

FREQUENCY OF OSTEOMALACIA IN PERIMENOPAUSAL WOMEN

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ABSTRACT

Background: Osteomalacia is a metabolic bone disorder characterized by defective mineralization of osteoid, primarily resulting from vitamin D deficiency. Perimenopausal women are particularly susceptible because of hormonal changes and disturbances in calcium-phosphate metabolism. This study aimed to determine the frequency of biochemical osteomalacia and evaluate its associated biochemical predictors among perimenopausal women.

Methods: A hospital-based observational cross-sectional study was conducted among 113 perimenopausal women aged 45–55 years attending the Orthopaedics Outpatient Department of a tertiary care hospital. Clinical assessment and biochemical evaluation, including serum vitamin D, calcium, phosphorus, and alkaline phosphatase (ALP), were performed. Biochemical osteomalacia was diagnosed using standard Nasser's criteria. Statistical analysis was carried out using SPSS version 26.0.

Results: Biochemical osteomalacia was identified in 54 (47.8%) participants. Vitamin D deficiency was present in 70.8% of women. Patients with osteomalacia had significantly lower serum vitamin D (20.8 ± 6.5 vs. 26.9 ± 8.2 ng/mL), calcium (8.86 ± 0.89 vs. 9.63 ± 0.72 mg/dL), and phosphorus (3.36 ± 0.78 vs. 3.92 ± 0.65 mg/dL), with significantly higher ALP levels (152.4 ± 88.3 vs. 103.6 ± 52.7 U/L) (all $p < 0.05$). Multivariate analysis identified hypophosphatemia (AOR=6.75), elevated ALP (AOR=5.96), vitamin D deficiency (AOR=5.82), and hypocalcemia (AOR=4.21) as significant independent predictors. Vitamin D deficiency demonstrated the highest diagnostic sensitivity (100%) with AUC (0.82).

Conclusion: Biochemical osteomalacia is highly prevalent among perimenopausal women. Routine assessment of vitamin D, calcium, phosphorus, and ALP may facilitate early diagnosis and timely management, thereby reducing long-term skeletal complications.

KEYWORDS: Biochemical Osteomalacia, Perimenopausal women, Vitamin D deficiency, Alkaline phosphatase, Serum calcium, Serum phosphorus, Metabolic bone disease, and Bone mineralization.

1. INTRODUCTION

Osteomalacia is an acquired metabolic bone disorder characterized by defective mineralization of preformed osteoid in the mature skeleton, resulting in reduced bone strength, impaired biomechanical properties, and increased susceptibility to insufficiency fractures.^{1,2} Unlike osteoporosis, which is characterized by reduced bone mass with preserved mineralization, osteomalacia represents a qualitative defect in bone mineralization that is potentially reversible with appropriate treatment.³ Clinically, patients commonly present with diffuse bone pain, proximal muscle weakness, gait disturbances, fatigue, and recurrent low-energy fractures. Osteomalacia remains frequently underdiagnosed because its manifestations overlap with degenerative, inflammatory, and age-related musculoskeletal disorders encountered in routine orthopedic practice.^{4,5} Perimenopausal women constitute one of the most vulnerable populations for developing metabolic bone disorders owing to the combined effects of declining estrogen levels, inadequate dietary calcium intake, reduced physical activity, and impaired vitamin D metabolism.⁶ Although osteoporosis receives considerable clinical attention during the menopausal transition, biochemical osteomalacia is often overlooked despite requiring an entirely different therapeutic approach.⁷ Delayed diagnosis may expose women to persistent skeletal pain, proximal myopathy, pseudofractures, delayed fracture healing, deformities, and avoidable disability, thereby substantially impairing quality of life.⁸

Vitamin D deficiency, the principal etiological factor for osteomalacia, has emerged as a major global public health concern. Nearly half of the world's population has suboptimal serum 25hydroxyvitamin D concentrations, with women demonstrating a disproportionately higher prevalence because of biological, nutritional, and socio-cultural factors.⁹ The burden is particularly alarming in India, where abundant sunlight paradoxically coexists with widespread hypovitaminosis D. Hospital- and community-based studies have consistently reported vitamin D deficiency in 70–90% of Indian women, especially during the perimenopausal and postmenopausal periods, predisposing them to impaired calcium-phosphate homeostasis and defective bone mineralization.^{10,11}

