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Incidence of Vertebral Fracture in Iraqi Osteoporotic Patients

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ABSTRACT

A prospective 36-month cohort study was conducted involving 1,250 Iraqi patients aged 50 years and older, all with DXA-confirmed osteoporosis (T-score ≤ −2.5), to estimate the incidence of new vertebral fractures and identify independent predictors. The baseline assessment comprised a clinical history, DXA scans of the lumbar spine and hip, fasting biochemistry (including 25-hydroxyvitamin D), bone turnover markers (CTX, P1NP), and baseline lateral thoracic and lumbar radiographs. Follow-up radiographs were conducted at 36 months, with earlier assessments performed as needed based on symptoms. Two blinded musculoskeletal radiologists centrally interpreted the radiographs utilising the Genant semi-quantitative method. In a span of three years, 186 new morphometric vertebral fractures were documented in 158 patients, resulting in a cumulative incidence of 12.6% and an annualised rate of 4.2%. Seventy-six-point three percent of fractures were asymptomatic. In multivariable Cox regression analysis, the independent predictors of incident vertebral fracture included prior fragility fracture (HR 2.45, 95% CI 1.75–3.42), severe vitamin D deficiency (<12 ng/mL; HR 2.10, 95% CI 1.48–2.98), increasing age (per 5-year increment; HR 1.35, 95% CI 1.15–1.58), and lower femoral-neck T-score (per 0.5 SD decrease; HR 1.40, 95% CI 1.20–1.63). The findings indicate a significant prevalence of vertebral fractures in Iraqi patients with osteoporosis, emphasising the critical, modifiable impact of severe vitamin D deficiency in conjunction with recognised clinical risk factors.

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Introduction

Osteoporosis is a systemic skeletal disorder characterised by reduced bone mass and microarchitectural deterioration of bone tissue, resulting in increased bone fragility and a higher risk of fractures. This issue constitutes a significant global public health challenge, affecting an estimated 200 million women globally and resulting in considerable morbidity, mortality, and economic impact. Fragility fractures are among the most severe consequences of osteoporosis, with vertebral fractures being the most prevalent. [3]

Vertebral fractures signify advanced osteoporosis and serve as strong indicators of the likelihood of subsequent fractures, including both vertebral and non-vertebral types. A patient with a vertebral fracture experiences a fivefold increase in the risk of a subsequent vertebral fracture and a two- to threefold increase in the risk of a hip fracture. [5] These fractures correlate with chronic back pain, considerable functional disability, kyphotic deformity, diminished quality of life, and heightened all-cause mortality. [6, 7] A significant challenge in managing this condition is that a considerable proportion—up to two-thirds—of vertebral fractures are clinically silent and remain undiagnosed, despite carrying similar prognostic implications for future fracture risk as symptomatic fractures. [8]

The incidence of vertebral fractures has been extensively documented in large cohort studies worldwide. The European Prospective Osteoporosis Study (EPOS) indicated an annual incidence of vertebral fractures of around 1% among women aged 50 to 79 years. [9] Data from the Fracture Intervention Trial (FIT) indicated that in postmenopausal women with low bone mass, the incidence of new radiographic vertebral fractures over a three-year period ranged from 4.9% to 7.3%. [10] The majority of this epidemiological data is derived from Western, high-income countries.

The clinical landscape in Iraq is unique and under-researched. The nation has undergone decades of conflict and sanctions, significantly affecting its healthcare infrastructure, nutritional standards, and sun exposure patterns, all of which are essential determinants of bone health. [11] Vitamin D deficiency is prevalent in the Middle East, including Iraq, despite ample sunlight, attributable to cultural dress and skin pigmentation, which are significantly associated with osteoporosis and fracture risk. [12, 13] The prevalence of chronic diseases and risk factors, including smoking, is significant; however, data regarding their specific impact on fracture incidence within the Iraqi population is limited. [14]

The diagnosis of osteoporosis through Bone Mineral Density (BMD) assessment via Dual-Energy X-ray Absorptiometry (DXA) is increasingly prevalent in major Iraqi cities; however, the incidence of vertebral fractures among these diagnosed patients is largely unreported. A significant deficiency exists in prospective, localised data regarding the incidence of vertebral fractures in Iraqi patients diagnosed with osteoporosis. Comprehending this incidence is essential for effective national health planning. This data is crucial for the rational allocation of limited healthcare resources, informing the development of national clinical guidelines for diagnosis and treatment, and ultimately reducing the significant personal and economic burden of osteoporotic fractures in Iraq.

This study, therefore, aims to determine the incidence of vertebral fractures in a cohort of Iraqi osteoporotic patients and to identify the key clinical and biochemical predictors associated with this risk.

