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Original Research Article

Study of Serum Alkaline Phosphatase in Bone Metabolic Disorders: A Retrospective Overview

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Abstract

Background: Disorders of the skeleton involve derangements of remodeling, mineralization, and the structural integrity of the skeleton. Serum alkaline phosphatase (ALP) is one of the main laboratory indicators reflecting the activity of the osteoblasts and the synthesis of bone. It is imperative to distinguish the variations of ALP in the various biochemical bone disorders to facilitate the proper diagnosis and to attend to the clinical problem.

Objectives: To evaluate serum ALP levels in various bone metabolic disorders and determine their diagnostic significance in differentiating high-turnover and low-turnover bone diseases.

Methods: A retrospective observational study involving a total of 100 patient records diagnosed between January 2023 and December 2024 was conducted at Shree Narayan Medical College. Details gathered were age, gender, diagnoses, ALP levels and other biochemical measurements relevant including calcium, phosphate, Vitamin D and PTH. For statistical evaluation, descriptive statistics for all variables were used, while ALP for different disorders was compared using ANOVA, and correlation of ALP with Vitamin D and PTH was determined using Pearson correlation.

Results: In a study sample of 100 participants, the average age was 48.6 ± 12.4 years, and the participants were predominantly female (60%) rather than male (40%). The most prevalent of the conditions were osteoporosis (35%), and then there was osteomalacia, or vitamin D deficiency (30%), as well as hyperparathyroidism (20%) and Paget's disease (10%), and bone metastasis (5%); of the sample most, if not all, of the bone diseases were present, and osteoporosis was the most common. The serum levels of ALP differed greatly from one another, raising 110 ± 25 IU/L in osteoporosis, 185 ± 40 IU/L in osteomalacia, 240 ± 55 IU/L hyperparathyroidism, 380 ± 90 IU/L Paget and 310 ± 70 IU/L in bone metastasis. 72% of the sample showed an increase in ALP. ALP showed a statistical difference in the diagnostic groups ($p < 0.001$) using an ANOVA statistical test. The positive correlation associated with ALP and the PTH was ($r = 0.62$), and there was a negative correlation showing ALP with vitamin D levels ($r = -0.51$).

Conclusion: ALP is a clinically relevant biomarker for bone metabolic abnormalities due to its sensitivity and low cost. It is diagnostically relevant due to its significant elevation in conditions of high turnover such as Paget's disease, hyperparathyroidism, osteomalacia, and bone metastasis. For precise evaluation, ALP should be interpreted in conjunction with calcium, phosphate, Vitamin D, and PTH. More prospective studies involving the analysis of ALP isoenzymes should be conducted.

Keywords: Serum Alkaline Phosphatase, Bone Metabolic Disorders, Osteomalacia, Hyperparathyroidism, Paget's Disease, Osteoporosis, Bone Turnover, Vitamin D, PTH, Retrospective Study.

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Introduction

Bone diseases are on the rise. While this is largely a socio-economic concern, the impact is felt the most in regions where bone diseases can be more easily avoided through preventative measures, appropriate nutrition, and earlier diagnostics. These disorders are diverse and include diseases like osteoporosis, osteomalacia, rickets, Paget's disease, hyperparathyroidism, and bone malignancies. These disorders, while having different diseases, share the same economic pattern [1]. They are characterized by having disruptions in bone remodeling, insufficient repair, and various forms of calcium-phosphate metabolism imbalances, or hormonal diseases [2]. There are many disorders, and the impact of these disorders is significant. They are characterized by the subsequent morbidity of the population, loss of physical function, and loss of life overall. These disorders also lead to

complications that are severe [3]. These include fragility fractures, skeletal deformities, chronic musculoskeletal pain, and long-term disabilities. The socio-economic impact is also considerable. The loss of productivity overall is significant, and the loss of mobility is profound. Ultimately, the socio-economic impact also manifests as permanent loss to society [4]. The earlier bone disorders are identified, the better the prognosis, cycle of supportive therapy, and the overview of clinical routine management can be modified [5]. In this regard, biochemical indicators of bone turnover, or more simply, bone turnover are some of the most blood tests, and turned out to be very important to us. Among them, alkaline phosphate is a sanguinary marker offering good clinical practice due to the fact that it is directly associated with osteoblastic activity and the process of bone formation.

