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Research Article

Evaluation of osteoporosis using calcaneal QUS and FRAX score as a screening tool in a semi urban tertiary care hospital of South India

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ABSTRACT

Background: Osteoporosis is a silent, often found late, underdiagnosed disease characterized by low bone mass leading to increased susceptibility to fractures. With an increasingly aging population, the proportion of patients with osteopenia and osteoporosis are increasing in both developed and developing countries. The available data on osteoporosis is scanty from India.
Methods: The objective was to measure the bone mineral density (BMD) of the patients using calcaneal Quantitative Ultrasound (QUS) and determine the risk factors along with the FRAX score. This was a hospital based cross sectional study conducted in a tertiary care hospital done on 183 out patients. BMD was measured using calcaneal QUS & T scores were calculated along with the FRAX score.
Results: The prevalence of osteoporosis was 29.5% and osteopenia was 42.1%.The age wise analysis of BMD revealed males have the tendency to lose their bone mass after the age of 40 years while in females, the trend begins a decade earlier. The mean BMD of post-menopausal females was significantly lower compared to pre-menopausal females (-2.72 ± 1.33 vs -1.63 ± 1.06, $P < 0.0001$).Linear regression analysis revealed a complex linear relationship between the FRAX score and the BMD and it was statistically significant.
Conclusions: Calcaneal QUS can be used as a screening tool to screen for and detect osteoporosis. It is economical, portable and easily available in many parts of the country. DEXA scan, the gold standard test to diagnose osteoporosis can be used to confirm the diagnosis in selected cases.

Keywords: Osteoporosis, Osteopenia, BMD, FRAX score, Calcaneal QUS

INTRODUCTION

Osteoporosis is defined as a systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture.[1] It is a major public health problem resulting in substantial morbidity and socio-economic burden worldwide. It is primarily a disease of the elderly and with the longevity of Indians increasing; it is a time bomb waiting to erupt. In this current scenario, the disease has still has not gained its requisite attention, and is yet to be recognized as a major public health problem in India. A conservative estimate made in 2003 put the number of Indians at risk of developing osteoporosis by the year 2013 as 36 million.[2] Mithal et al estimates that currently 50 million Indians are living with osteoporosis or osteopenia.[3]

The risk factors identified worldwide for development of osteoporosis are female sex, old age, small thin build or

lower BMI, Asian ethnicity and family history of fractures, vitamin D deficiency and low calcium intake. In a recent study carried out among post-menopausal women in northern India, lower educational status (defined as studied less than XII class), duration of menopause greater than five years, age at menarche (fourteen years and beyond), age at menopause (before 45 years), parity of more than three have all been identified as risk factors for osteoporosis.[4]

Osteoporosis is usually asymptomatic, and it can be discovered only by means of X-rays or bone mineral density measurement. Measurement of bone mineral density (BMD) is an important tool in the early diagnosis of osteoporosis, such that effective preventive and therapeutic measures can be initiated at the earliest. The gold standard for measuring bone density is the Dual energy X-ray absorptiometry (DEXA) method. However the availability of the machines is estimated to be about 250 in number in India (which is about 2 per 10 million populations) with the majority of them in urban centers where about 30% of the population resides.[2] The remaining 70% population resides in rural areas where access to medical facilities still remains very poor.

In this context, the use of an alternative and economical method to screen for bone mineral density is the need of the hour in our country. Calcaneal Quantitative Ultrasound (QUS) is an alternative which has to be evaluated in the context of use as a screening tool for low bone mineral density. It is cost effective, portable and has no risk of radiation exposure.[5] The other alternative for screening for risk of osteoporotic fractures is the use of India specific Fracture Risk Assessment Score (FRAX) calculator without the use of BMD.[6]

With this background, we have tried to assess the risk factors associated with development of osteoporosis and estimate the bone mineral density in a population drawn from urban, semi-urban and rural areas of Tamilnadu.

METHODS

This study was carried out as a hospital based cross-sectional study among the subjects who attended the outpatient services of a tertiary care hospital located in a semi-urban area of Tamilnadu. Due permission and acceptance were obtained from the Institutional Scientific Research Board (SRB) and Institutional Ethics Committee (IEC), before the start of the study, ensuring due compliance with ethical guidelines covering human trials. The written informed consent was obtained in the participant's native language prior to the commencement of study.

A total of 250 men and women aged above 20 years were screened for the study. Participants with conditions predisposing to secondary osteoporosis like type 1 diabetes mellitus, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism, chronic malnutrition, or malabsorption and chronic liver diseasewere excluded from the study. Out of 250 participants, only 183 were found to be eligible for the study, by fulfilling the inclusion and exclusion criteria. Of the 183 eligible participants included in the study, 79 were males and 104 were females.