In the absence of renal or hepatic disease, biochemical osteomalacia is currently diagnosed using practical biochemical criteria, including reduced serum 25-hydroxyvitamin D, elevated alkaline phosphatase, low serum calcium, and reduced serum inorganic phosphorus.^{1,12} Bone biopsy remains the diagnostic gold standard but is invasive and impractical for routine clinical use, biochemical assessment provides a feasible and reliable alternative for identifying patients in routine orthopedic practice. However, data regarding the actual burden of biochemical osteomalacia among Indian perimenopausal women remain undocumented.^{13,14}

Therefore, the present study was undertaken to estimate the burden of biochemical osteomalacia among perimenopausal women attending a tertiary care hospital and to evaluate the key biochemical markers associated with the disease.¹⁵ The findings are expected to provide valuable evidence that may facilitate early diagnosis, timely intervention, and improved orthopedic management of this preventable metabolic bone disorder.

2 MATERIALS AND METHODS

2.1 Study Design And Setting

This hospital-based observational cross-sectional study was conducted in the Department of Orthopaedics, Teerthanker Mahaveer Medical College and Research Centre (TMMC&RC), Teerthanker Mahaveer University, Moradabad, Uttar Pradesh, India. The study was carried out over a period of 18 months after obtaining approval from the Institutional Ethics Committee (IEC No. PG 2024-25/123) and the College Research Committee (CRC). The study was conducted in accordance with the ethical standards approved by the Indian Council of Medical Research (ICMR) guidelines. Written informed consent was obtained from all participants before enrolment.

2.2 Study Population

The study included perimenopausal women attending the Orthopaedics Outpatient Department (OPD) with clinical features suggestive of metabolic bone disease. Perimenopause was defined as the transitional period preceding menopause and extending up to one year after the final menstrual period, typically occurring between 45 and 55 years. Consecutive eligible patients fulfilling the predefined inclusion criteria were recruited.

2.3 Inclusion and Exclusion Criteria

Women aged 45–55 years presenting with diffuse musculoskeletal pain, proximal muscle weakness, generalized fatigue, muscle cramps, myalgia, arthralgia, or skeletal deformities suggestive of osteomalacia were included. Patients with chronic liver disease, chronic kidney disease, renal osteodystrophy, malignancy, surgically induced menopause, or those receiving medications known to affect bone metabolism, including antiepileptic drugs, were excluded. Women unwilling to provide written informed consent were also excluded.

2.4 Clinical, Radiological and Biochemical Assessment

Following enrolment, demographic characteristics, menstrual history, medical history, and drug history were recorded using a standardized case record form. A comprehensive clinical examination was performed to assess bone tenderness, proximal muscle weakness, gait abnormalities, and skeletal deformities.

Plain radiographs of clinically indicated skeletal regions were obtained whenever necessary to identify radiological features suggestive of osteomalacia, including Looser's zones (pseudofractures) and cortical thinning.

Venous blood samples were collected under aseptic precautions for estimation of serum 25hydroxyvitamin D [25(OH)D], serum alkaline phosphatase (ALP), serum calcium, and serum inorganic phosphorus. All biochemical investigations were performed in the institutional central laboratory using standardized analytical methods and calibrated instruments to ensure accuracy and reproducibility.

2.5 Diagnostic Criteria

Biochemical osteomalacia was diagnosed according to Nasser's criteria, in the absence of renal or hepatic disease, when at least two of the following abnormalities were present: serum 25-hydroxyvitamin D concentration <30 nmol/L, elevated serum alkaline phosphatase, reduced serum calcium, and reduced serum inorganic phosphorus.¹² This biochemical definition provides a practical and reliable approach for diagnosing osteomalacia in routine clinical practice where bone biopsy is not feasible.