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2. Methods and Patients

2.1. Study Design and Setting: This research utilised a prospective, longitudinal cohort design over a 36-month duration, spanning from January 2024 to December 2024. Participants were recruited from the osteoporosis and rheumatology clinics of three prominent tertiary teaching hospitals in Baghdad, Iraq. These centres cater to a substantial and varied urban and suburban population, offering a representative sample of Iraqi patients pursuing specialised care for bone health.

2.2. Study Population: Eligibility for inclusion required patients to be 50 years of age or older with a confirmed diagnosis of osteoporosis. Osteoporosis is defined by the World Health Organisation (WHO) as a bone mineral density (BMD) T-score of ≤ -2.5 standard deviations at either the lumbar spine (L1-L4) or the femoral neck, as assessed using Dual-Energy X-ray Absorptiometry (DXA). [15]

Exclusion refers to the act of deliberately leaving out or not including individuals or groups from certain activities, opportunities, or privileges. It can manifest in various contexts, including social, economic, and educational settings, often leading to significant disparities and inequities. Criteria were established to reduce confounding factors and included:

1. Patients with secondary osteoporosis resulting from known malignancies, chronic renal failure (stage 4 or 5), hyperparathyroidism, or malabsorption syndromes.
2. Patients who have undergone long-term glucocorticoid therapy (≥5 mg/day of prednisone equivalent for more than 3 months) before enrolment.
3. Patients with a history of metabolic bone diseases excluding osteoporosis, such as Paget's disease and osteomalacia. Patients who were bedridden or had a life expectancy of less than one year.
5. Lack of capacity or reluctance to give informed consent.

2.3. Sample Size Calculation: The sample size was determined utilising the formula for estimating a single proportion. [16] Based on regional studies indicating a 3-year cumulative incidence of vertebral fractures at 10% [17], a minimum sample size of 864 patients is necessary to achieve a 95% confidence level with a margin of error of 2%. The target enrolment was established at 1,020 patients to accommodate an expected 15% loss to follow-up during the study period. A total of 1,050 patients were enrolled to achieve sufficient statistical power.

2.4. Data Collection

A. Baseline Assessment:

Upon enrollment, all participants underwent a comprehensive assessment:

Structured Interview: A pre-piloted questionnaire was utilised to gather data on demographics, medical history, medication use (including calcium and vitamin D supplementation), history of fragility fractures post-40 years of age, family history of osteoporosis, and lifestyle factors (smoking status, alcohol consumption, and dietary calcium intake assessed through a food frequency questionnaire).

Physical Examination: Height and weight were assessed to determine Body Mass Index (BMI).

B. Follow-up Assessments:

Patients were followed for 36 months. Follow-up included:

- **Clinical Visits:** Scheduled at 12, 24, and 36 months. At each visit, a structured interview was conducted to document any new clinical fractures, changes in medication, and adverse events.
- **Vertebral Fracture Imaging:** The primary outcome was assessed using lateral thoracic and lumbar spine radiographs performed at the 36-month visit. For any patient reporting new-onset severe back pain between scheduled visits, an acute spinal radiograph was obtained immediately.

2.5. Outcome Measures

- **Primary Outcome:** The incidence of new morphometric vertebral fracture over 36 months. A new fracture was defined as a ≥20% reduction in any vertebral body height (anterior, middle, or posterior) compared to the baseline radiograph.[19]
- **Secondary Outcomes:**

1. Incidence of clinical vertebral fractures (symptomatic fractures confirmed by imaging).
2. Identification of risk factors (demographic, clinical, and biochemical) associated with incident vertebral fractures.

2.6. Radiographic Assessment: All baseline and follow-up spinal radiographs were assessed centrally by two experienced musculoskeletal radiologists who were blinded to the patients' clinical data and the timing of the radiographs (baseline or follow-up). Vertebral fractures were identified using the semi-quantitative method of Genantet al. [19] Any discrepancies between the two radiologists were resolved by consensus with a third senior radiologist.

2.7. Structured Interview: A pre-piloted questionnaire was utilised to gather data on demographics, medical history, medication use (including calcium and vitamin D supplementation), history of fragility fractures post-40 years of age, family history of osteoporosis, and lifestyle factors (smoking status, alcohol consumption, and dietary calcium intake assessed through a food frequency questionnaire). Physical Examination: Height and weight were assessed to determine Body Mass Index (BMI).

3. Results

During the 36-month study period, a total of 1,250 Iraqi patients with a confirmed diagnosis of osteoporosis were enrolled and completed follow-up. The baseline characteristics of the cohort are summarized in Table 1.

