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Original Article

Fracture risk prediction & kidney function at different stages of chronic kidney disease: A correlation study

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***Background & objectives*: Mineral bone disease commonly occurs in individuals with chronic kidney disease (CKD) and increases fracture risk due to deficiency in bone quality and quantity. The FRAX score attempts to estimate fracture risk better. The primary aim of this study was to evaluate the prediction and correlation of fracture risk with different stages of CKD.**

***Methods*: This was a correlational study. Data were collected from 95 individuals at different stages of CKD using non-probability consecutive sampling. The clinical and laboratory parameters were compared with the FRAX score in all CKD patients.**

***Results*: A total of 95 CKD patients with a mean age of 51.42±9.95 yr were selected. Of these, 66.3 per cent between 40-55 yr, 25.3 per cent were 56-70 yr, and 8.4 per cent were ≥70 yr. There were 62 (65.3%) males and 33 (34.7%) females, and more than half (60%) were from rural areas. Age (*P*<0.001), occupation (*P*<0.005), and area of residence (*P*<0.003) showed a significant association with the FRAX score for major osteoporotic fracture risk. The FRAX score for predicting hip fracture risk showed a significant association with factors such as age, occupation, and area of residence, with *P* values of <0.001, 0.003, and 0.031, respectively. Additionally, the FRAX score for assessing the risk of major osteoporotic fractures demonstrated a significant association with various stages of CKD (*P*=0.018). Similarly, for hip fracture, there was a significant increase in the risk between stage III and V CKD patients (*P*=0.038).**

***Interpretation & conclusions*: Based on the study findings it was found that the FRAX score was significantly associated with different stages of CKD, both for major osteoporotic as well as hip fracture risk.**

Key words Bone mineral density - chronic kidney disease - DEXA scan - FRAX score - fracture risk

Chronic kidney disease (CKD) is a prevalent health issue and is emerging as a significant cause of mortality[1]. CKD affects an estimated 10 to 13 per cent of individuals worldwide, representing a significant global health concern[2]. A population-based study in India reported age-adjusted and crude incidence rates

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of end-stage renal disease (ESRD) at 151 and 232 per million people, respectively[3]. CKD patients have an elevated risk of bone mineral disease, which has long contributed to increased morbidity and reduced quality of life[4,5]. By the time patients begin dialysis, at least 50 per cent have experienced fractures due to reduced bone mass and impaired bone microarchitecture, a condition that worsens as kidney function declines[6].

The CKD Registry of India collects data from numerous centres; however, there is still a lack of comprehensive information regarding the profile of untreated CKD-MBD (mineral bone disease) in patients before initiating dialysis and in those on maintenance haemodialysis (MHD)[7]. The prevalence of renal osteodystrophy (ROD) is reported to range between 90 per cent and 100 per cent among individuals with advanced kidney disease and those undergoing MHD[8,9]. Advanced imaging methods, such as dual-energy X-ray absorptiometry (DEXA) for assessing bone volume and mineralisation, and quantitative computerised tomography (CT) for evaluating bone volume and structure, can non-invasively measure aspects of ROD. FRAX is a tool that aids clinicians and researchers in identifying individuals who are at high risk for fragility fractures, but its effectiveness in the CKD population needs further evaluation[10]. The FRAX tool significantly improved the ability to identify individuals at high risk for fragility fractures[11-14]. This issue has, however, not been extensively studied in the Indian CKD population so far. While FRAX can serve as a reliable tool for assessing fracture risk in CKD stages I–III, there is limited information on its effectiveness for predicting fracture risk in individuals with advanced CKD. Hence, this study was designed to assess the relationship between FRAX scores in different stages of CKD.

Materials & Methods

The non-experimental correlational research was conducted in July-December 2023 in the department of Nephrology, All India Institute of Medical Sciences Jodhpur, a tertiary care teaching hospital in Rajasthan, India. The institute's ethical clearance was obtained from the Institutional Ethics Committee. The confidentiality and anonymity of the subjects was maintained throughout the study. The non-probability consecutive sampling technique was used to recruit the patients with CKD.

