatment required and treatment not required groups, based on the ten-year risk of hip fracture and major osteoporosis-related fracture. This was done by using the criteria of ten-year hip fracture risk of $\geq 3\%$ or a ten-year risk of a major osteoporosis-related fracture of $\geq 20\%$ as assessed with the FRAX. Participants who had borderline scores were asked to undergo DEXA scan to quantify osteoporosis and assess the need for treatment.

Chi-square test was applied to test association between variables and $p < 0.05$ considered statistically significant. All statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS) version 20.0.

RESULTS

A total of 500 FRAX medical questionnaires, with equal number in each gender, were collected. The mean BMI of the participants was 25.1 ± 4.9 kg/m². The mean age of the study participants was 54.8 ± 2.9 years. The average age of males (57.2 ± 12.7 years) was higher than females (52.5 ± 12.6 years). History of rheumatoid arthritis was absent in males and none of the females were smokers. 29.2% and 17.6% of the male and female participants, respectively, had previous history of fracture (Table 1). The average 10 year Major Osteoporotic Fracture Risk was 4.2 ± 5.8 (minimum 0.5; maximum 39.0). Hip fracture risk average was 1.8 ± 3.7 (minimum 0.0; maximum 22.0).

Participants with a ten-year risk of a major osteoporosis-related fracture $\geq 20\%$ or a ten-year hip fracture risk $\geq 3\%$ were advised treatment for osteoporosis. Out of the 500 participants 95 required treatment as per the National Foundation recommendations. The requirement of treatment did not differ significantly between genders (44 females vs. 51 males) (Figure 1). Eight male participants and 9 female participants with a ten-year risk of a major osteoporosis-related fracture of 15-20% were advised for

further evaluation with a DEXA scan (Figure 2). Out of the 17 participants who were advised DEXA, 5 male participants and 6 female participants got DEXA scan done. One male and 3 female participants who had T-score ≥ -2.5 were further started on treatment. All the participants requiring DEXA scan were above or equal to the age of 63 years indicating the significance of osteoporosis in the aging Indian population. Out of the 72 male chronic smokers, treatment requiring patients were 31 (43.1%). The treatment requiring for osteoporosis were significantly high in smokers compared to non-smokers ($p < 0.001$) (Figure 3). The treatment requiring participants were significantly high among participants with previous history of fracture compared to no history of previous fracture both in male ($p < 0.001$) and female ($p < 0.001$) (Figure 4 and 5). Statistically significantly higher proportion of participant requires the treatment among those with glucocorticoids compared with no glucocorticoids, both in male ($p < 0.001$) and female ($p = 0.007$) (Figure 6 and 7). Requirement of treatment was significantly ($p < 0.001$) higher among those with rheumatoid arthritis compared with no rheumatoid arthritis (Figure 8). Most of the participants in the treatment required group were either elderly males or females, smokers, on glucocorticoid treatment or suffered from rheumatoid arthritis.

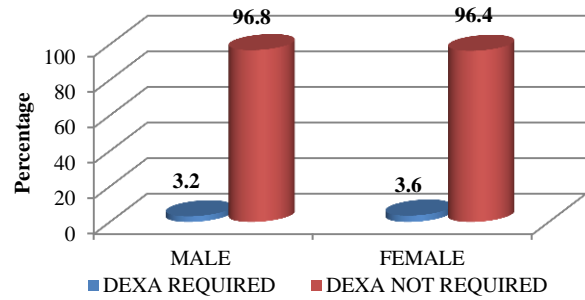


Figure 2: Distribution of DEXA requirement by gender.

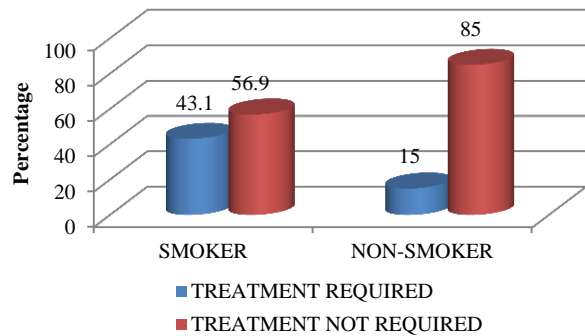


Figure 3: Smoking status and treatment requirement, males.

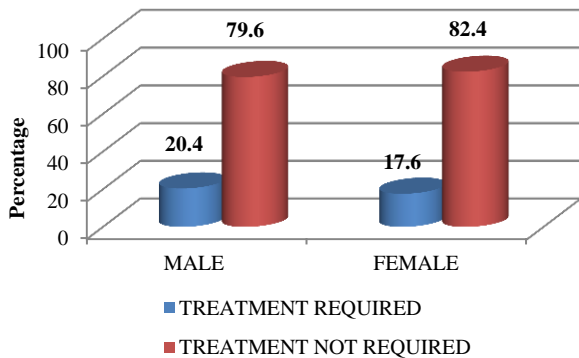


Figure 1: Distribution of treatment requirement by gender.

