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Estimation of **T** scores with **H**ologic using **N**at**I**ve vs. **C**aucasian data in Indi**A**ns (**ETHNICA**): a single center retrospective study

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Abstract

Background The Dual-energy X-ray absorptiometry (DXA) scan is considered the current gold standard for the estimation of bone mineral density (BMD). Normative BMD data for the generation of T scores is based on data pertaining to young Caucasian white women from the NHANES-III study. However, there have been reports of significant ethnic variations in the normal BMD values, which could under/over-diagnose osteoporosis. The Indian Council of Medical Research (ICMR) has given the normative BMD data for Indians. Our study compares machine-generated T-scores (T_{std}) based on Caucasian BMD reference data with calculated T-scores based on ICMR reference data (T_{ICMR}).

Methods **ETHNICA** was a retrospective study involving 1144 individuals who underwent DXA study (*Hologic*®) at our centre. 835 females and 309 males aged between 18 and 95 were included. A total of 3420 BMD values at bilateral hips and L1-L4 levels of spine were analysed. The age distribution differed from that of the NHANES-III and ICMR reference dataset, which primarily includes younger individuals (20–29 years) as it was done to standardize T score. Gender-specific ICMR BMD and standard deviation (SD) for each site were used to calculate T_{ICMR}. This was compared with *Hologic*-generated T_{std}, and the differences were analysed.

Results The prevalence of osteoporosis was significantly lower using ICMR data compared to NHANES-III data, with a greater reduction seen in males (16.8 to 7.1%) than in females (26.6 to 18%). Similarly, a larger increase in individuals classified with normal BMD was seen in males (59.5 to 76.1%) compared to females (41.2 to 59.6%).

Conclusion We conclude that if we use NHANES-III BMD reference data, there is a significant overdiagnosis of osteoporosis and osteopenia in India. We recommend the adoption of representative regional reference standards for the diagnosis.

Keywords Osteoporosis, NHANES-III, DXA study, Bone mineral density, ETHNICA

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Introduction

Osteoporosis is one of the most common bone diseases. In Indian women, the osteoporosis prevalence ranged between 8 and 62% in various studies [1]. Low bone mineral density(BMD), combined with the reduction of osseous tissue, predisposes individuals to fragility and increases the fracture risk [2]. Around 17.1% of apparently healthy women above 50 years of age were found to have vertebral fractures [3]. After the first introduction of single photon absorptiometry(SPA) in 1963, several developments led to the new age DXA scan, which is now considered the best modality for the estimation of BMD and diagnosis of osteoporosis [4]. T-scores are standard deviations(SD) derived based on the individual's BMD compared against the reference standards. Currently, the data from the USA-based NHANES-III study is the basis for this reference [5]. Comparative studies have shown that the BMD of the healthy Indian population is significantly lower than the NHANES-III reference standard [6, 7]. Therefore, an important question arises as to whether we should be using ethnicity-specific BMD reference data to diagnose osteoporosis. In this study, we aim to determine the impact of using indigenous normative data for the estimation of osteoporosis in the Indian population.

Methods

ETHNICA (**E**stimation of **T** scores with **H**ologic using **N**at**I**ve vs. **C**aucasian data in Indi**A**ns) was a retrospective study done in our center in Chennai, India. Our study aims to assess the impact of using Indian Council of Medical Research (ICMR)-based bone mineral density (BMD) data compared to the Caucasian-derived NHANES-III reference in evaluating T-scores in Indian population, focusing on the implications for the diagnosis and classification of osteoporosis. The institutional ethics committee approved the study. Both males and females aged 18–95 years who underwent DXA scans were included in the study. Patients underwent DXA as part of screening for osteoporosis in at-risk populations (e.g., postmenopausal women, elderly individuals, individuals with low BMI) and for evaluation of bone health due to specific clinical indications (e.g., suspected osteoporosis, history of fragility fractures, chronic glucocorticoid use). Eligible patients had complete anthropometric data, including weight, height, and BMI, along with at least one valid BMD measurement at the left hip, right hip, or lumbar spine.