Sample size: The sample size was determined based on a comparable study[15], utilising the prevalence formula $N=(Z1-\alpha/2)^2(p)(q)/d.^2$ Here, d represents the margin of error, set at five per cent (0.05). The value t=1.96 corresponds to the standard deviation score for a 95 per cent confidence interval. The assumed or estimated proportion was *P*=5.9 per cent (0.059), and q was calculated as 1-*P*=0.941. The sample size was estimated as 86.

Inclusion/exclusion criteria: The participants included were CKD patients with estimated glomerular filtration rate (eGFR) $\leq$ 60 ml/min/1.73m^2 not on dialysis and age $\geq$40 yr attending nephrology OPD. Those with skeletal deformities and diagnosed with osteoporosis were excluded.

Study parameters: The patients' demographic and clinical profile, including age, BMI, education, occupation, dietary habit, area of residence, family history of CKD, duration of symptoms, and stages of CKD, were noted. Age, haemoglobin, serum uric acid level, serum electrolytes, total protein, serum albumin, serum globulin, liver function test, phosphorus, calcium, serum PTH level, and vitamin D level were estimated. For the assessment of bone mineral density, we used a DEXA scan (Manufacturer- Hologic Horizon A) of the neck of the femur, and fracture risk was calculated by using the FRAX Score tool[16] with the clinical risk factor response records as 'yes' or 'no', and BMD (bone mineral density) and calculated major osteoporotic fracture risk and hip fracture risk.

Statistical analysis: The data were organised and analysed using SPSS version 29.0 (IBM corp., TX, USA) for macOS. Descriptive statistics were performed, including mean, standard deviation, frequency, and percentage distribution. For inferential statistics, the Kolmogorov-Smirnov Test was used to check data normality. The results indicated that the data did not follow a normal distribution ($P<0.05$), leading to the use of non-parametric tests. Spearman's coefficient was applied for continuous variables, the Mann-Whitney U test for comparisons between two groups, the Kruskal-Wallis test for comparisons involving more than two groups, and regression analysis was conducted to determine factors influencing the FRAX score in CKD patients based on clinical parameters.

Results

The mean age of the participants was 51.42±9.95 yr. Of the total numbers of CKD patients, 66.3 per cent were between 40-55 yr, 25.3 per cent were 56-70 yr,

Table I. Baseline characteristics of study population (total number=95)

Parameters	Number (%)
Age (in yr) mean±SD	51.42±9.955
40-55	63 (66.3)
56-70	24 (25.3)
>70	08 (08.4)
Gender	
Male	62 (65.3)
Female	33 (34.7)
Occupation	
Unemployed	34 (35.8)
Public Sector	03 (03.2)
Business/other	58 (61)
Area of residence	
Urban	38 (40)
Rural	57 (60)
Dietary habits	
Vegetarian	72 (75.8)
Non vegetarian	23 (24.2)
Cause of CKD	
Diabetes mellitus	15 (15.8)
Hypertension	32 (33.7)
Stone disease	06 (06.3)
CGN	14 (14.7)
Other cause	28 (29.5)
Stages of CKD	
Stage III	20 (21.1)
Stage IV	24 (25.3)
Stage V	51 (53.7)
Body mass index, mean±SD	23.15±3.37
Underweight	07 (7.4)
Normal weight	61 (64.2)
Overweight	25 (26.3)
Obesity	02 (2.1)
Laboratory parameters	
Serum creatinine (mg/dl)	5.32±3.19
Serum urea (mg/dl)	86.63±49.81
eGFR	17.96±13.36
Serum potassium (mEq/l)	4.76±0.851
Serum chloride (mEq/l)	101.25±5.31
Serum calcium (mg/dl)	8.389±1.268
Serum phosphorus (mg/dl)	5.28±2.02
Vitamin D level (ng/ml)	17.31±13.17
Serum iPTH (pg/ml)	349.81±564.71
Femoral neck BMD	0.690±0.138
T score	-1.383±1.156
FRAX-score (%)	
Major osteoporotic fracture risk	
Overall	3.36±3.38
CKD 3	1.94±1.42
CKD 4	3.18±3.97
CKD 5	4.01±3.67
Hip fracture risk	
Overall	1.17±1.75
CKD stage III	0.55±0.74
CKD stage IV	1.26±2.23
CKD stage V	1.38±1.76