The most common locations of ALP include the liver, intestines, and placenta, but the bone isoenzyme, expressed by osteoblasts, is integral to the hydrolysis of phosphate esters and subsequent supplementation of phosphates needed to form hydroxyapatite, and is therefore important to skeletal mineralization. Increased osteoblastic activity results in raised levels of ALP, and is thus a marker of conditions associated with increased bone turnover. ALP in serum is inexpensive, easy to measure, and reproducible; it is of high availability and thus is a baseline test in the investigation of bone diseases, and particularly in economically developing countries [6]. ALP is useful in the differentiation of high-turnover versus low-turnover bone diseases. For instance, in Paget's disease of bone, which is associated with excessive bone turnover and high remodeling, ALP is markedly raised, and so is the case in hyperparathyroidism which involves excessive parathyroid hormone secretion that promotes bone resorption and subsequently rapid bone formation [7]. On the other hand, osteoporosis, typically of the postmenopausal and aging type, is a low-turnover disease that is associated with ALP levels remaining in the normal and low range, or only mildly elevated levels. Secondary causes, however, such as vitamin D deficiency, may be involved. ALP is also mildly raised in osteomalacia and rickets, and is a result of excess osteoblastic activity that is a compensatory response to a mineralization defect [8].

Furthermore, elevated alkaline phosphatase (ALP) level can be an important marker in malignancy-related bone disorders such as bone metastasis or multiple myeloma, where there are abnormal osteoblastic or osteolytic changes affecting the microarchitecture of the bone. Although ALP is readily available and is well-known as a marker in bone disorders, there are discrepancies in the clinical usage of ALP in clinical diagnostic practice due to the insufficient documentation of ALP levels and its clinical assortment in various regional and institutional healthcare settings and disparities in bone metabolic disorders in India [9]. Moreover, ALP values are subject to variation due to demographic factors such as age, sex, malnutrition, and comorbidities, and such factors need to be fully understood in order to define clinical cut-off levels for the values of ALP which are reasonable for the local population. Due to the complexity and heterogeneity of the bone metabolic disorders, especially in the tertiary care centers, there is need to conduct an analysis of real-life data of ALP in specific low bone mass conditions and how this affects patient care [10]. Data from ALP in retrospective studies based in hospitals is valuable as it allows the use of clinical documents available to discover patterns and relationships which may be missed in other study designs [11].

In view of this information, the current study, which looks at the level of serum ALP in patients with bone metabolic diseases, was conducted during our traineeship at Shree Narayan Medical College, a tertiary care centre with a varied patient demographic. Analyzing data from 100 patients, the study attempts to investigate the ALP differentials in a more detailed manner across different categories of the diseases, attempt to ALP and surrounding demographic parameters, and attempt to determine the significance of ALP in terms of a biomarker for differentiating the types of diseases. We initiated the study to fill the existing gap of data and to provide the regional clinical practice with a better grasp of the ALP parameters, and to improve the diagnostic and surveillance capabilities of the metabolic bone disease care practitioners.

Furthermore, the study seeks to demonstrate the ALP trends to help more economically and more progressively in the screening, diagnosis, and detailed management of bone metabolic diseases. This is especially pertinent when sophisticated imaging is not available, or certain biochemical techniques are not in a place for a workplace.

In the end, the research is intended to enhance clinical decision support by emphasizing the importance of ALP within the clinical context, advocating for its concurrent use with other calciotropic biochemical entities, including serum calcium, phosphate, vitamin D, and parathyroid hormone levels. The study findings intend to more firmly establish the incorporation of biochemical markers during the assessment of clinical bone health and improve the comprehensive and evidence-based management of bone metabolic disorders within the Indian healthcare system.

Methods

Study Design: In this investigation, the researchers employed a retrospective observational study design, employing systematic review and review of previously recorded patient data. This design was chosen because of the its ability to evaluate a wide variety of clinical laboratory parameters while spotting a specific pattern across a distinct set of diagnoses without having to perform additional procedures on the patient. Retrospective designs are especially useful in studies that involve biochemical markers such as serum alkaline phosphatase (ALP), since they enable the assessment of the actual clinical trends that are captured in the hospital record system.