Exclusion criteria included patients with secondary causes of osteoporosis, such as diagnosed metabolic bone diseases (e.g., Paget's disease), known endocrinopathies affecting bone metabolism (e.g., hyperparathyroidism, Cushing's syndrome), or chronic kidney disease stages 4–5. Patients with a history of prior treatment affecting bone density, including bisphosphonates, denosumab, teriparatide, or hormone replacement therapy, were excluded, as were those with fractures resulting from high-energy trauma or conditions unrelated to osteoporosis. Additionally, patients with incomplete data, including missing BMD values at all three sites(L1-L4 spine, right and left hip) or insufficient demographic or anthropometric information, were excluded from the study. A total of 1144 subjects who underwent DXA scans over six months (February 2023 to July 2023) were recruited after applying the inclusion and exclusion criteria.

The study population included 835 females and 309 males between the ages of 18 to 95 years. The age distribution differed from that of the NHANES-III and ICMR reference dataset, which primarily includes younger individuals (20–29 years) as it was done to standardize T score. The BMD measurements were performed using a single Hologic Discovery Wi DXA system. The machine was calibrated daily using a phantom provided by the manufacturer. Assessments were conducted in the standard operating mode. Bone area demarcation was performed using the system's automated protocol, with manual adjustments to the region of interest as necessary to correct errors such as misalignment or artifacts. The weight was recorded using a standard electronic weighing scale and it was measured in kilograms (Kg). The height was measured in centimeters (cm) using a stadiometer. Body mass index (BMI) was measured in Kg/m^2 and was calculated using the formula: weight in Kg divided by height in meters squared. Daily quality control (QC) of the Hologic machine was done using the manufacturer-provided phantom, and the machine was calibrated. The BMD examination of the study participants was done only if the value of the phantom was within the normal range. BMD was measured in g/cm2 at three sites [left and right hip (total proximal femoral BMD), L1-L4 level of spine]. After excluding 12 missing data points due to incomplete patient records, a total of 3420 BMD values were available for analysis.

Participants with a T-score between −1 and +1 were classified as normal. The participants whose T scores ranged between −1 and −2.5 were classified as osteopenic, and those with a T score ≤ -2.5 were considered osteoporotic. The T scores generated by hologic using the hologic database (HD) were denoted by T_{std}. As per the Indian Council of Medical Research database (ICMRD), in the healthy Indian population, the mean BMD ± SD (gm/cm2) at the hip for males was 0.988 ± 0.131, while it was 0.901 ± 0.111 for females. Similarly, at the level of the spine, the mean BMD ± SD (gm/cm2) for males was 0.976 ± 0.105, and it was 0.954 ± 0.095 for females [6]. This site and gender-specific ICMR reference BMD and SD data were used to calculate T_{ICMR} using the formula:

T score = (BMD subject - BMD reference)/ SD reference, in which BMD subject is the BMD measured by

Table 1 Characteristics of the study population at baseline

Characteristics (*n* = 1,144)	Mean ± SD	Range
Age(years)	57.50 ± 12.11	18–95
Gender		
Males	309(27%)	
Females	835(73%)	
Height (cm)	157.51 ± 9.29	132.5–189.0
Weight (kg)	66.54 ± 13.56	25.0-152.40
Body mass index(BMI)	26.79 ± 4.82	11.89–49.24

Hologic. BMD reference and SD reference were based on ICMRD [8]. The T_{std} and T_{ICMR} were then compared using statistical analysis, and *P*-values were measured to look for significant differences. Further analysis was done with gender-specific and BMI-specific variables.

Statistical analysis

Descriptive statistics were presented with frequency (percentage) and Mean (SD) for the categorical and continuous factors, respectively. The normality of the data was checked by using the Shapiro-Wilk test. Student's t-test/Mann Whitney U test was used to determine the significant difference in mean value between two independent groups. ANOVA/Kruskal Wallis test was used to determine the significant difference between locations. Chi-square/Fisher's exact test was used to determine the association between two independent categorical factors. Spearman rank order correlation was used to determine the significant relationship between two independent factors. A *P*-value of less than 0.05 was considered statistically significant. The statistical agreement between the HD and ICMRD for the classification of osteoporosis and osteopenia was assessed using the weighted kappa score which was then categorised based on Koch and Landis classification. Bland-Altman plot was used to assess the level of agreement between T scores calculated with the two databases. All statistical analyses were done using SPSS software. (IBM, 28.0)

Table 2 Classification of study subjects based on T_{std} and T_{ICMR}

Classification based on Tstd↓	Classification based on T_{ICMR}→		
	Normal, (*n* = 733)	**Osteopenia, (*n* = 239)**	**Osteoporosis, (*n* = 172)**
Normal, (n = 528)	523	2	3
Osteopenia, (n = 342)	209	128	5
Osteoporosis, (n = 274)	1	109	164

