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Assesment of Major Osteoporotic Fractures in Sub-Urban Population of Muzaffarnagar on Frax Method- A Study

KEYWORDS: FRAX, OSTEOPOROSIS, MAJOR FRACTURES

Nagar M.M	Kumar Arvind	Singh Kuldip
Associate professor, Department of Orthopaedics SGRRIM&HS medical college, patelnagar, dehradun,uttarakhand	Associate Professor Muzaffarnagar, Medical College Muzaffarnagar, U.P.	Professor Muzaafarnagar Medical College, Muzaffarnagar, U.P

INTRODUCTION

Since a long time, it was in our mind that it would be a good service to our society and nation if we could know who are the patients with weak bones and are susceptible to fractures.

We know that osteoporosis is a silent disease until it is complicated by fractures, fractures that can occur following minimal trauma.

These fractures are common and cause an enormous medical and personal burden on aging individuals and a major economic toll on the nation.

Diagnosed osteoporosis is based on the measurement of BMD.

A clinical diagnosis can often be suspected in at-risk individuals who sustain a low-trauma fracture.

BMD is expressed in absolute terms of grams of mineral per square centimeter scanned (g/cm2) and as a relationship to two norms: compared to the expected BMD for the patient's age and sex (Z-score), or compared to "young normal" adults of the same sex (T-score).

The difference between the patient's score and the norm is expressed in standard deviations (SD) above or below the mean.

Usually, 1 SD equals 10 to 15 percent of the BMD value in g/cm2.

A decline in BMD begins during young adulthood, accelerates in women at menopause and continues to progress in postmenopausal women and men age 50 and older.

The BMD diagnosis of normal, low bone mass, (osteopenia) or established osteoporosis is based on the WHO diagnostic classification

Normal: BMD is within 1 SD of a "young normal" adult (T-score at -1.0 and above).

Low bone mass ("osteopenia"):- BMD is between 1.0 and 2.5 SD below that of a "young normal" adult (T-score between -1.0 and -2.5).

Osteoporosis: - BMD is 2.5 SD or more below that of a "young normal" adult (T-score at or below -2.5). Patients in this group who have already experienced one or more fractures are deemed to have severe or "established" osteoporosis.

Note: - Although these definitions are necessary to establish the presence of osteoporosis, they should not be used as the sole determinant of treatment decisions.

Bone mineral density (BMD) is considered as a major determinant of bone strength, and assessment of BMD at the femoral neck using dual-energy x-ray absorptiometry (DXA) is often performed to diagnose osteoporosis.

The ability to accurately predict the risk of fracture in a patient is highly useful for clinicians in order to select the most appropriate treatment and management interventions.

A patient has a clinical diagnosis of osteoporosis when their T-score is 2.5 SD or more below that of the young adult mean (T-score ≤–2.5 SD).1

A T-score ≤–2.5 SD has been shown to accurately predict fracture risk in up to half of women aged over 50 years,[2]

The risk of fractures in osteoporosis is also dependent on many other factors in addition to BMD.

We must know that patients reported to be at low fracture risk according to their BMD assessment will still go on to experience fractures. On another hand, not all patients with a T-score ≤–2.5 SD will inevitably develop fractures.

It is important to note that besides clinical risk factors, the risk of fracture also varies with geographical location throughout the world.[3],

Algorithms have been developed based on average 10-year hip fracture probability according to epidemiological data for index countries, based on FRAX models in different parts of the world

Currently, FRAX® algorithms have been developed for Austria, China, Germany, France, Italy, Japan, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the USA.

Therefore, in situations where there is no FRAX® algorithm specific to a particular country, a representative country should be chosen that is similar in terms of fracture risk.

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FRAX® tool is not a substitute for a detailed clinical evaluation and physicians must be aware of its limitations when they interpret results in the clinic.

Many of the risk factors used in FRAX®, such as cigarette smoking, alcohol consumption, and use of glucocorticoids, are dose dependent.[4,5,6] for these, FRAX® uses risk ratios based on an average dose. Similarly, the risk of fracture increases with the number of prior fractures, 7,8and a previous vertebral fracture is a particularly strong risk factor.

