Original Article

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A New Vitamin D Deficiency Cut-Off Value in Basrah, Iraq

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ABSTRACT

Background: Vitamin D deficiency is a common health issue worldwide. Clinical observations have shown that most healthy individuals living in Iraq and the Middle East are vitamin D deficient. This study aimed to establish the true cut-off value for vitamin D deficiency (25(OH)D) in Basrah, Iraq, by analyzing the value at which parathyroid hormone (PTH) begins to rise above its reference range. **Aim**: This study sought to determine the true cut-off value for vitamin D deficiency (25(OH)D) in Basrah, Iraq by analyzing the value at which PTH starts to exceed its reference range. **Methods**: A cross-sectional study was conducted involving 874 apparently healthy subjects from Basrah, Iraq. Serum calcium, creatinine, vitamin D and PTH levels were measured for each participant. Individuals with impaired renal function and primary hyperparathyroidism were excluded from the study. The association between serum 25(OH)D and PTH was examined using multiple logistic regression analysis. The best cut-off value of serum 25(OH)D to predict elevated PTH was determined using receiver operating characteristic (ROC) analysis. **Results**: The mean values of 25(OH)D and PTH were 16.9 ± 14.9 ng/ml and 129.1 ± 110.5 pg/ml, respectively. If the universal cut-off values were applied, 25-hydroxyvitamin D deficiency was identified in 599 subjects (68.5%) and was inversely related to PTH. Only 139 subjects (15.9%) had optimal 25(OH)D levels. Secondary hyperparathyroidism was found in 487 subjects (45.7%). Using ROC analysis, a serum 25(OH)D value of 12.5 ng/ml was identified as the best cut-off point to predict secondary hyperparathyroidism in the population (sensitivity: 88.2%, specificity: 53.6%). The number of subjects classified as vitamin D deficient decreased to 461 (52.7%) when the new cut-off value was applied. **Conclusions**: The cut-off value for vitamin D deficiency needs to be redefined in areas where the disease is unexpectedly prevalent. A single cut-off value cannot be universally applied worldwide due to genetic and environmental variations. The new cut-off value is lower than that used globally. Further studies are required to establish new cut-off values.

Keywords: Vitamin D, 25-hydroxyvitamin D, parathyroid hormone, Iraq.

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INTRODUCTION

Vitamin D deficiency is a significant global health concern.[1] Low levels of vitamin D can lead to serious health consequences, including but not limited to low bone mineral density, fractures, falls, depression, cognitive decline, and autoimmune diseases.[2-6] There is an inverse relationship between vitamin D and parathyroid hormone (PTH) levels. Hypovitaminosis D results in hypocalcemia by affecting the intestinal absorption of calcium, stimulating the parathyroid gland to produce more PTH to maintain normal calcium levels in the blood by increasing calcium release from the bones.[7] This physiological phenomenon has been utilized to use high PTH levels as a surrogate marker of hypovitaminosis D, thereby determining the cut-off value of vitamin D among healthy individuals. 25-hydroxyvitamin D (25(OH)D) is considered the best marker for monitoring vitamin D status, as it reflects vitamin D synthesized from skin exposure to sunlight and dietary intake.[8] The widely used cut-off value in both public and private healthcare settings in Iraq defines vitamin D deficiency as a level below 20 ng/ml, based on recommendations from the Endocrine Society Task Force on vitamin D in the U.S.[9] and a large-scale regional study conducted in the Middle East.[10] The application of current cut-off values for vitamin D levels has resulted in significantly higher prevalence rates, likely overestimating hypovitaminosis D. Two studies conducted in Iraq reported the prevalence of hypovitaminosis D to be 74.5% and 62.5%.[11,12] Other studies from the region have reported even higher prevalence rates (83.6% and 95.3% in Saudi Arabia).[13,14] Clinical observations indicate that a majority of individuals in Iraq and the Middle East labeled as vitamin D deficient appear to be healthy and asymptomatic. It seems that the principle of "one size does not fit all" applies to the definition of vitamin D deficiency definition in different parts of the world, suggesting that the human body's response to vitamin D levels depends on several factors, including ethnicity, skin pigmentation, latitude, environment, and cultural practices. [1,7] Overestimating the true prevalence of hypovitaminosis D has implications for the health system such as unnecessary investigations like DEXA scans and repeated vitamin D level assessments, prescribing unnecessary vitamin D supplements, and ultimately increasing the burden on individuals and the healthcare system in terms of cost and time. This study aims to define the best cut-off value for hypovitaminosis D in Basrah, Iraq, adequate for maintaining bone health, as reflected by a PTH level < 65 pg/ml.