CKD, chronic kidney disease; CGN, chronic glomerulonephritis, eGFR, estimated glomerular filtration rate; iPTH, intact parathyroid hormone; BMD, bone mineral density; FRAX, fracture risk assessment tool

and 8.4 per cent were ≥70 yr. The number of males was (65.3%), more than females (34.7%). More than half (60%) of total participants were from rural areas. 21.1 per cent, 25.3 per cent, and 53.7 per cent of patients were on CKD stages III, IV and V, respectively. Among laboratory parameters, mean serum creatinine was 5.32±3.19 mg/dl, serum urea level was 86.63±49.81 mg/dl, and mean eGFR was 17.96±13.36 ml/min. Bone mineral markers like serum calcium were 8.38±1.26 mg/dl, phosphorus was 5.28±2.02 mg/dl, serum vitamin D was 17.31±13.17 ng/ml, and iPTH was 349.81±564.71 pg/ml. The average femoral neck BMD of the study participants was 0.69±0.138. Table I presents the baseline characteristics of the study population.

Age was significantly associated with the FRAX-Score for major and hip osteoporotic fracture risk. In addition, occupation, area of residence, and stage of CKD were significantly associated with the FRAX score, as shown in supplementary table I, supplementary figures 1 and 2. Among laboratory parameters, eGFR, serum urea, serum chloride, and BMI were significantly associated with FRAX-Score (Supplementary Table II). In regression analysis, age, occupation, area of residence, and stage of CKD were independently associated with FRAX-Score for major osteoporotic fracture risk in this study (Table II; Fig. 1). Age, occupation, and resident area were significantly associated with the FRAX score for hip fracture risk. Overall, the FRAX-Score for hip fracture risk was not associated with the CKD stage; however, there was a significant increase in the hip fracture risk when stages III and V were compared (Fig. 2; Table III). In the different stages of CKD, the FRAX-Score

Table II. Regression analysis of factors affecting FRAX-score for major osteoporotic and hip fracture risk in CKD patients

Parameter	Major osteoporotic risk			Hip fracture risk		
	OR	CI (95%)	*P* value	OR	CI (95%)	*P* value
BMI	1.072	-0.046 to 0.185	0.239	1.032	-0.085 to 0.147	0.6
Serum urea (mg/dl)	1.006	-0.004 to 0.016	0.235	1.009	-0.001 to 0.019	0.095
Serum chloride (mEq/l)	1.015	-0.004 to 0.033	0.122	1.011	-0.008 to 0.03	0.244
eGFR	1.061	-0.009 to 0.128	0.088	1.05	-0.014 to 0.124	0.119
Age (yr)						
40-55	0.035	4.868 to -1.816	<0.001	0.084	-3.95 to -1.009	0.001
55-70	0.280	-2.862 to 0.318	0.117	0.265	-2.905 to 0.252	0.100
>70	-	-		-	-	
Occupation						
Unemployed	0.874	-1.175 to 0.905	0.80	0.947	-1.099 to 0.991	0.919
Public Sector	20.257	0.600 to 5.417	0.014	63.159	1.651 to 6.64	0.001
Business/Other	-	-		-	-	
Area of Residence						
Urban	4.914	0.724 to 2.46	<0.001	2.904	0.212 to 1.919	0.014
Rural	-	-		-	-	
Stage of CKD						
Stage III	0.020	-6.189 to -1.618	0.001	0.070	-4.918 to -0.393	0.021
Stage IV	0.201	-2.862 to - 0.346	0.012	0.331	-2.364 to -0.153	0.085
Stage V	-	-		-	-	

Significant at $P<0.05$; BMI, body mass index; eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease; OR, odds ratio; CI, confidence interval