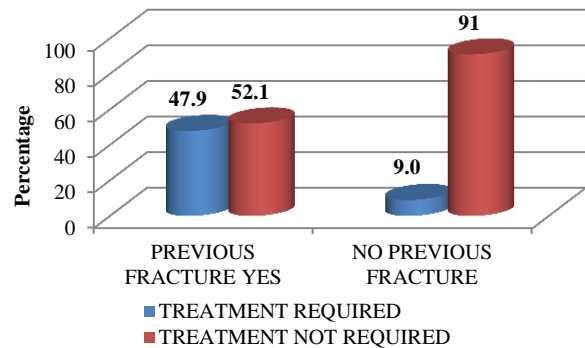


Figure 4: Previous fracture history and requirement of treatment, males.

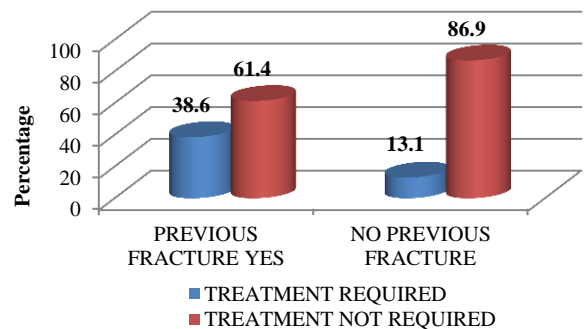


Figure 5: Previous fracture history and requirement of treatment, females.

Table 1: Baseline characteristics and fracture risk of the participants.

Characteristics	Men (n=250)	Women (n=250)
Age (years)	57.2±12.7	52.5±12.6
BMI (Kg/ m ²)	25.2±5.1	25.0±4.8
Previous fractures	73 (29.2%)	44 (17.6%)
Glucocorticoids	25 (10.0%)	15 (6.0%)
Rheumatoid arthritis	0	21 (8.4%)
Smoking	72 (28.8%)	0
Major osteoporotic fracture risk*	4.0±4.6	4.5±6.7
Hip fracture risk*	1.8±3.3	1.8±4.0

*As calculated from FRAX™ tool using the India specific WHO fracture risk assessment algorithm.

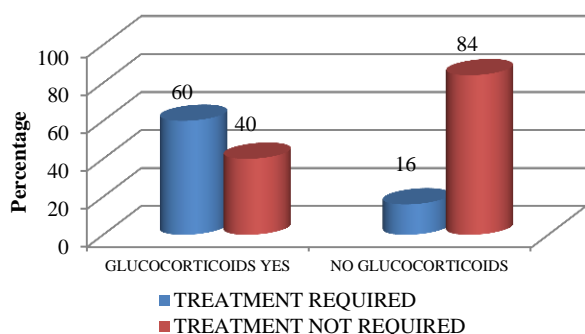


Figure 6: Glucocorticoids status and requirement of treatment, males.

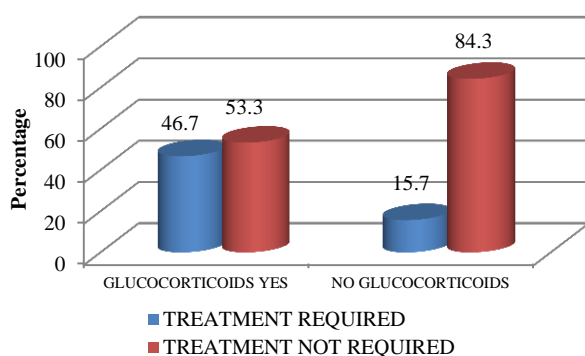


Figure 7: Glucocorticoids status by requirement of treatment, females.

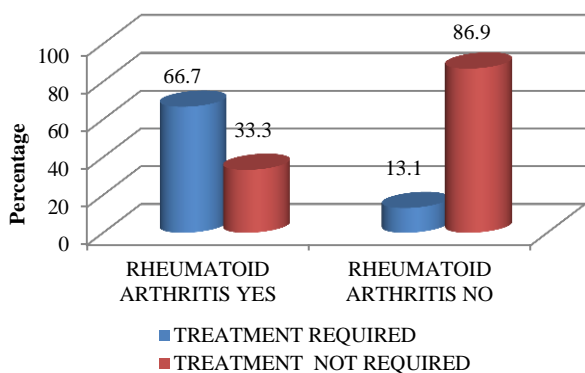


Figure 8: Rheumatoid arthritis females and the requirement of treatment.