MATERIALS AND METHODS

This cross-sectional study was conducted on 874 apparently healthy subjects aged 18-65 years from both sexes in Basrah, Southern Iraq, between June-August 2019. The minimum required sample size to achieve representative results was calculated at 362, based on the assumption that the population of Basrah at the time of the study was 2,900,000, with a prevalence of hypovitaminosis D extracted from a previous study at 62% [12] and a confidence level of 95%. Patients with a past medical history of primary hyperparathyroidism, an estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73 m², those who had taken vitamin D supplements within the preceding six months, and lactating or pregnant women were excluded. A total of 1,082 participants were initially enrolled in the study. After applying the exclusion criteria, 874 participants were selected for final assessment. The study flow chart during recruitment is shown in (Fig. 1). Verbal informed consent was obtained from all participants. Ethical approval was granted by the Research Ethics Committee at Basrah Health Directorate.

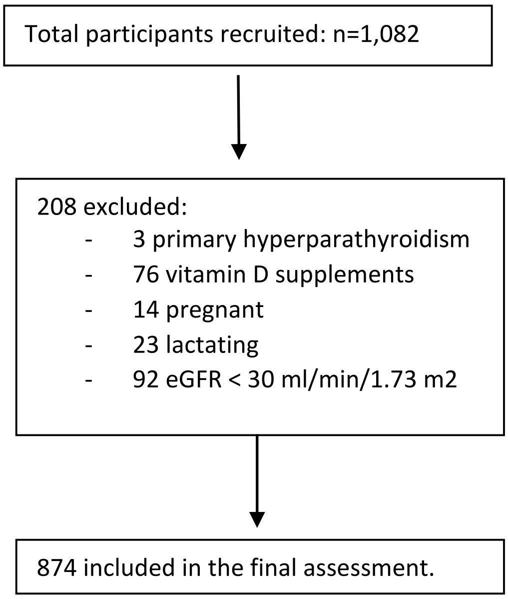

Figure 1: Flow chart of the study.

Blood samples were collected for kidney function tests, serum calcium, serum phosphorus, serum albumin, 25(OH)D levels, and PTH levels. Electrochemiluminescence immunoassay using the Roche Elecsys Cobas e411 analyzer (Roche Diagnostics, GmbH, Mannheim, Germany) was used to measure serum 25(OH)D and PTH levels. All other biochemical tests were measured using a routine chemistry analyzer (Beckman Coulter, Inc., California, USA). Vitamin D status was categorized into three groups: deficiency (<20 ng/ml), insufficiency (20-30 ng/ml), and sufficiency (30-100 ng/ml). Data analysis was performed using IBM SPSS Statistics version 23.0. Continuous variables were expressed as means and standard deviations, while categorical variables were presented as proportions and percentages. The association between serum 25(OH)D and PTH was analyzed using multiple logistic regression. The optimal cut-off value of a given test. PTH cut-off value of 65 pg/ml was used to reflect hyperparathyroidism. The 95% confidence intervals and p-value < 0.05 were used to report the precision and statistical significance of the estimates, respectively.