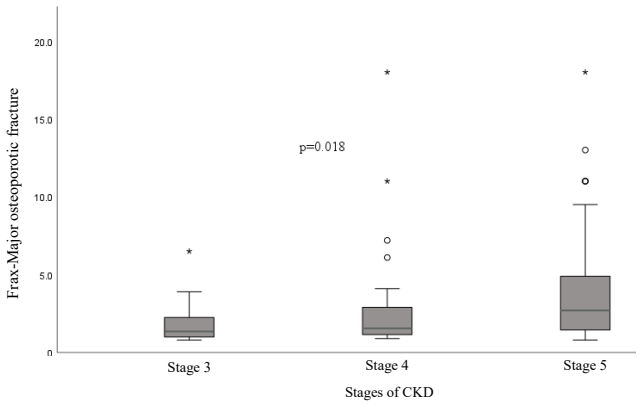

Fig. 1. FRAX Score of major osteoporotic fracture among individuals with different stages of CKD. The boxplot diagram shows that the average 10-yr probability of major osteoporotic fracture risk in stage V was observed to be significantly higher (P= 0.018) than that in stage IV and stage III. Further investigation through post hoc testing revealed that there was a statistically significant difference found between major osteoporotic fracture risk for stage IV and stage V patients with CKD (P=0.017) and similarly stage III and stage V patients with CKD (P=0.010).

for major osteoporotic fracture and hip fracture risk, age strongly contributes to fracture risk (Fig. 3 and 4). Table III shows that in CKD stage III, 50 per cent of the participants were normal, 40 per cent had osteopenia, and 10 per cent had osteoporosis. In CKD stage IV, 29.2 per cent of participants were normal, 54.4 per cent had osteopenia, and 16.7 per cent had osteoporosis. Similarly, in CKD stage V, 25.5 per cent had normal BMD, 64.7 per cent had osteopenia, and 9.8 per cent had osteoporosis.

Discussion

While diabetes, hypothyroidism, and chronic liver disease are recorded as secondary causes of osteoporosis, it is interesting to note that CKD has not been incorporated in the same, despite studies showing a higher risk of fragility fractures. The original FRAX score development dataset included some patients with reduced eGFR, but the number was not significant enough to incorporate CKD as an isolated factor for osteoporosis[17-19]. The present study demonstrates that advanced age significantly increases FRAX-scores for major osteoporotic and hip fractures. The association of fractures with age in CKD and the non-CKD population is well established[17,18]. This finding is in line with the study done by Li *et al*[20], where the risk of osteoporotic fracture increased in elderly patients. Our findings align with previous studies highlighting age as a critical factor in fracture risk. A study done by Zhang *et al*[21] found that patients aged >70 yr had significantly higher fracture risks compared to younger non-CKD

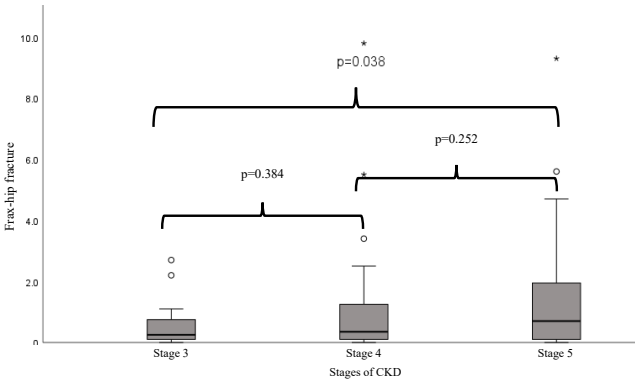

Fig. 2. FRAX Score of hip fracture among individuals with different stages of CKD. The boxplot diagram shows that the average 10-year probability hip fracture risk increases with stage of CKD. Further investigation through post hoc testing revealed that there was a statistically significant difference found between hip fracture risk for stage III and stage V patients with CKD (*P*= 0.038).

patients, which is consistent with our finding of higher major osteoporotic and hip fracture risks in older age groups. A similar study done by Drake *et al*[22] showed that increased age increases the risk of fracture.

Data on socioeconomic factors affecting the FRAX score and fracture risk within the general population is available but absent in CKD patients. The findings of this study revealed that major osteoporotic fracture and hip fracture risks are higher in the urban population than in the rural population, similarly, to the findings of Matsuzaki *et al*[23]. In a systematic review comparing BMD among urban and rural residents, it was noted that BMD was five per cent lower in the urban population in high-income countries; results from low and middle-income countries did not show a significant difference in the pooled analysis. However, there are other studies which have shown urban population has less osteoporosis than rural[24,25]. However, the present study is in contrast with the findings by Zheng *et al*[25], which revealed that the prevalence of osteoporosis is higher in rural (10.33%) populations as compared to urban (5.52%). In addition, a systematic review[26] analysed the relationship between the risk of osteoporotic fractures and socioeconomic factors - income, education, occupation, area of residence, and marital status. It was observed that there was a strong level of evidence for being married, a low level of evidence for being employed and having a larger house size, and no significant evidence for the level of income or educational qualification for a lower risk of fractures[26]. In the present study, the type of occupation had an impact on the FRAX-Score, which needs further study to confirm this finding.