DISCUSSION

Osteoporotic fractures are a cost in terms of morbidity and mortality for older people and a burden financially for the health sector of any society. Identification of high-risk subjects and early intervention are the important steps in the prevention of fractures.¹⁰ The present guidelines in India recommend that postmenopausal women with a prior fragility fracture may be considered for interventions without the necessity for a BMD test (other than to monitor treatment).¹¹ Prior to the introduction of FRAX tool, there was no universally

accepted screening tool for osteoporosis in India. On the basis of a series of meta-analyses undertaken to identify clinical risk factors for osteoporosis, the Fracture Risk Assessment Tool (FRAX) was developed.^{12,13} FRAX was released in 2008 by the World Health Organization and was developed and validated under the direction of Professor John Kanis with the support of many individuals and organizations including the American Society for Bone and Mineral Research, the National Osteoporosis Foundation, the International Society for Clinical Densitometry, and the International Osteoporosis Foundation.

The FRAX tool which requires only a few minutes can be introduced as an Out Patient Department (OPD) screening tool for the prediction of fractures in men and women more than 40 years of age. High risk subjects are elderly population, post-menopausal women, people with previous history of fractures, steroid intake, smokers and ones with history of rheumatoid arthritis. These patients were advised to get a DEXA scan to quantify the osteoporosis, which is useful in deciding the management. FRAX allows fracture risk to be calculated for countries where the incidences of both fractures and mortality are known. By 2050, the incidence of hip fracture worldwide in men is projected to increase by 310% and 240% in women.¹⁴ These values can be drastically reduced if use of FRAX tool is implemented as an OPD routine procedure for high risk subjects.

In a study conducted in Japan, FRAX was used in determination of cut-off values during the primary screening in specific health check-ups. Subjects who exhibited FRAX cut-off values of $\geq 10.5\%$ for women and $\geq 8\%$ for men were advised to be screened at a medical institution.¹⁵ In a study by Bliuc et al showed that men with osteoporotic fractures have a much higher mortality and morbidity when compared to women.¹⁶ This emphasises the fact that men must also be screened and equally treated for osteoporosis like women. There is lack of data from India regarding morbidity among men with osteoporosis. In the study by Marwaha et al osteoporosis was reported to be 26.4% in male subjects and osteopenia 54.3% in male subjects.¹⁷ Shetty et al reported slightly lesser values of osteoporosis (20%) and slightly higher values of osteopenia (58%) in south Indian men aged above 50 years.¹⁸ Whereas in our study out of 250 male participants, 5 (2%) and 51 (20.4%) participants were found to satisfy the criteria of $\geq 20\%$ major osteoporotic risk and $\geq 3\%$ hip fracture risk respectively.

Most studies done worldwide and in India show that females have increase risks of fractures due to high chances of developing osteoporosis. This was in contrast to our observations which showed higher number of men requiring treatment than women (51 out of 95). The mean values of males and females for major osteoporotic and hip fracture do not show much difference may be due to omission of use of BMD for assessment of FRAX.

The graphs obtained after associating various variables and treatment requirement shows that variables like gender, smoking habits, use of glucocorticoid and bone diseases like rheumatoid arthritis were important factor in determining the risks of major osteoporotic and hip fracture. In a study conducted in Copenhagen, tobacco smoking was concluded to be an independent risk factor for hip fracture in men and women and that approximately 19% of all hip fractures could be prevented if tobacco smoking was eliminated.¹⁹ In a study done by Karine et al in 2015 it was reported that previous and current exposure to glucocorticoids increases the risk of fracture and bone loss.²⁰

It has been emphasized by many authors that the calculated ten-year fracture probability is only a guideline for treatment decisions. Specific treatment decisions should be individualized, based on the risk factors mentioned in the study. Some clinical risk factors, such as the use of glucocorticoids, have been considered as the only indications for treatment.²¹ Furthermore, fracture risk probabilities calculated with FRAX are not valid for patients who have already received treatment for osteoporosis such as bisphosphonates.

The availability of Indian data on the FRAX site is a great boon to Indian endocrinologists and patients. One can use web or paper-based calculations as an OPD procedure to show patients their 10 year risk of hip fracture or major osteoporotic fracture. This clinical tool helps motivate the patients to accept appropriate therapy, and sensitizes her or his community to implement preventive measures. The current version of FRAX® does not incorporate fall-related risk factors, even though falls are known to be a strong risk factor but the major plus point is it aids to enhance patient assessment by the integration of clinical risk factors alone without the need to assess BMD.²²

CONCLUSION

With the expansion of FRAX to include Indian and Chinese data, this clinical tool has now covered all the major ethnic groups of the world. In our study we found that more men needed treatment for osteoporosis than women. In a country like India where most of the people do not have access to tertiary health care facilities, FRAX without BMD test can be used as a screening tool to plan preventive strategies which in turn will decrease the morbidity, mortality, and economic costs associated with them. However, further studies are needed to look at the impact of these in a larger cohort of elderly men and woman. It will enable the health planning bodies to come up with clinical practice guidelines relevant in our Indian context.

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Conflict of interest: None declared

Ethical approval: The study was approved by Pondicherry Institute of Medical Sciences Ethics committee - IEC/RC/14/149

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