Study Setting: The Shree Narayan Medical College triage center the department of Biography and the department of Orthopaedics formed alliances for conducting the research. There is a great variety of clientele and patients that the center attends to. Biochemical test and ALP enzyme levels testing in the clinical lab of the center are consistent, reliable, and adhere to predetermined testing protocols.

Study Duration: Data were collected from January 2023 to December 2024 to allow time to gather enough data that consist of different types of bone metabolic disorders to establish a sufficient data set that can be used for in-depth analysis.

Sample Size: Out of the records that were initially retrieved, 100 records that fit the criteria of the study were retrieved for the final analysis. The sample size was considered sufficient in order to facilitate the carrying out of the analysis, as well as, to compare among the different diagnoses of the population.

Inclusion Criteria

- Diagnosed with a confirmed bone metabolic disorder such as osteoporosis, osteomalacia, rickets, Paget's disease, hyperparathyroidism, or bone metastasis.
- Availability of complete biochemical laboratory reports, including serum ALP levels and relevant clinical information.

Exclusion Criteria

- Individuals with known liver diseases or hepatobiliary abnormalities, as these conditions can elevate ALP independently of bone pathology.
- Patient records with incomplete biochemical or clinical data, which would compromise the accuracy of analysis.

Data Collection Procedure: Data extraction was carried out using a structured proforma specifically designed for this study. The information retrieved from medical records included demographic details such as age and gender, clinical diagnosis indicating the type of bone metabolic disorder, and biochemical parameters such as serum ALP levels along with calcium, phosphate, and Vitamin D levels whenever available. All collected data were thoroughly anonymized to maintain patient confidentiality and ensure ethical handling of medical information.

Statistical Analysis: Statistical data from the study were processed using statistical analysis software. The results from descriptive statistical analyses such as mean, standard deviation, and percentage distributions were summarized as demographics, and as findings from biochemical tests. Comparison of ALP levels with different diagnoses was done using one-way ANOVA, or independent t-test, depending on how many groups were present. ALP levels were then correlated with other biochemical parameters using Pearson correlation coefficients. All statistical analyses were two-tailed, and significance was accepted at the 0.05 level.

Results

Table 1: Demographic Characteristics of Study Participants (N = 100)

Parameter	Findings
Total Participants	100
Mean Age (years)	48.6 ± 12.4
Gender Distribution	Females: 60% (n=60) Males: 40% (n=40)

Analysis of this demographic shows that the participants of this study were largely middle aged, as the average age across the cohort was around 49. The higher ratio of females, suggest that the condition studied, disorder of bone metabolism, is more prevalent, probably due to the presence of certain hormonal factors such as postmenopausal estrogen deficiency whicf has been shown to hasten the process of bone turnover. The differences in gender distribution may also explain why further screening and preventive measures are warranted in the female population, as they are more vulnerable to developing osteoporosis and other disorders of metabolic bone disease.

Table 2: Distribution of Bone Metabolic Disorders

Bone Disorder	Frequency (%)
Osteoporosis	35%
Osteomalacia / Vitamin D Deficiency	30%
Hyperparathyroidism	20%
Paget's Disease	10%
Bone Metastasis	5%

According to the data, most of the sample cases, which are 65% in all, have either Osteoporosis, osteomalacia, or a Vitamin D deficiency.

This shows how common the lower bone health is, as the sample cases have common hormonal imbalance or nutritional deficiencies and lead a sedentary lifestyle. There was a slightly smaller proportion of cases with Hyperparathyroidism and Paget's disease, but it was still of clinical significance, showing High turnover bone disorders.

Although bone metastasis cases are the least common, they are still significant and clinically important, as they lead to complications and cause altered patterns of bone remodeling to a high degree.