All the participants after agreeing and signing the informed consent were interviewed and the responses regarding the possible risk factors were recorded. Height in meters and weight in kilograms were recorded and Body Mass Index (BMI) was calculated for all individualsusing Quetlet formula. Bone Mineral Density (BMD) was measured at the calcaneum by Quantitative Ultrasound (QUS) technique using Hologic bone sonometer and T-Scores were calculated based on WHO criteria [Table 1].[7]All participants who were above the age of 40 also had their FRAX score for 10 year risk of major osteoporotic bone fracturewithout BMD calculated with the help of the online calculator.[6]

The data analysis was carried out using Chi square tests, unpaired student's t test, and Analysis of One way Variance (ANOVA) as appropriate with the help of Graph pad Prism 6 software. Univariate linear regression analysis was also done with the same software. The statistical significance was set at P value ≤0.05.

Table 1: WHO Classification of BMD.

T Score	Classification
T > - 1.0	Normal
-1.0 > T > -2.5	Osteopenia
T < - 2.5	Osteoporosis

RESULTS

In our present study, there were 183 participants of which 79 (43%) were male and 104 (57%) were female with their age ranging from 20 to 80 years. The mean age of the study participants was 41.21 ± 14.85 years. (95% CI 39.05 – 43.38). The mean height of the study subjects was 157.97 ± 9.71 cm (95% CI 156.55 – 159.38) and the mean weight was 61.86 ± 12.59 kg. (95% CI 60.03 – 63.70) Their mean BMI was 25.00 ± 4.85 kg/m2. (95% CI 24.30 – 25.72) The mean T-Score for the entire group was -1.99 ± 1.29 (95% CI -2.18 to -1.81).

Based on the WHO threshold T-Score for Osteopenia and Osteoporosis, 28.4% (n = 52) participants were found to have T-Scores which were within normal range, 42.1% (n = 77) participants had osteopenia and 29.5% (n = 54) had osteoporosis. The baseline characteristics of the three groups of patients are described in Table 2. The age sex distribution of mean BMD values of the study subjects is given in Table 3.

The age wise analysis of BMD reveals that men have the tendency to lose their bone mass after age of 40 years whereas women tend to lose it a decade earlier coinciding

probably with the onset of the perimenopausal period. The mean BMD of post-menopausal women was significantly lower than pre-menopausal women (-2.72 ± 1.33 vs -1.63 ± 1.06, P < 0.0001). Long term use of steroids was associated with a significantly lower BMD (-2.52 ± 1.36 vs -1.76 ± 1.19, P = 0.0002).

Table 2: Baseline characteristics of study population.

	Normal (n = 52)	Osteopenia (n = 77)	Osteoporosis (n = 54)	
Age[1]	34.16 ± 13.59	42.34 ± 14.41	46.43 ± 14.25	P<0.0001 [HS]
Females	25 (48.08%)	43 (55.84%)	36 (66.67%)	P = 0.0389 [S]
Mean BMI[2]	24.70 ± 4.73	25.78 ± 5.03	24.20 ± 4.60	P = 0.157 [NS]
Use of steroids	7 (13.46%)	26 (33.77%)	30(55.56%)	P = 0.002 [S]
Postmenopausal	6 (24%)	19 (44.19%)	23 (63.89%)	P = 0.008 [S]
Smoking	5 (9.61%)	6 (7.79%)	7 (12.96%)	P=0.21 [NS]
Fracture history	6 (11.54%)	9 (11.69%)	8 (14.81%)	P = 0.838 [NS]

NS = not significant, S = significant, HS = highly significant

The BMD of patients residing in an urban, semi urban and rural area did not show any statistical difference (-1.84 ± 1.23 vs - 2.05 ± 1.33 vs - 2.09 ± 1.32, P = 0.528). The BMD of patients consuming a pure vegetarian diet was also not statistically significant when compared to patients consuming a mixed diet (-2.03 ± 1.19 vs -1.99 ± 1.31, P = 0.887). Smoking was also not associated with a statistically significant difference (-2.10 ± 1.30 vs -1.75 ± 1.20, P = 0.2776).

Table 3: Bone mineral density in various age groups.

Age group (Years)	Males		Females	
	Mean BMD	95% CI	Mean BMD	95% CI
20 – 30	-1.42 ± 1.14	-1.88 to -0.96	-1.49 ± 0.97	-1.86 to -1.12
31 – 40	-1.44 ± 1.27	-2.20 to - 0.67	-2.06 ± 1.15	-2.53 to -1.58
41 – 60	-2.00 ± 1.23	-2.45 to -1.55	-2.54 ± 1.42	-3.00 to -2.09
> 60	-2.72 ± 1.23	-3.67 to -1.77	-2.65 ± 1.3573	-3.62 to -1.68
P value	0.025792 [S]		0.004115 [S]	

NS = not significant, S = significant, HS = highly significant

The FRAX scores of the patients in various groups is given in Table 4. Linear regression analysis revealed complex linear relationship between the FRAX score and the BMD (Table 5) and it was statistically significant (FRAX score = -0.4671 x BMD + 1.585, P = 0.005).