2.6 Sample Size Estimation

The sample size was calculated using the standard formula for estimation of prevalence:

$$n = \frac{Z_{12-\alpha/2}^2 \times p \times (1-p)}{d^2}$$

where Z = 1.96 for a 95% confidence interval, p represents the anticipated prevalence obtained from previous Indian studies, and d denotes the allowable absolute precision. Based on the calculation, the minimum required

sample size was 95 participants. To compensate for possible incomplete data and non-response, additional eligible participants were enrolled.

2.7 Statistical Analysis

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. The Chi-square test was used for comparison of categorical variables, while the independent Student's t-test or Mann–Whitney U test was applied for continuous variables, depending on data distribution. A two-tailed p value <0.05 was considered statistically significant.

3. RESULT

Table 1 show the baseline characteristics and frequency of biochemical osteomalacia among 113 perimenopausal women. Most participants were aged 45–50 years (69.91%), with a mean age of 48.98 ± 2.69 years, while 30.09% were aged 50–55 years. Musculoskeletal pain was the most common symptom (39.82%), followed by myalgia (23.89%), tiredness (22.12%), and muscle spasm (14.16%). Normal serum calcium, phosphorus, and ALP levels were observed in 76.11%, 66.37%, and 83.19% of participants, respectively, whereas hypocalcemia (20.35%), hypophosphatemia (18.58%), elevated ALP (16.81%), and vitamin D deficiency (70.8%) were also noted. The mean serum calcium, phosphorus, ALP, and vitamin D levels were 9.23 ± 0.67 mg/dL, 3.86 ± 0.68 mg/dL, 115.96 ± 66.07 U/L, and 23.22 ± 7.96 ng/mL, respectively. Figure 1 shows that 54 (47.8%) women had biochemical osteomalacia, while 59 (52.2%) did not, indicating that nearly half of the study population was affected.

Table 1: Frequency of Biochemical Osteomalacia

Age Group	Number (n)	Percentage (%)	Mean Age ± SD
45–50 Years	79	69.91	48.98 ± 2.69 years
50–55 Years	34	30.09	
Clinical Parameter			
Musculoskeletal Pain	45	39.82	
Myalgia	27	23.89	
Tiredness	25	22.12	
Muscle Spasm	16	14.16	
Biochemical Parameter		Mean ± SD	
Serum Calcium (mg/dL)			
<8.8	23	20.35	9.23 ± 0.67
8.8–10.3	86	76.11	
>10.3	4	3.54	
Serum Phosphorus (mg/dL)			
<3.4	21	18.58	
3.4–4.5	75	66.37	3.86 ± 0.68
>4.5	17	15.04	
Serum ALP (U/L)			
<44	0	0	
44–147	94	83.19	115.96 ± 66.07
>147	19	16.81	
Serum Vitamin D (ng/mL)			
<30	80	70.8	
30–75	33	29.2	23.22 ± 7.96
≥75	0	0	

Table 1 compares the biochemical parameters between women with and without biochemical osteomalacia. Women with osteomalacia had significantly lower mean serum vitamin D (20.8 ± 6.5 vs. 26.9 ± 8.2 ng/mL), serum calcium (8.86 ± 0.89 vs. 9.63 ± 0.72 mg/dL), and serum phosphorus (3.36 ± 0.78 vs. 3.92 ± 0.65 mg/dL) than those without osteomalacia (all $p < 0.001$). In contrast, the mean serum alkaline phosphatase level was significantly higher in the osteomalacia group (152.4 ± 88.3 vs. 103.6 ± 52.7 U/L; $p = 0.002$), indicating significant biochemical differences between the two groups.

Table 2: Comparison of Biochemical Parameters Between Osteomalacia and NonOsteomalacia Groups

Parameter	Osteomalacia (n=54) Mean $\pm$ SD	No Osteomalacia (n=59) Mean $\pm$ SD	p-value
Vitamin D	20.8 $\pm$ 6.5	26.9 $\pm$ 8.2	<0.001
Calcium	8.86 $\pm$ 0.89	9.63 $\pm$ 0.72	<0.001
Phosphorus	3.36 $\pm$ 0.78	3.92 $\pm$ 0.65	<0.001
ALP	152.4 $\pm$ 88.3	103.6 $\pm$ 52.7	0.002

Table 3 shows that vitamin D deficiency was present in 54 women with osteomalacia compared to 26 women without osteomalacia ($p < 0.001$). Similarly, hypocalcemia was observed in 18 vs. 5 women ($p = 0.001$), hypophosphatemia in 19 vs. 2 women ($p < 0.001$), and elevated ALP in 17 vs. 2 women ($p < 0.001$) in the osteomalacia and non-osteomalacia groups, respectively. Figure 2 graphically depicts the higher frequency of these biochemical abnormalities among women with osteomalacia compared with those without osteomalacia.