RESULTS

A total of 874 subjects were included in the study. The mean value for vitamin D was 16.9 ± 14.9 ng/ml, while the mean value for PTH was 129.1 ± 110.5 pg/ml. Vitamin D levels were inversely related to PTH levels. If the current cut-off values for serum vitamin D levels were applied, hypovitaminosis D would be diagnosed in 599 (68.5%) subjects of the current cohort. Similarly, only 139 subjects (15.9%) had optimal 25(OH)D levels (Fig. 1). Secondary hyperparathyroidism was observed in 487 subjects (45.7%). A linear association was observed between PTH and vitamin D levels (Fig. 2).

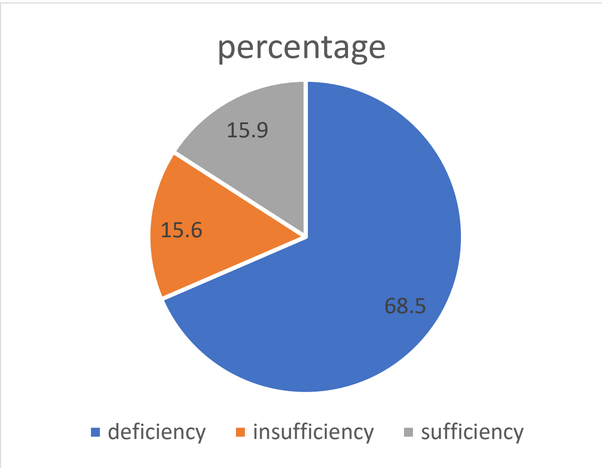

Figure 2: Distribution of participants according to vitamin D status based on the currently used cut-off values: deficiency (<20 ng/ml), insufficiency (20-30 ng/ml), sufficiency (30-100 ng/ml).

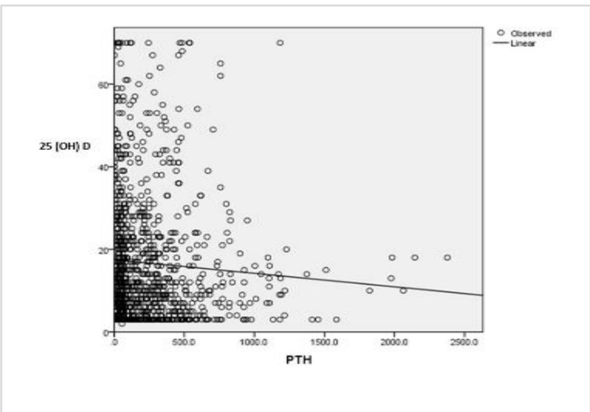

Figure 3: Scatter plot between 25(OH)D and PTH levels.

Using ROC analysis, we identified four possible points on the curve to be considered as the best cut-off values (labeled a, b, c, and d), as shown in Figure 4. The area under the curve (AUC) was 0.743 (0.633-0.854) (p-value < 0.001) (Figure 4). The AUC summarizes the overall performance of the model, with higher AUC values indicating better discrimination. Generally, an AUC > 0.7 indicates excellent discrimination. In our study, the AUC was above 0.7, indicating that it performs better than chance or random selection. To decide on the best cut-off value among the four selected points, the point closest to the upper left corner of the ROC diagram represents the best choice. In our analysis, point **c** was slightly closer to the upper left corner than the other points; however, the sensitivity of point **c** was 58.8%, which can result in missing many true positive cases (see Table 1). On the other hand, point **a** was as close to the upper left corner as the other points and had higher sensitivity and a higher Youden index, calculated as sensitivity + specificity − 1, making point **a** the best choice. Accordingly, the serum 25(OH)D value of 12.5 ng/ml (point **a**) was selected as the optimal cut-off point to predict secondary hyperparathyroidism in the population, with a test sensitivity of 88.2% and test specificity of 53.6%.