DISCUSSION

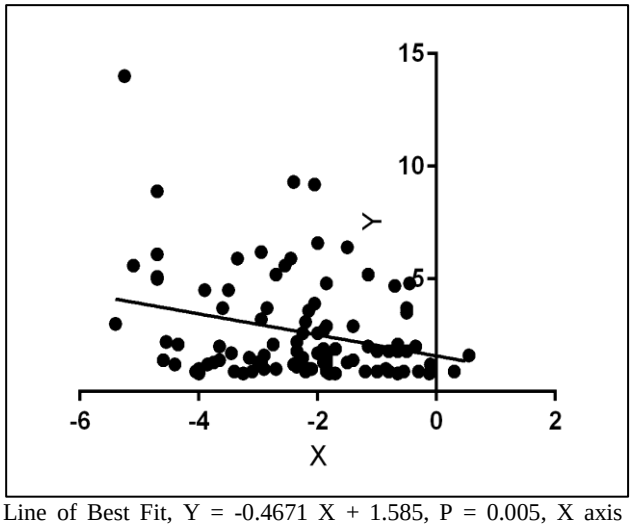
The prevalence of osteoporosis in the present study was 29.5% and osteopenia was 42.1%. This is similar to the values reported by Shatrugna et al (29% and 52%) and Marwaha et al (39% and 45%).[8,9] These values were higher than expected, probably a reflection of the use of the manufacturer's standards for Caucasian population for calculating T score. When the data generated by ICMR for Indian reference standard was used, the prevalence of osteoporosis at the spine reduced from 42.7% to 27.7% in a study carried out by Paul et al.[10] There is an emerging need to produce valid evidences to support the Indian reference standard. The actual prevalence of the disease in the community has to be established so that appropriate interventions can be planned by the government and the medical fraternity.

Table 4: FRAX scores of subjects above 40 years of age.

	< 1.00	1.00 to 1.99	2.00 to 2.99	≥ 3.00
Normal BMD	8	9	4	6
Osteopenia	4	17	5	9
Osteoporosis	6	13	4	16

Identifying individuals with low bone mass remains a clinical challenge in our country. QUS remains the commonest modality of measuring bone density of cancellous bone (peripheral bone measurement) in the heel, with its own advantages. Hence QUS method can be useful particularly in situation where DEXA is not available especially for screening individuals with low bone mass, who otherwise will remain undiagnosed.[11,12] Saito et al have demonstrated the usefulness of measuring BMD by calcaneal QUS and showed its good correlation

to the values obtained by DEXA method when treating patients of chronic kidney disease with raloxifene.[13] Frediani et al also showed that both QUS and DXA were able to discriminate women with fracture from women without fracture and independently contributed to determining the association with fracture.[14]



Line of Best Fit, Y = -0.4671 X + 1.585, P = 0.005, X axis showing T score and Y axis showing FRAX score

Figure 1: Linear regression analysis of BMD and FRAX score.

Chan et al studied the risk of fracture in patients using calcaneal ultrasound and DEXA and found that calcaneal bone mineral density assessment is an independent predictor of fracture risk in women with non-osteoporotic BMD. They also found that WHO criteria can also be used for calcaneal measurements.[15] In a study carried out in Jammu and Kashmir by Sharma et al, the use of same WHO reference standards helped identify women at risk of developing osteoporosis who otherwise would not have been identified.[16]

Osteoporosis among women has always received its fair share of attention. However it has not received its due respect when dealing with men of the same age group. Bliuc et al showed that men with osteoporotic fractures have a much higher mortality and morbidity when compared to women.[17] This leads to the worrisome fact that men must also be screened and equally treated for osteoporosis like women. However, there is lack of adequate data from India regarding morbidity among men with osteoporosis. In the study by Marwaha et al osteoporosis was present in 26.4% of male subjects and osteopenia was present in 54.3% of male subjects, which is slightly higher compared to the findings of 33.33% and 44.16% respectively in this study.[9] Also Shetty et al reported slightly lesser values of osteoporosis (20%) but slightly higher values of osteopenia (58%) in south Indian men aged above 50 years when compared to this study.[18]

In this study, the bone mineral density decreased as the age advances among men, especially after 40 years of age which is also identical to the findings by Agarwal and Sharma who found that BMD decreases as age advances in a study carried out among 200 healthy men aged above 50 years.[19] The current guidelines suggest screening for osteoporosis in asymptomatic Caucasian men above 70 years of age and in men in the age group 50-69 with additional risk factors but there is a paucity of recommendations for Indian men.[20] The usual thumb rule is to screen one decade earlier in Indian men when compared to the western recommendations and this is again mirrored in the findings that bone mineral density tends to decrease beyond 40 years of age in men.

So in a resource constrained economic setting of our country, calcaneal ultrasound measurements may act as a good screening tool for identification of patients with low bone mineral density and who may then be screened formally with DEXA for accurate diagnosis.

CONCLUSIONS

Osteoporosis is an emerging silent disease which is often diagnosed only at a late stage. Osteoporosis and osteopenia is invariably present among the female population. BMD measurements are the important tool in diagnosing osteoporosis early. Calcaneal QUS can be used as a screening tool to diagnose osteoporosis which is economical as well as available in many places. DEXA scan, the gold standard test to diagnose osteoporosis can be used to confirm the diagnosis in selected cases. Large scale population screening trials at the community level will be needed at the earliest to define the problem, identify India specific parameters and create India specific, gender specific recommendations.

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