Table 3: Association of Biochemical Markers with Osteomalacia

Variable	Osteomalacia	No Osteomalacia	p-value
Vitamin D deficiency	54	26	<0.001
Hypocalcemia	18	5	0.001
Hypophosphatemia	19	2	<0.001
Elevated ALP	17	2	<0.001

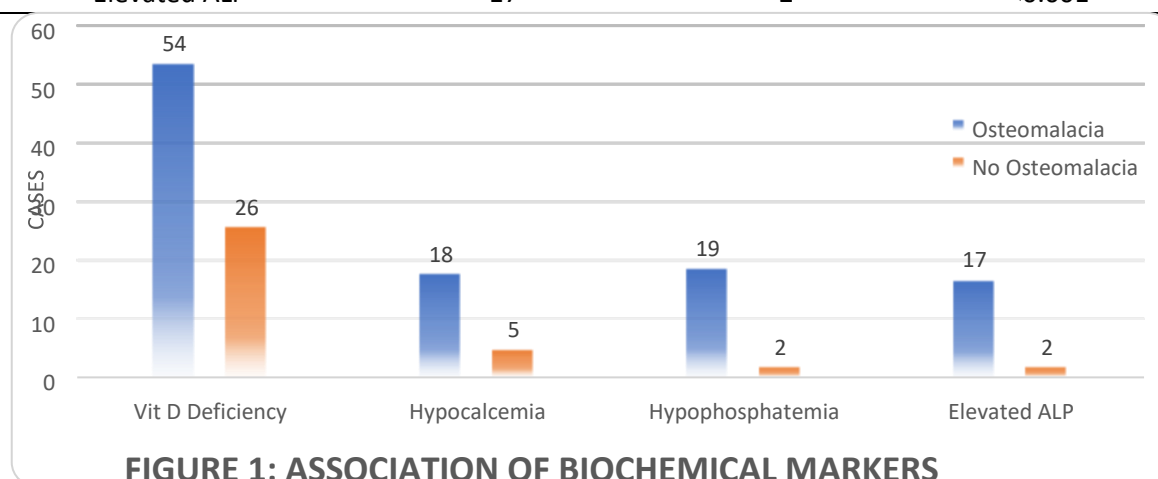


Table 4 demonstrates that vitamin D deficiency (AOR = 5.82; 95% CI: 2.45–13.82; $p < 0.001$), hypocalcemia (AOR = 4.21; 95% CI: 1.52–11.64; $p = 0.005$), hypophosphatemia (AOR = 6.75; 95% CI: 2.10–21.70; $p = 0.001$), and elevated ALP (AOR = 5.96; 95% CI: 1.85–19.18; $p = 0.002$) were identified as significant independent predictors of biochemical osteomalacia. In contrast, age was not significantly associated with osteomalacia (AOR = 1.08; 95% CI: 0.91–1.28; $p = 0.36$). Figure 3 visually demonstrates the adjusted odds ratios and 95% confidence intervals of these predictors, confirming hypophosphatemia as the strongest independent predictor, followed by elevated ALP, vitamin D deficiency, and hypocalcemia.