In this study using the Indian FRAX calculator, the average probability of major osteoporotic fractures in stage V was significantly higher (*P*=0.018) compared to stages IV and III. Post hoc testing further indicated a significant difference in the risk of major osteoporotic

Table III. Factors affecting FRAX score and bone mineral density (BMD)

Parameters	Normal, n (%)	Osteopenia, n (%)	Osteoporosis, n (%)	Total
Age (in yr)				
40-55	23 (36.51)	34 (53.97)	6 (9.52)	63
56-70	6 (25)	15 (62.5)	3 (12.5)	24
>70	1 (12.5)	5 (62.5)	2 (25)	8
Occupation				
Unemployed	10 (29.41)	18 (52.94)	6 (17.65)	34
Public Sector	0 (0)	3 (100)	0 (0)	3
Business/Other	20 (34.48)	33 (56.9)	5 (8.62)	58
Area of residence				
Urban	9 (23.68)	23 (60.53)	6 (15.79)	38
Rural	21 (36.84)	31 (54.39)	5 (54.39)	57
Stages of CKD				
Stage III	10 (50)	8 (40)	2 (10)	20
Stage IV	7 (29.2)	13 (54.4)	4 (16.7)	24
Stage V	13 (25.5)	33 (64.7)	5 (9.8)	51

WHO defines osteoporosis as a T-score of ≤ -2.5 standard deviations (SD). Osteopenia is characterized by a T-score ranging from -1 SD to -2.4 SD, while a normal bone density is indicated by a T-score of > -1 SD

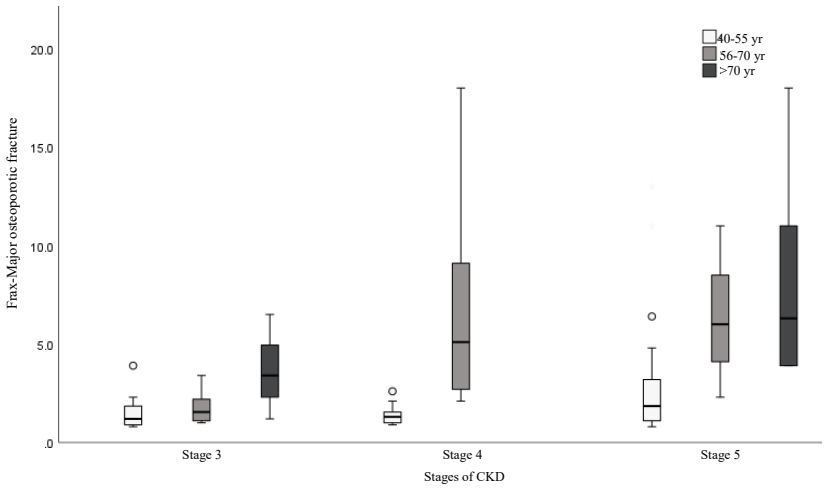

Fig. 3. Clustered Boxplot of FRAX-Score for Major Osteoporotic Fracture by Stage of CKD by Age. CKD stage and age significantly impact major osteoporotic fracture risk .