Results

Of the 1144 patients who underwent DXA study in our centre, 835 were females and 309 were males. The study population had a mean age of 57.50 ± 12.11. The mean BMI was 26.79 ± 4.82. (Patient characteristics are mentioned in detail in Table 1)

Advancing age and being underweight were associated with lower T scores in both groups. T_{ICMR} was significantly higher than T_{std} at all sites (left hip, right hip and spine) and across all groups (normal, osteopenia and osteoporosis) *(P-value < 0.001)*. The highest difference between T_{std} and T_{ICMR} was noted at the level of the spine for the normal population(-1.0;*P-value < 0.001)*(Fig. 1*)*.

205 patients who were classified to have abnormally low BMD (T-score< -1.0) as per T_{std} were reclassified as normal according to T_{ICMR} (Table 2).

37.22% of the osteoporotic population by T_{std} were classified into either osteopenia or normal under the T_{ICMR}. *(*Fig. 2*)* A total of 999 BMD values came under low BMD as per T_{std}, while it reduced to 681 according

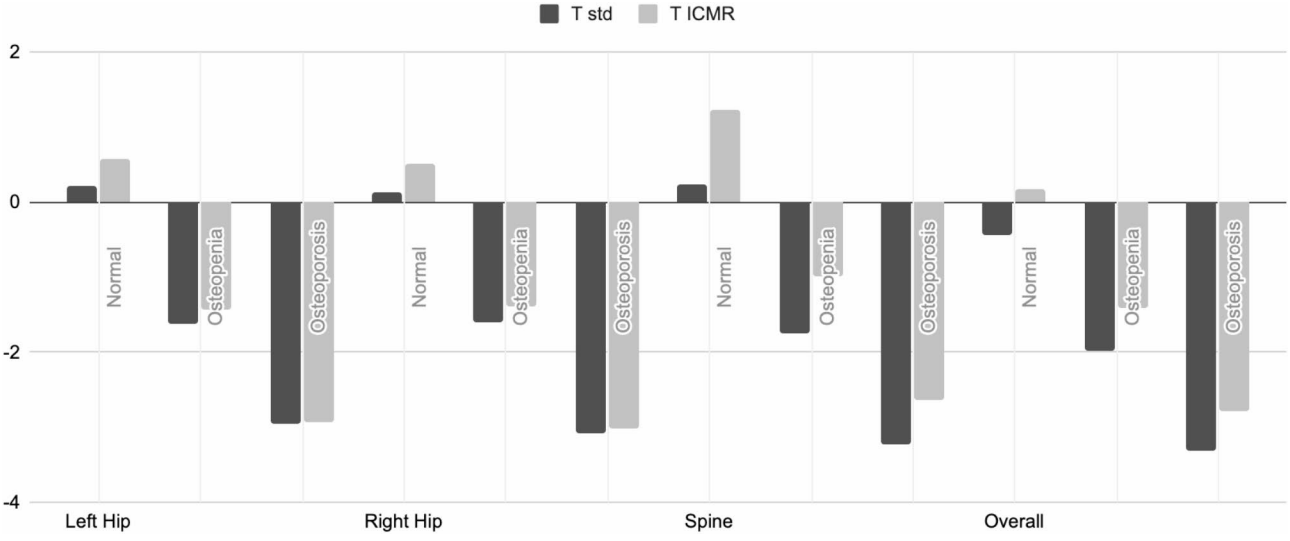

Fig. 1 Comparison between mean Tstd and T_{ICMR} scores across normal, osteopenic, and osteoporotic populations at individual sites (left hip, right hip, lumbar spine) and their overall levels (lowest of all three sites)