Table 4: Multivariate Logistic Regression Analysis for Predictors of Osteomalacia

Variable	β Coefficient	Adjusted (AOR)	Odds Ratio	95% Confidence Interval	p-value
Vitamin D deficiency	1.76	5.82		2.45 – 13.82	<0.001

Hypocalcemia	1.44	4.21	1.52 – 11.64	0.005
Hypophosphatemia	1.91	6.75	2.10 – 21.70	0.001
Elevated ALP	1.78	5.96	1.85 – 19.18	0.002
Age	0.08	1.08	0.91 – 1.28	0.36

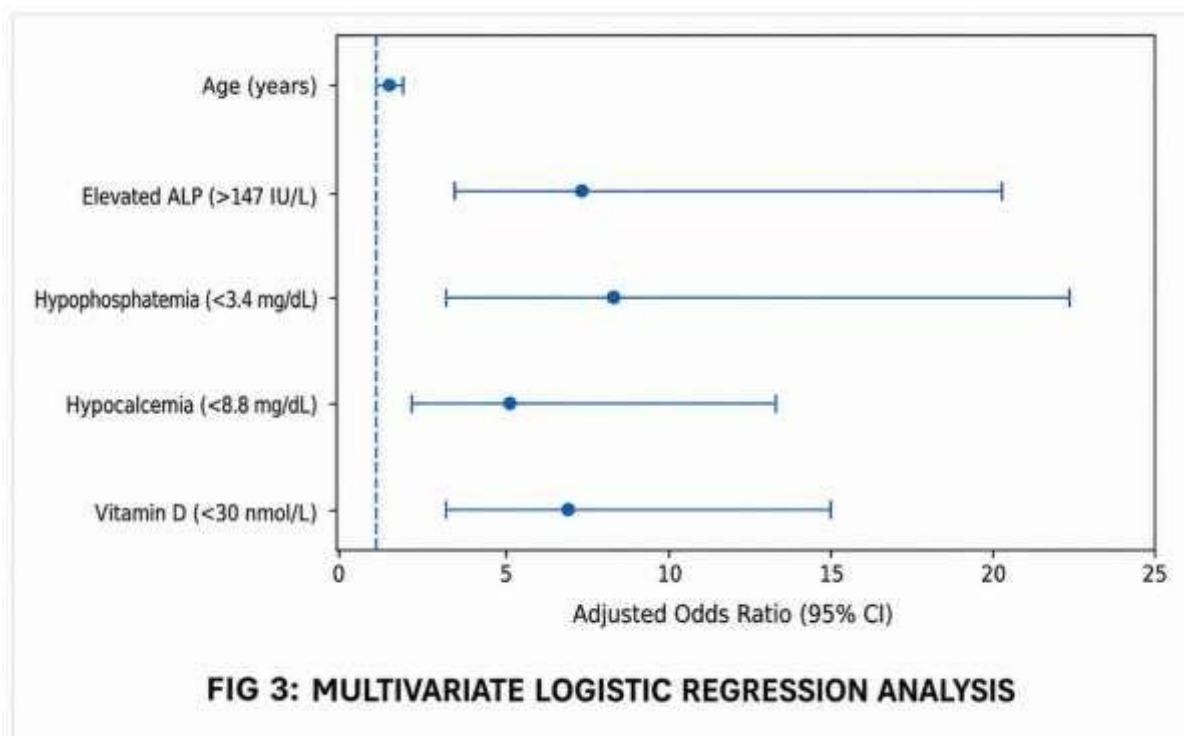
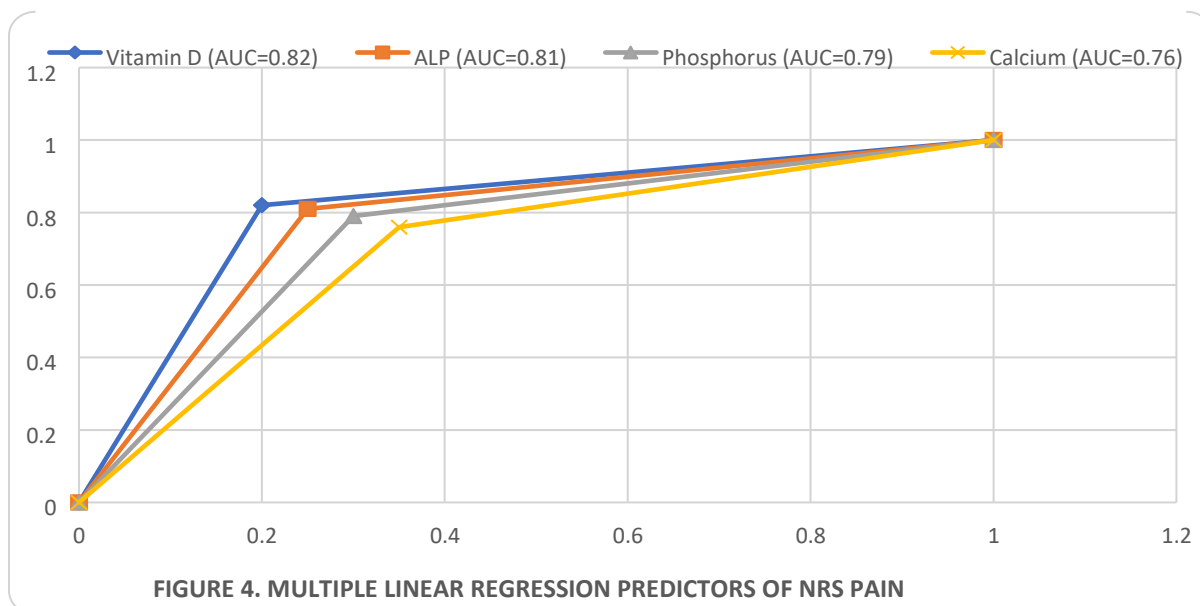