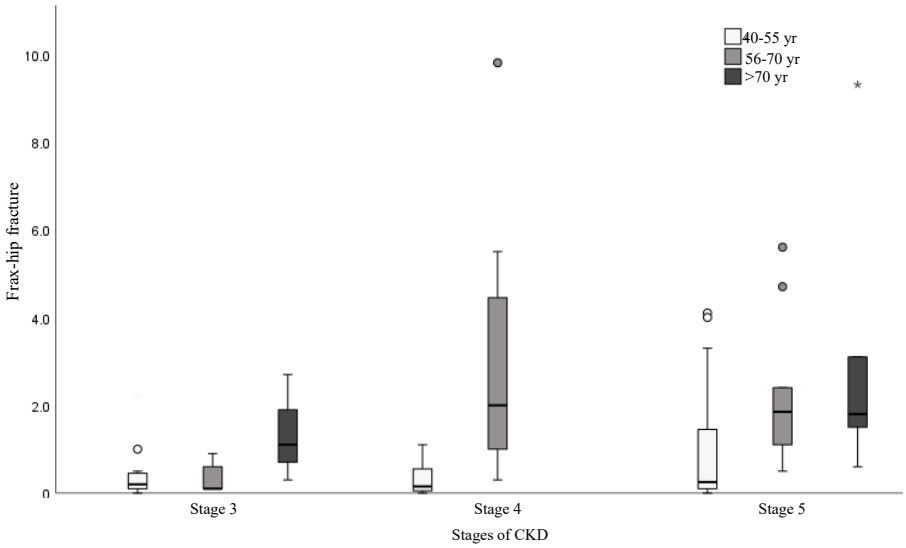

Fig. 4. Clustered Boxplot of FRAX-Score for Hip Osteoporotic Fracture risk by stage of CKD by Age. It highlights the impact of CKD and age with different stages and age groups. Both CKD stage and age had significant impacts on Hip osteoporotic fracture risk, especially when comparing stages III and V and age groups 40-55 and >70 yr.

fractures between CKD stage IV and stage V (P=0.017), as well as between stage III and stage V (P=0.010). Additionally, the average probability of hip fractures was significant between stages III and V (P=0.038) in CKD patients. Our findings align with those of Manda *et al*[2], who reported an increase in the 10-year probability of major osteoporotic fractures in CKD stage IV (9.47±2.62%) compared to CKD stage III (1.92±0.8%) (P<0.0001). The results of our study suggest that patients in advanced stages of CKD (stages IV and V) have higher FRAX scores for major osteoporotic fractures compared to those in stage III (P=0.018). This is consistent with a study by Pimental *et al*[27], which found that fracture risk increases as kidney function declines, likely due to the mineral and bone disorders prevalent in advanced CKD.

In our study, 56.8 per cent of CKD participants had osteopenia, and 11.6 per cent had osteoporosis. Osteopenia can develop into osteoporosis if left untreated. The prevalence of osteopenia in our study is consistent with findings from Aggarwal *et al*[28], who reported osteopenia and osteoporosis rates of 42 per cent and 8.5 per cent, respectively. Additionally, research by Akkupalli *et al*[29] found that among CKD patients, the prevalence of osteopenia and osteoporosis was both 33.3 per cent each, respectively. Jha *et al*[30] also noted that the prevalence of osteopenia and

osteoporosis in CKD patients was 37 per cent and 12 per cent, respectively. Likewise, Govindarajan *et al*[31] reported a prevalence of 23.2 per cent for osteopenia and 8.3 per cent for osteoporosis among CKD patients. Our findings align with those of other earlier research in the Indian CKD population.

The present study did suffer from certain limitations. The study's cross-sectional nature did not allow estimates of the fracture incidence to be calculated, and the FRAX score was used as a corollary for the same. Additionally, our study was done in an Indian population, limiting generalisability to the entire CKD population. While the FRAX score considers a good number of variables, including BMD at the femoral neck, density only represents the strength of the bone. Other parameters, such as bone quality and turnover, as measured by the trabecular bone score, bone biopsy, and biomarkers, also impact the risk of fractures and were omitted. Newer iterations of the FRAX score, which include the TBS, have also come up but require further validation.

Overall, this study not only validated the use of the FRAX score in the Indian CKD population but also demonstrated the effect of decreasing eGFR on the risk of fragility fractures. Importantly, it also fills the gap in terms of the role that socioeconomic and environmental factors play in the development of fragility fractures. Disparities in terms of area of residence, occupation, and education status are a stark reality in middle-and low-income countries like ours and warrant inclusion into a FRAX score specific to the Indian population. Moreover, long-term follow up studies are needed to establish the connection between CKD and fracture rates.

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***Conflicts of Interest*:** None.

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