Due to a lack of substantial clinical data, the clinician should also be aware that several risk factors for fracture have not been included in the FRAX® algorithm.

These include factors such as biochemical markers of bone turnover, the risk of falls, the occupation of the patient, diet, exposure to the sun, physical labor and previous pharmacological treatment.

In the clinic, this information may also need to be taken into account if necessary.

Sites of "major osteoporotic fractures": are hip, spine (based on clinical findings), shoulder and forearm.

Fracture Risk Assessment Tool (FRAX)
The Fracture Risk Assessment Tool (FRAX) was developed by the World Health Organization (WHO) task force in 2008, to provide a prediction tool for assessing an individual's risk of fracture in order to provide general clinical guidance for treatment decisions.

It is available online for calculations (Fig-1)
FRAX was motivated by a desire to incorporate non-Bone Mineral Density (BMD) clinical risk factors into the assessment of a patient's fracture risk, and therefore, risk can be calculated with or without knowledge of BMD.

When BMD is entered, FRAX uses the BMD of the femoral neck, in addition to the other validated clinical risk factors, to estimate risk and probability of fracture in the next 10 years in untreated patients ages 40 to 90 years of age.

* Be sure to pick a country under Calculation Tool after you access the FRAX tool; (we selected the country India in our study).

Fig-1

Patients and Methods
Bone mass density was calculated in 403 patients of age group ranging between 40 years to 90 years.

For this 194 males and 209 females were selected, at KHATAULI suburban area of district Muzaffarnagar, U.P. India, using guidelines of FRAX TOOL CALCULATOR.

Calculation tool was taken for country INDIA under ASIA region specified in the tool.

All the instructions for RISK-FACTORS were included in our study in the form of Questionnaire, to determine the fracture probability of major osteoporotic fractures, predicted by this tool.

(FRAX tool - University of Sheffield www.shef.ac.uk/FRAX/tool.aspx* .)(Fig-1).

Following are the risk factors and their details as given with the tool applied (FRAX.)

Previous fracture
A special situation pertains to a prior history of hip fracture. A fracture detected as a radiographic observation alone counts as a previous fracture. A prior clinical fracture is a strong risk factor.

Smoking, alcohol, glucocorticoids.
Although these risk factors appear to have a dose-dependent effect for osteoporosis, means higher is the dose or exposure, greater is the risk. , However, dose factor has not been taken into account, in FRAX tool.

Rheumatoid arthritis (RA)
RA is a risk factor for fracture. However, osteoarthritis is, if anything, protective, therefore the diagnosis of RA must be based on clinical or laboratory evidence.

Bone mineral density (BMD)
For BMD calculation site and reference, technology is DXA at the femoral neck., T-scores are based on the reference values for women aged 20-29 years.

The same absolute values are used in men.

Results
In our study, we observed that In both male and female patients maximum no. of osteopenia cases were found in age group 40 years to 50 years.

Most of the cases in our study were in the age group between 40 years to 50 years and minimum in the age group 81 years to 90 years.

The maximum number of osteopenia cases was found in the age group 40 years to 50 years (20.9%males and 17.2% females).

The incidence of osteoporosis was maximally observed in the age group of 40 years to 50 years in males (7.2%), and 51 years to 60 years in females (7.2%), indicative of the notable decrease in bone density and thereby bone strength was after the age of 50 years in the female population.

As far as fracture probability of major osteoporotic fractures is concerned (score 20%or more) was found only in two females aged 65 and 70 years.

No male patient was found susceptible to major fractures

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for ten years due to osteoporosis, in our study

The number of patients who require attention (that is score between 10% to 20%) was only one female (66years of age).

Recommendations
BMD testing is recommended to all those who have had a fracture earlier, to determine the degree of disease severity.

Initiate treatment in those with hip or vertebral (clinical or morphometric) fractures.

Therapy must be started with BMD T-scores ≤ -2.5 at the femoral neck or spine by dual-energy x-ray absorptiometry (DXA), after appropriate evaluation, as per FRAX recommendations

In postmenopausal women and men age 50 and older with low bone mass (T-score between -1.0 and -2.5, osteopenia) at the femoral neck or spine.