Table 5 demonstrates the diagnostic performance of the evaluated biochemical markers for detecting osteomalacia. Vitamin D deficiency exhibited the highest sensitivity (100%) and negative predictive value (100%), although its specificity was 55.93%. In contrast, hypophosphatemia and elevated ALP demonstrated the highest specificity (96.61% each), with positive predictive values of 90.47% and 89.47%, respectively. Hypocalcemia also showed high specificity (91.52%) but relatively low sensitivity (33.33%). Figure 4 further supports these findings by demonstrating that vitamin D had the highest diagnostic accuracy (AUC = 0.82), followed by ALP (AUC = 0.81), phosphorus (AUC = 0.79), and calcium (AUC = 0.76), indicating that vitamin D is the most sensitive screening marker, whereas hypophosphatemia and elevated ALP are more useful for confirming the diagnosis of biochemical osteomalacia.

TABLE 5: Diagnostic Accuracy of Biochemical Markers

Marker	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Vitamin D deficiency	100	55.93	67.5	100
Hypocalcemia	33.33	91.52	78.26	63.53
Hypophosphatemia	35.19	96.61	90.47	64.4
Elevated ALP	31.48	96.61	89.47	63.74



4. DISCUSSION

The present study evaluated the prevalence and biochemical predictors of osteomalacia among 113 perimenopausal women aged 45–55 years. Nearly half of the study population (47.8%) fulfilled the criteria for biochemical osteomalacia, indicating that this condition remains an important but frequently overlooked metabolic bone disorder in women during the perimenopausal period. The mean age of the participants was 48.98 ± 2.69 years, with most women (69.91%) belonging to the 45–50-year age group. Musculoskeletal pain was the predominant presenting symptom (39.82%), followed by myalgia (23.89%), tiredness (22.12%), and muscle spasm (14.16%). Furthermore, vitamin D deficiency was highly prevalent (70.8%), while hypocalcemia (20.35%), hypophosphatemia (18.58%), and elevated alkaline phosphatase (16.81%) were also commonly observed.

The observed prevalence of biochemical osteomalacia (47.8%) is considerably higher than that reported by Al-Daghri et al.16, who documented biochemical osteomalacia in Arab adolescents using mineralization abnormalities, and by Peyman Mirghaderi et al.17, who reported biochemical osteomalacia in 41.7% of elderly patients. The relatively higher prevalence in the present study may be attributed to the inclusion of perimenopausal women, among whom declining estrogen levels, poor dietary calcium intake, limited sunlight exposure, and lifestyle-related vitamin D deficiency collectively increase the risk of impaired bone mineralization.