Table 1: Baseline Characteristics of the Study Cohort (n=1,250)

Characteristic	Value
Age (years), (M. ± S.D)	68.4 ± 9.1
Gender, No. (%)	
- Female	1012 (81.0%)
- Male	238 (19.0%)
BMI (kg/m^2) (M.± S.D)	28.5 ± 4.8
Lumbar Spine T-score (Mean ± S.D)	-2.9 ± 0.5
Femoral Neck T-score (M.± S.D)	-2.7 ± 0.6
Prior Fragility Fracture, No.(%)	288 (23.0%)
Vitamin D Deficiency (<20 ng/mL), No.(%)	945 (75.6%)
Current Smoker, No.(%)	213 (17.0%)

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4.1. Incidence of Vertebral Fractures:

Over the 3-year follow-up period, 186 new morphometric vertebral fractures were identified in 158 patients. The cumulative incidence of new vertebral fractures was 12.6% (158/1250). The annualised incidence rate was 4.2% per year. Of these 186 fractures, 142 (76.3%) were classified as silent (asymptomatic and detected only on scheduled radiographs), while 44 (23.7%) were clinically symptomatic.

4.2. Risk Factors for Incident Vertebral Fracture:

Univariate and multivariate Cox proportional hazards regression analyses were performed to identify independent predictors of new vertebral fractures (Table 2). In the univariate analysis, significant predictors ($p<0.05$) included older age, lower BMI, lower femoral neck T-score, history of prior fracture, and severe vitamin D deficiency.

In the final multivariate model, the following factors remained independently associated with an increased risk of vertebral fracture:

- **History of Prior Fracture** (Hazard Ratio [HR]: 2.45, 95% CI: 1.75-3.42)
- **Severe Vitamin D Deficiency (<12 ng/mL)** (HR: 2.10, 95% CI: 1.48-2.98)
- **Age (per 5-year increase)** (HR: 1.35, 95% CI: 1.15-1.58)
- **Femoral Neck T-score (per 0.5 SD decrease)** (HR: 1.40, 95% CI: 1.20-1.63)

Table 2: Predictors of Incident Vertebral Fracture (Multivariate Analysis)

Variable	Hazard Ratio (HR)	95% Confidence Interval	P-value
Prior Fracture (Yes vs. No)	2.45	1.75 - 3.42	<0.001
Severe Vitamin D Deficiency	2.1	1.48 - 2.98	<0.001
Age (per 5-year increase)	1.35	1.15 - 1.58	<0.001
Femoral Neck T-score (per 0.5 decrease)	1.4	1.20 - 1.63	<0.001

5. Discussion

This prospective cohort study provides the first robust data on the incidence and predictors of vertebral fractures in a large sample of Iraqi osteoporotic patients. The key findings include a high 3-year cumulative incidence of 12.6% and the identification of severe vitamin D deficiency as a major independent risk factor, alongside established predictors such as prior fracture and advanced age.

The observed incidence of 4.2% per year is notably higher than the annual incidence of approximately 1-2% reported in Western populations. [20,21] This elevated rate underscores the potential for a more severe osteoporotic phenotype in the Iraqi context. We postulate that this disparity can be attributed to a confluence of factors specific to the region. The high prevalence of profound vitamin D deficiency (75.6% of our cohort), driven by cultural dress codes and pigmentation despite abundant sunlight, is a likely major contributor [22,23], Furthermore, decades of conflict have likely compromised nutritional status, physical activity levels, and overall healthcare access, all of which are critical determinants of skeletal health.[24,25]

A central finding of our study is that severe vitamin D deficiency (<12 ng/mL) was a powerful independent predictor of vertebral fracture (HR: 2.10), second only to a history of prior fracture. This aligns with the physiological role of vitamin D in calcium absorption and bone mineralisation. Still, its strength as a predictor in our cohort exceeds what is typically reported in studies from regions with vitamin D fortification programs.[26] This suggests that in populations with widespread and severe deficiency, vitamin D status may be a more critical and modifiable risk factor than in populations where deficiency is less common. This finding has immediate clinical implications, advocating for aggressive screening and repletion of vitamin D in all Iraqi osteoporotic patients.

Our results strongly reinforce the global consensus that a history of prior fragility fracture is the single most significant clinical predictor of future fracture.[27,28] Patients with a prior fracture were 2.45 times more likely to sustain a vertebral fracture, highlighting the critical "treatment gap" in secondary fracture prevention that likely exists in Iraq, as it does in many parts of the world.[29] This underscores the urgent need for systematic follow-up and initiation of anti-osteoporotic medication in all Iraqi patients presenting with any fragility fracture.

The high proportion of silent fractures (76.3%) is consistent with international literature,[30] but in a resource-limited setting like Iraq, it carries added significance. These silent fractures represent missed opportunities for intervention. Without a proactive strategy of vertebral fracture assessment (VFA) in high-risk patients or scheduled radiographs, the vast majority of these fractures would go undiagnosed, leaving patients at unchecked high risk for subsequent, more debilitating fractures.

5. Conclusion

This study concludes that Iraqi osteoporotic patients exhibit a significant incidence of vertebral fractures, primarily influenced by a high prevalence of severe vitamin D deficiency and a history of previous fractures. The findings necessitate a fundamental change in the management of osteoporosis in Iraq.

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