An absolute indication of therapy is required in cases with 10-year major osteoporosis-related fracture probability ≥ 20% based on the WHO model (FRAX®; www.NOF.org and www.shef.ac.uk/FRAX).

Current FDA-approved pharmacologic options for osteoporosis prevention and/ or treatment are bisphosphonates (alendronate, ibandronate, risedronate and zoledronic acid), calcitonin, estrogens and/or hormone therapy, parathyroid hormone (teriparatide) and estrogen agonist/antagonist (raloxifene).

DISCUSSION:-
Bone mineral density is used for the diagnosis of osteoporosis and to assess fracture risk, it has become increasingly, but that bone mineral density reflects only one component of bone strength.

Recently, FRAX was developed to calculate age-specific fracture probabilities in men and women including the clinical risk factors and the bone mineral density at the femoral neck.

Treatment of osteoporosis should be considered for patients with low bone mineral density and a ten-year risk of hip fracture of ≥3% or a ≥20% ten-year risk of a major osteoporosis-related fracture, as assessed with FRAX.

Biochemical bone marker measurements levels can be used not only to monitor treatment efficacy but also to assess fracture risk and help select patients for therapy.

Antiresorptive medications are most appropriate for patients with high bone turnover while anabolic agents demonstrate efficacy in both low and high-turnover conditions

The National Osteoporosis Foundation recommendation is to use FRAX® only when the decision to treat or not to treat is difficult, i.e. mainly in postmenopausal women without osteoporosis and without prevalent fracture

FRAX® has been included as a tool for identifying postmenopausal women in recently updated guidelines published by the National Osteoporosis Foundation in the United States and by the National Osteoporosis Guideline Group [NOGG]), in the UK .

Limitations of FRAX

The International Osteoporosis Foundation, who have supported FRAX, list these limitations on their website

- Does not accommodate all known risk factors.
- Lacks detail on some risk factors.
- Depends on the adequacy of epidemiological information.
- Limited country models available.
- Model relevant only for untreated patients
- Does not replace clinical judgment

Many people confuse the results of FRAX with the recommendations for treatment based on the results. The FRAX does the best job available for predicting fractures, but it can't tell if a treatment will safely reduce the fracture rate or not. That will depend on other factors such as the underlying diseases, allergies, risks of medicines, interactions with other medicines, cost, and safety. There are still many unanswered questions.

Conclusions
Development of the FRAX® tool enables physicians working in primary health care to calculate the future risk of osteoporotic fractures in patients through the integration of a range of clinical risk factors with or without BMD measurements.

This improves the sensitivity of future fracture risk assessments based on BMD measurements alone.

The incorporation of the FRAX® tool into practice guidelines around the world provides an updated means of categorizing patients requiring treatment for osteoporosis and/or BMD assessments.

Nevertheless, the FRAX® tool should not replace the detailed clinical evaluation and additional clinical factors that are not currently included in the FRAX® models.

India stands in category low on world data for incidence of major osteoporotic fractures; in present study also numbers of male or female patients were low matching the world data, as a whole

Available world data shows there is no previous study for assessment of major osteoporotic fracture on FRAX method in India.

Sri-lankan studies (the neighbor country) also with low incidence of such fractures assessed on FRAX method

However the present study includes small group, so we recommend more and detailed studies on this subject on larger groups with long-term follow-up and treatment results of the cases who are found to be having probabilities of major osteoporotic fractures using FRAX method.

Present observation also shows that both males as well as in females require further studies, evaluation, and active measures, especially after the 60 years of age in females for prevention and treatment of major osteoporotic fractures probability, in this area.

The strengths of our study include the assessment of fracture risk in relevant population i.e. a random population without any selection biases.

It is anticipated that the development of new imaging tools to evaluate bone quality will improve the assessment

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of a patient's fracture risk and response to treatment in the future.

Age Group (in yrs)	No. of patients	Percentage age of total patient	Sex	
			Male	Female
40-50	197	49.13%	114	83
51-60	111	27.20%	38	73
61-70	44	10.92%	19	25
71-80	36	9.18%	15	21
81-90	15	3.47%	8	7
	403	100	194	209

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