Musculoskeletal pain was the most frequent clinical complaint in the present study. This finding is consistent with the classic description by Al-Rawi et al.18, who identified diffuse bone pain, back pain, proximal muscle weakness, and waddling gait as the most common manifestations of osteomalacia. Similarly, Sitta et al.19 described chronic generalized body pain and muscle weakness as the predominant presenting features in a patient with severe vitamin D deficiency-related osteomalacia. These observations reinforce that persistent musculoskeletal symptoms in perimenopausal women should prompt clinicians to investigate underlying metabolic bone disease rather than attributing them solely to aging or menopause.

Vitamin D deficiency emerged as the most striking biochemical abnormality in the present study, affecting 70.8% of participants. Women with osteomalacia had significantly lower vitamin D levels than those without osteomalacia (20.8 ± 6.5 vs. 26.9 ± 8.2 ng/mL; $p < 0.001$). This finding is comparable with the study by Vasudevan et al.20, who reported vitamin D deficiency in 89.1% of perimenopausal women in Kerala, emphasizing the widespread burden of hypovitaminosis D in Indian women. Likewise, Jaya Chawla et al.21 demonstrated that vitamin D deficiency was one of the strongest contributors to reduced bone mineral density among women over 40 years of age.

The present study also demonstrated significantly lower serum calcium (8.86 ± 0.89 vs. 9.63 ± 0.72 mg/dL; $p < 0.001$) and phosphorus (3.36 ± 0.78 vs. 3.92 ± 0.65 mg/dL; $p < 0.001$), together with significantly higher alkaline phosphatase levels (152.4 ± 88.3 vs. 103.6 ± 52.7 U/L; $p = 0.002$) among women with osteomalacia. These biochemical findings closely resemble those reported by Al-Rawi et al.18, who observed reduced calcium and phosphate concentrations with markedly elevated alkaline phosphatase in patients with primary osteomalacia. Similar biochemical abnormalities were also described by Peyman Mirghaderi et al.17, where

hypocalcemia, hypophosphatemia, elevated alkaline phosphatase, and vitamin D deficiency were common among patients with histologically confirmed osteomalacia.

Multivariate logistic regression identified vitamin D deficiency (AOR=5.82; 95% CI: 2.45– 13.82; $p<0.001$), hypocalcemia (AOR=4.21; $p=0.005$), hypophosphatemia (AOR=6.75; $p=0.001$), and elevated alkaline phosphatase (AOR=5.96; $p=0.002$) as independent predictors of biochemical osteomalacia, whereas age was not significantly associated (AOR=1.08; $p=0.36$). These findings support the observations of Arti Bhan et al.22, who emphasized that biochemical markers remain fundamental for diagnosing metabolic bone diseases, and Peris et al.23, who recommended comprehensive biochemical evaluation before establishing a diagnosis of osteomalacia or osteoporosis.

The diagnostic accuracy analysis further demonstrated that vitamin D deficiency had the highest sensitivity (100%), negative predictive value (100%), and overall diagnostic performance (AUC=0.82). In contrast, hypophosphatemia and elevated alkaline phosphatase exhibited the highest specificity (96.61% each), indicating excellent confirmatory value despite lower sensitivity. These findings are in agreement with Pepe et al.24 and Halloran et al.25, who emphasized that vitamin D assessment serves as the most effective screening tool, while additional biochemical markers, including phosphate and alkaline phosphatase, improve diagnostic confidence and help distinguish osteomalacia from other metabolic bone disorders.

5. CONCLUSION

In conclusion, the present study demonstrated that the frequency of biochemical osteomalacia is high among perimenopausal women, affecting nearly half (47.8%) of the study population. Vitamin D deficiency was the most common biochemical abnormality and emerged as the most sensitive marker for detecting osteomalacia, while hypophosphatemia and elevated alkaline phosphatase were the strongest independent predictors and highly specific diagnostic indicators.

6. SIGNIFICANCE

These findings emphasize the importance of routine biochemical screening, particularly assessment of serum vitamin D, calcium, phosphorus, and alkaline phosphatase, in perimenopausal women presenting with musculoskeletal symptoms. Early identification and timely management of these abnormalities may help prevent disease progression, improve bone health, and reduce the risk of future fractures and disability.

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