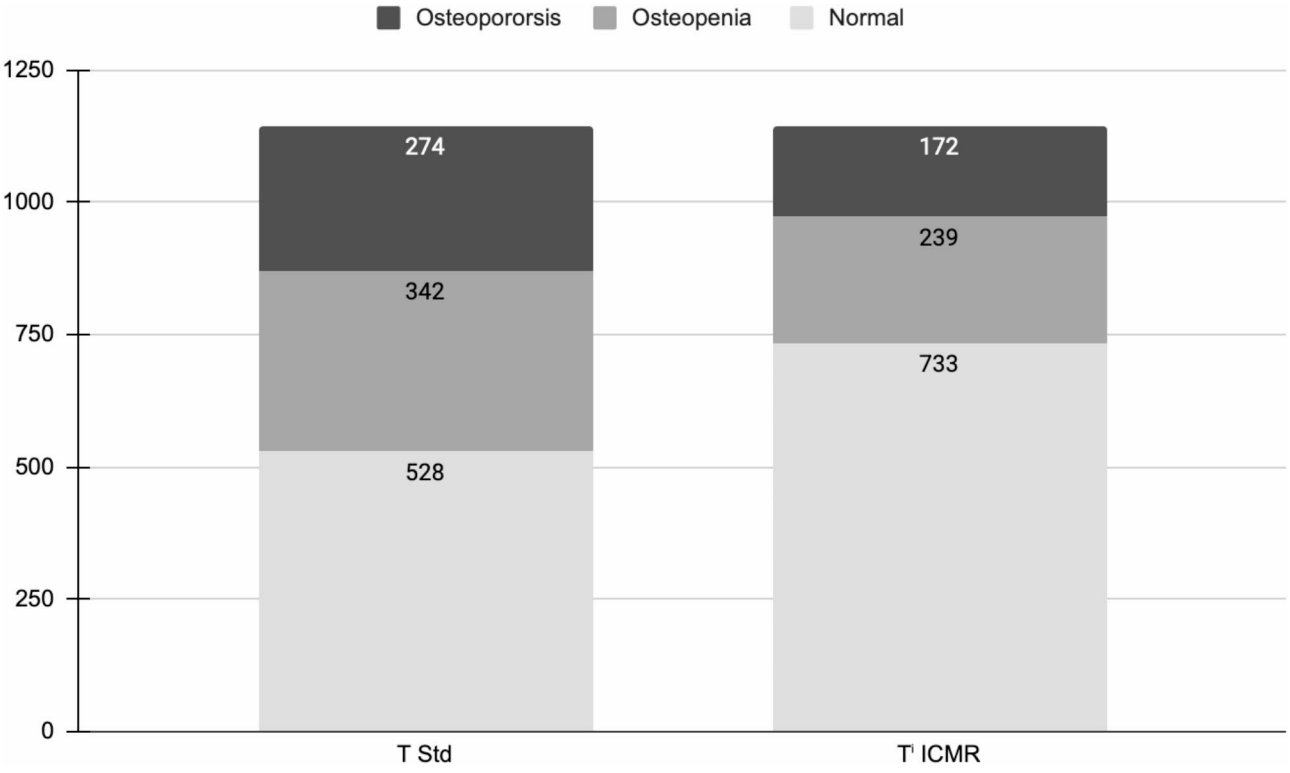

Fig. 2 Bar chart depicting the difference between the number of individuals classified as normal, osteopenic and osteoporotic as per T_{std} and T_{ICMR}

Table 3 Sex-specific prevalence of osteoporosis, osteopenia and normal T scores based on T_{std} and T_{ICMR}

Gender	Classification	Number of participants as per T_{std}(*n*%)	Number of participants as per T_{ICMR}(*n*%)	*P*-value
Males (n = 309)	**Normal**	184 (59.5)	235 (76.1)	< 0.001
	Osteopenia	73 (23.6)	52 (16.8)	
	Osteoporosis	52 (16.8)	22 (7.1)	
Females (n = 835)	**Normal**	344 (41.2)	498 (59.6)	< 0.001
	Osteopenia	269 (32.2)	187 (22.4)	
	Osteoporosis	222 (26.6)	150 (18)	

to T_{ICMR}. The study population showed significantly higher T scores in both males and females as per ICMR reference standards (Males-*P*-value < 0.001, Females-*P*-value < 0.001). Body mass index-specific T scores have followed the same pattern (*P*-value < 0.001).

The prevalence of osteoporosis reduced from 26.6 to 18% in women upon adopting ICMRD. (*P*-value < 0.001). Also, in postmenopausal women, the prevalence of osteoporosis reduced from 32.11 to 22.12% after adopting ICMRD(*P*-value < 0.001). Similar observations were made in women above 65 years of age, wherein the prevalence reduced from 41.5% with T_{std} to 33.13% with T_{ICMR}(*P*-value < 0.001). In parallel with this, osteoporosis in men reduced from 16.8 to 7.1% with the Indian database (*P*-value < 0.01). In men above 70 years of age, 50% of them were diagnosed with osteopenia or osteoporosis with T_{std}, while the percentage reduced to 30.82% with T_{ICMR} (*P*-value < 0.001). More than 15% of men(*P*-value < 0.001) and women(*P*-value < 0.001) separately, who were earlier considered to have low BMD, were reclassified to have normal BMD with the indigenous database (Table 3).