Table 3: Mean Serum ALP Levels across Disorders

Disorder	Mean ALP (IU/L)	Interpretation
Osteoporosis	110 ± 25	Mild elevation/normal
Osteomalacia	185 ± 40	Moderate elevation
Hyperparathyroidism	240 ± 55	Significantly elevated
Paget's Disease	380 ± 90	Markedly elevated
Bone Metastasis	310 ± 70	High elevation

There were clear differences across diagnostic categories in the level of serum ALP and this demonstrated the degree to which the enzyme is sensitive to underlying bone turnover. Among the several conditions studied, Paget's disease had the highest ALP which is expected given the unregulated and excessive bone remodeling that occurs in this disease. Also indicative of high osteoblastic activity were the significantly increased ALP levels found in hyperparathyroidism and bone metastasis. Osteomalacia had a moderate increase in levels attributable to the ineffectual mineralization and osteoporosis had a slight increase in levels.

ALP was statistically significantly different according to ANOVA, confirming that ALP is a clinically useful biomarker.

Table 4: Correlation of ALP with Biochemical Parameters

Parameter	Correlation (r)	Interpretation
PTH	+0.62	Positive correlation
Vitamin D	–0.51	Negative correlation
Gender	Not significant	—

The relationships described show one explaining the other. Hyperparathyroidism elevates ALP levels, and elevated levels of ALP indicate that higher levels of bone turnover are present. Enzyme Vitamin D deficiency and ALP deficiency do show a moderate, negative, and Vitamin D deficiency, which leads to impaired mineralization and compensatory increases in metabolic activity and Vitamin D deficiency.

Impaired Vitamin D activity shows a vitamin D deficiency. Here the metabolic problems show the Vitamin D deficiency and the vitamin D deficiency more than sex as a vitamin D deficiency and the vitamin D deficiency indicating increased activity levels show robust impaired metabolism.

Discussion

Interpretation of Serum ALP Patterns across Disorders: The results obtained from this study show how serum alkaline phosphatase (ALP) levels differentiate among different bone metabolic disorders and show how they reflect different disorders' pathophysiologies.

The significantly increased ALP levels (mean 380 ± 90 IU/L) seen in Paget's disease are in line with the severe osteoclastic and osteoblastic activity seen in this disorder. ALP levels are reported to increase by 10x in active Paget's Disease which was reported by Siris et al. ALP was the most sensitive and specific biochemical indicator of disease activity in Paget's Disease and was greatly supported by the data from the participants in this study. In relation to this, hyperparathyroidism also displayed significantly increased ALP levels (240 ±

55 IU/L) which also reflects the increased rate of bone turnover that occurs due to the elevated levels of parathyroid hormone (PTH). This also agrees with the findings of Silverberg and Bilezikian, from whom the results showed that ALP levels were highly correlated with the severity of primary hyperparathyroidism which they presented. The increase in ALP levels due to the hormonal changes and the strong correlation between the PTH levels and the ALP levels (r = 0.62) show the effect it had on the bone remodeling.

Bone-alkaline phosphatase (BALP) levels were noted to suffer an increment due to bone-alkaline phosphatase (BALP) levels suffer an increment due to and Vitamin D deficiency and osteomalacia. Having increment levels of ALP (185 ± 40 U/L) in contrast to the normal U/L range of osteoblastic activity arises to balance the compensation for substandard mineralization. [13] and [14] studies reported ALP to be osteomalacia's earliest and most reliable biomarkers, and that remains analytically true, especially among the nutritionally deprived. This affirms our outcomes given the surging levels of Vitamin D deficiency estimates within the Indian subcontinent. ALP levels in osteoporotic entities of the bone were 110 ± 25 U/L; therefore, the condition refers to a low-turnover bone disease except in a few rare secondary incidences. ALP values were described to be normal in primary osteoporosis by a study of the [15]. The results corroborate ALP's limited diagnosis of isolated osteoporosis, but its predominately placid role in differentiating osteoporosis from osteomalacia is highly regarded.

Correlation of ALP with Other Biochemical Parameters: The correlation analysis offers valuable perspectives on metabolic interplay. The PTH correlation with ALP changes significantly based on clinical context, owing to the possibility that increased PTH levels might promote osteoblast activity, leading to increased ALP production. The works of Minisola et al. and others have described the PTH-ALP hypothesis and have suggested ALP elevation as an adjunctive biomarker in the clinical assessment of hyperparathyroid bone disease. Our findings support the hypothesis.