The percentage difference between Tstd and T_{ICMR} is 36.2%. In our study, a kappa value of 0.469 was obtained (*P*-value < 0.001), which denotes moderate agreement between HD and ICMRD for osteoporosis as well as osteopenia according to Koch and Landis classification. Figure 3 shows the Bland-Altman plot displaying level of agreement between Tstd and T_{ICMR}.

Discussion

Our study reveals that there is significant overestimation of osteoporosis and osteopenia in the Indian population if we use NHANES III reference database for normative BMD. The reference data given by ICMR are specific to the Indian population and estimate the T-scores correctly. In line with our findings, some other studies done in India (given below) also showed similar findings. Low BMD, along with altered microstructure, makes individuals with osteoporosis susceptible to fragility fractures. Worldwide, around 9 million fractures are considered to be due to osteoporosis [9]. India alone experiences more

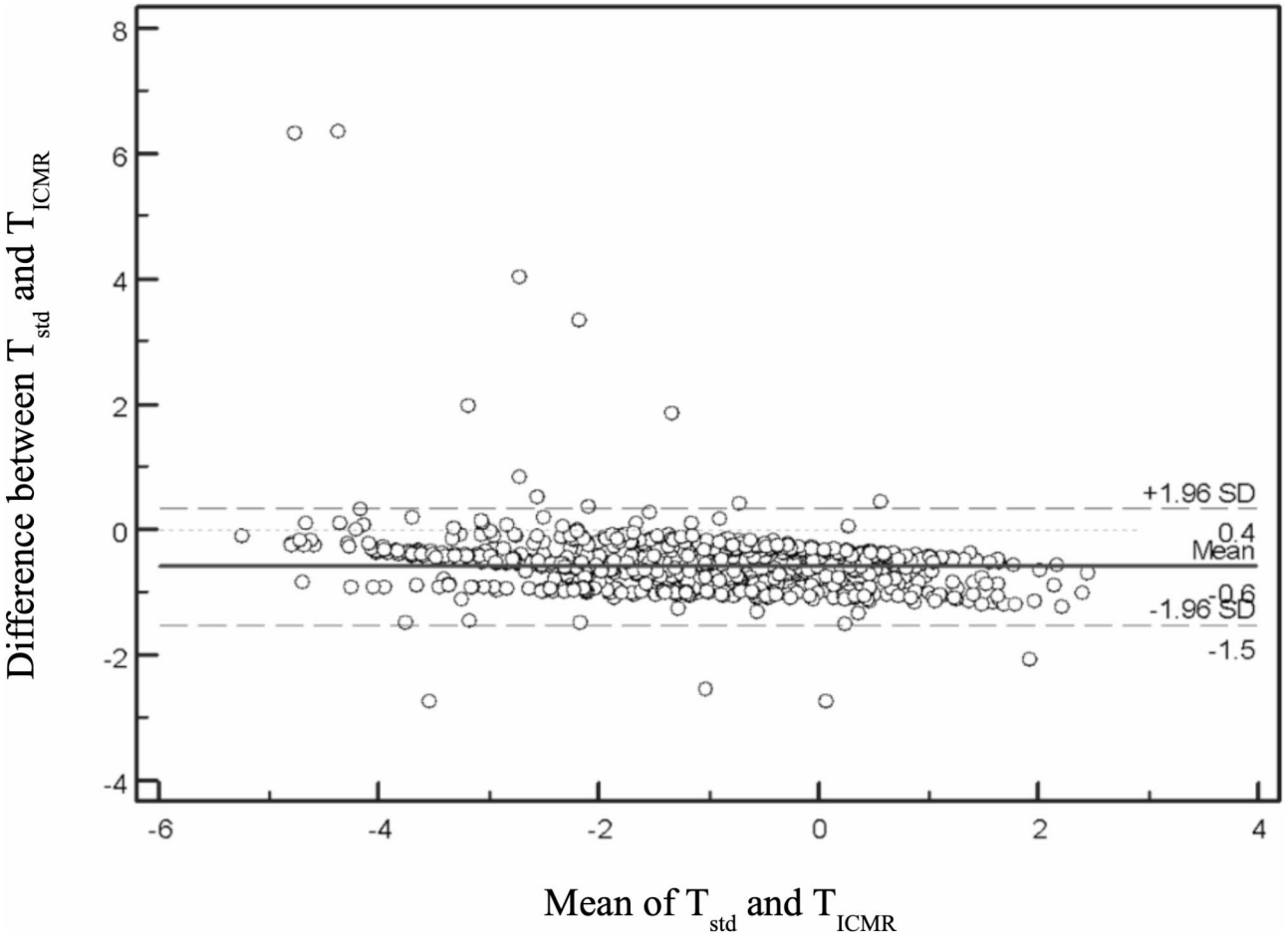

Fig. 3 The Bland-Altman plot displaying the level of agreement between Tstd and T_{ICMR}

than 2,50,000 hip fractures every year [8]. The problem is only getting bigger with the rise in the geriatric population, and hence, correct diagnosis and early treatment of osteoporosis is important to prevent fractures.

Any individual with a T score less than 2.5SD is osteoporotic. Also, authors often use the 'gradient of risk' for the prognostication of individuals. This gradient of risk for hip fracture is 2.6, which indicates that the risk of hip fracture increases 2.6 times for every SD reduction in hip BMD [10]. A study by Wang J et al. in China showed that the spine T score of -3.75 for Chinese women was equivalent to -2.44 for Italian women indicating the overestimated diagnosis of osteoporosis in Chinese [11]. Such a significant difference in T scores will have a major impact on the diagnosis and prognosis of individuals with osteoporosis, especially when applied to countries with large populations.

NHANES-III data was collected from 39,695 individuals across the USA between 1988 and 1994 [12]. Of this, 246 non-Hispanic white women between ages 20–29 underwent bone densitometry evaluation, and this data was used as a reference for calculating T scores by WHO [10, 12]. BMD is known to be affected by race, ethnicity, bone surface area, vitamin D and K levels, geographic conditions, physical activity and BMI [13]. Contemplating this, certain authors have questioned the relevance of the Caucasian reference range in other populations. When the NHANES III reference database was applied to Blacks and Mexican Americans in the USA, broad variation in the prevalence of osteoporosis was observed, which was minimized when race-specific data was used [14]. Similarly, studies from Denmark and the Middle East noted an overestimation of osteoporosis, while a study from Sweden observed an underestimation of osteoporosis with the NHANES-III reference data [15–17]. These observations are further strengthened by a large study done in 12 nations wherein authors noted that 12–20% of the global variation in standardized BMD could be explained by anthropomorphic variation while 4–10% could be explained by country of origin [18].

In India, population-based reference standards established by ICMR and PGIMER have shown that the mean BMD of the healthy Indian population is significantly lower than the NHANES-III/ *Hologic* reference range [6,

Table 4 Comparison of the prevalence of osteoporosis in Indian population based on Caucasian database vs. Indian database by various authors (Abbreviations:- NA- not available)

S No	Study	Study population (*n*)	Characteristics of the study population	Prevalence based on Caucasian database	Prevalence based on Indian database	Kappa value
1	Balachandran K et al. [20]	316	Above 65 years (46.84% females and 53.16% males)	26.58%	5.06%	κ = 0.389 (P-value < 0.05)
2	Cherian KE, et al. [21]	1956	Post menopausal women	39% (Lumbar spine)	32% (Lumbar spine)	κ = 0·74, (P-value-NA)
3	Our study	1144	835 females, 309 males	23.95%	15.03%	κ = 0.469, (P-value < 0.001)

7, 19]. Our study showed a prevalence of 23.95% of osteoporosis by HD but only 15.03% with the ICMRD. Similar observations were made by Balachandran K et al. and Cherian KE et al. [20, 21]*(*Table 4*)*. All of these studies reiterate the importance of using ethnicity-specific normative data in the estimation of osteoporosis.

The level of agreement between the databases is measured with kappa(κ), where the kappa value is between 0 and 1. The level of agreement is further classified based on Koch and Landis classification as 0-Poor agreement; 0.01-0.20- Slight agreement; 0.21-0.40- Fair agreement; 0.41-0.60-Moderate agreement; 0.61-0.80- Substantial agreement; 0.81-1.00- Almost perfect agreement. In our study, the level of agreement with the kappa value denotes the number of T scores that agree between the two databases. A value of 1 denotes perfect agreement, and − 1 denotes perfect disagreement between the databases. In our study there was "moderate agreement" between the two databases (κ value of 0.469, $P < 0.001$). This indicates that the two reference ranges agree only to some extent. However, the level of difference in estimation of osteoporosis as well as osteopenia was statistically significant and can have significant clinical impact. Hence it cannot be ignored.