The important correlation of ALP and Vitamin D, which is also negative (r = –0.51) is an interesting observation. The depression of Vitamin D status is associated with reduced bone mineralization which leads to an increased rate of bone turnover with a consequent increase in ALP. The observation is as expected in the field of metabolic bone and is consistent with a multi-centric study from India that described ALP as one of the major biochemical abnormalities in patients with severe Deficiency of Vitamin D. The study has shown metabolic and clinical significance as supported by the biological plausible correlation.

Comparison with Existing Research: Patterns exhibited in this study align closely with distributions recorded in the preceding studies. The impact recorded in Indian journals of Endocrinology and Metabolism illustrating postmenopausal osteoporosis and Vitamin D deficiency with osteoporosis (vitamin D deficiency) in 30% of cases, and the other Vitamin D deficiency widespread osteoporosis 35% were closely mirrored and validated. The findings of Coleman, and others, who constructioned a prognostic indicator, ALP, for skeletal metastasis and bone destruction, tumorated, were advanced, and the studies were in overall agreement with ALP. ALP is universally accepted. The variations of ALP in the other studies, and the studies in ours were in complete agreement. This suggests the factors impacting the biochemical functioning of ALP in cases of bone metabolic diseases are demographic and ethnically heterogeneous.

Strengths and Limitations: Access to actual clinical data and understanding clinical metrics across various bone conditions differs due to the study being based on the tertiary-care highlights the merits of this study. The 100 average patients make up a number large enough to do some meaningful comparative statistics to facilitate comparisons across the disorder groups. However, it is a weakness of the study that due to the retrospective nature of the design, complete biochemical profiles were not obtained for all patients. This study is, however, is missing the ALP isoenzyme fractionation. This is a weakness of the study since not separating bone fALP and hepatic ALP would have improved the diagnosis. The absence of the imaging reports is another weakness of the study. This is a weakness of the study and its implications could have been paired for the biochemical findings.

Clinical Implications: This study corroborates the usefulness of ALP as a low-cost and easily available biomarker for the initial assessment and for monitoring the progression of diseases of abnormal bone metabolism. Although ALP aboard is non-diagnostic, the addition of Vitamin D, calcium, phosphate and PTH has a much higher diagnostic accuracy. Clinicians must, however, exercise caution, as the extreme elevations in ALP are indicative of, and should signal the clinician to consider, a high turnover bone disorder such as Paget’s disease or hyperparathyroidism to initiate further testing and appropriate intervention.

Conclusion

This retrospective analysis emphasizes how useful serum alkaline phosphatase (ALP) can be as a reliable biochemical marker in clinically assessing bone metabolic disorders. Out of Shree Narayan Medical College's 100 patient files, ALP serum

levels and their corresponding bone conditions were isolated, showcasing how ALP serum levels can be used to reflect changes in numerous pathophysiological mechanisms. ALP levels are extremely sensitive towards high-turnover bone disorders, as demonstrated by the extreme levels of ALP in Paget's disease, hyperparathyroidism, osteomalacia, and bone metastasis. On the other hand, osteoporosis patients displayed ALP levels that were bland (mild / normal), confirming that ALP levels are left uninformative in regards to low-turnover skeletal conditions. Significant correlation between ALP and Vitamin D and PTH levels was also evident in the study. PTH and ALP's positive correlation, alongside the Vitamin D and ALP inverse correlation, are known well enough that their correlation strengthens the logic behind ALP as a laboratory tool. Given the conditions outlined, the use of ALP levels as a primary contact laboratory marker to clinically guide physicians towards the right clinical diagnosis (especially when advanced imaging and specialized laboratory tests are unfeasible) can definitely be a value in economically challenged settings.

In summary, the study demonstrates that serum ALP gives a reasonable, reliable, and affordable means of detecting metabolic bone disturbances, as well as assessing the levels of disease activity in a manner that adds clinical value and aids clinical decision-making. There is no question that future studies should be more extensive given problems in the previous studies like design and missing differentiation of ALP isoenzymes. If future studies integrate ALP isoenzymes to correct the under specification in the ALP variable, diagnoses would greatly improve along with the understanding of metabolic diseases of bone from the integration of ALP isoenzymes, radiographs and more complete blood tests.

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