A systematic review looking at the global prevalence of osteoporosis showed that Americans (12.4%) have a lower incidence of osteoporosis than Asians (16.7%) and Africans (39.5%) [22]. On the contrary, the age-standardized annual incidence of hip fractures in women shows that the lowest rates of hip fracture (< 200/1,00,000) were found in South Africa, India and China, while moderate (200–300/1,00,000) to high rates (> 300/1,00,000) were found in US and UK respectively [23]. This paradox of low rates of fractures despite the high prevalence of osteoporosis could be related to the complex interplay of many factors, of which over-diagnosis of osteoporosis using Caucasian data may have a major role.

Some authors recommended the usage of NHANES III data as the difference among various nations was not more than approximately 1 SD [10]. However, studies have shown that fracture risk doubles for every 1 SD of BMD below normal [24]. In our study, only 47.9% had low T scores with ICMRD when compared to 66.55% with HD. This indicates that even a small difference in mean BMD across nations can have an amplified impact, and hence, we recommend the use of native BMD data. Also, the International Society of Clinical Densitometry (ISCD) position statement of 2023 recommends the usage of local reference data only for the calculation of Z scores and not T scores [25]. However, since T scores determine the diagnosis and need for treatment, there is a necessity for adopting the regional reference standards. Diagnosing osteoporosis correctly helps in preventing fractures. Overestimation, on the other hand, may lead to unnecessary referrals and treatment, which can all add up to the healthcare burden. Hence, emphasis should be laid upon improving the sensitivity, specificity, and predictive value of DXA as it is central in the management of osteoporosis. Errors in the diagnosis can have far-reaching implications, from affecting the trial design of newer therapeutics for osteoporosis to the morbidity following fracture.

Therefore, based on our observations, we recommend the usage of indigenous reference standards for the diagnosis of osteoporosis. This will streamline the knowledge and resources of the intended population.

Limitations

It is a retrospective study conducted at a single center, which may limit the generalizability of the findings to the broader Indian population and our sample size was 1144 individuals. Another key limitation of our study is the lack of an independent validation dataset. This warrants further validation in larger, multicenter studies. Future research should address these limitations by incorporating larger sample sizes, multicenter collaboration, and prospective data collection to confirm the robustness and clinical relevance of adopting regional reference standards.

Conclusions

We conclude that there is overdiagnosis of osteoporosis and osteopenia in India by using NHANES III as the reference database for BMD. The difference is significant and cannot be ignored. We recommend the adoption of the representative regional reference standards for the diagnosis of osteoporosis. In view of the large and diverse population in the Indian subcontinent, newer studies with greater sample sizes and subgroup analyses of populations reflecting various genetic backgrounds can further improve the diagnostic accuracy of this test. Additionally, from time to time, the reference standards must be revisited and revised to reflect the study population.

Abbreviations

BMD	Bone mineral density
DXA	DXA scan
HD	Hologic database
ICMRD	Indian council of medical research database
QC	Quality control
SD	Standard deviation
T_{std}	T scores determined using the standard database (based on the NHANES III study)
T_{ICMR}	T scores determined using the ICMR database
NHANES III	The Third National Health and Nutritional Examination Study
FRAX	Fracture risk assessment tool

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Author contributions

The study was conceived, designed and substantially revised by NK, SLK. SLK was involved in data acquisition, analysis, drafting of the manuscript and facilitation of the study. DJ was involved in data acquisition and analysis. PKM was involved in analysis and substantial revision of the manuscript. LB was involved in analysis of the data. NK and HK critically reviewed the manuscript. All authors have approved the submitted version of the manuscript and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Data availability

Availability of data and materials: The data supporting the findings of this article is not publicly available. Questions about the data can be directed to the corresponding author.

Declarations

Ethics approval and consent to participate

The Institutional Ethical Committee Bio Medical Research, Apollo Hospitals, Chennai, approved the protocol (AMH-C-S-088/10–23). As all data was anonymously used and this study does not contain protected health information in accordance with the Declaration of Helsinki, the ethics committee approved a waiver of the requirement for informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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