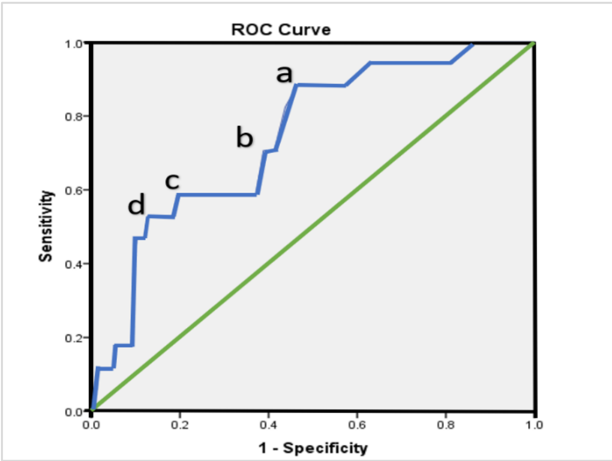

Figure 4: ROC curve to predict the best cut-off value for 25(OH)D.

AUC = 0.743 (0.633-0.854) (p-value < 0.001), Optimal value for vitamin D level = 12.5 ng/ml, Sensitivity =88.2%, Specificity = 53.6%, Positive log likelihood ratio = 1.9, Negative log likelihood ratio = 0.2, **a**: Cut-off value 12.5 ng/ml, **b**: Cut-off value 14.5 ng/ml, **c**: Cut-off value 22.5 ng/ml, **d**: Cut-off value 28.5 ng/ml. If the new cut-off values are applied, the number of subjects labeled with hypovitaminosis D will be reduced to 461 (52.7%).

Table 1: Coordinates of the ROC Curve

Table 1: Coordinates of the ROC Curve

1.00	1.000	1.000
2.50	1.000	.999
3.50	1.000	.865
4.50	.941	.813
5.50	.941	.761
6.50	.941	.709
7.50	.941	.667
8.50	.941	.625
9.50	.882	.578
10.50	.882	.545
11.50	.882	.508
12.50	.882	.464
13.50	.824	.438
14.50	.706	.413
15.50	.706	.389
16.50	.588	.371
17.50	.588	.349
18.50	.588	.324
19.50	.588	.309
20.50	.588	.287
21.50	.588	.271
22.50	.588	.246
23.50	.588	.226
24.50	.588	.215
25.50	.588	.204
26.50	.588	.195
27.50	.529	.183
28.50	.529	.165
29.50	.529	.153
30.50	.529	.144
31.50	.529	.133
32.50	.529	.127
33.50	.471	.119
34.50	.471	.114
35.50	.471	.111
36.50	.471	.109
37.50	.471	.103
38.50	.412	.098
39.50	.353	.095
40.50	.235	.095
41.50	.176	.090
42.50	.176	.084
43.50	.176	.075
44.50	.176	.068
45.50	.176	.062
46.50	.176	.061
47.50	.176	.058
48.50	.176	.053
49.50	.118	.049
50.50	.118	.047
51.50	.118	.046
52.50	.118	.043
54.00	.118	.037
55.50	.118	.035
56.50	.118	.029
57.50	.118	.025
58.50	.118	.023

59.50	.118	.021
60.50	.118	.020
61.50	.118	.018
63.00	.118	.016
64.50	.118	.015
66.00	.118	.014
68.00	.059	.013
69.50	.059	.012
71.00	.000	.000

DISCUSSION

The prevalence of hypovitaminosis D is high among the Iraqi people especially women.[11,12] The current cut-off values used in public and private healthcare settings in Iraq depend on international figures, primarily based on studies conducted on Caucasian subjects.[9,10] There is a growing body of evidence suggesting that a single cut-off value should not be universally applied, as different populations may require different cut-off values.[1,7,11-15] We conducted this study to estimate the best cut-off values for hypovitaminosis D applicable in Basrah, Iraq. The prevalence of hypovitaminosis D in the current study, using the international reference range, was 68.5%, irrespective of gender or age group. This prevalence is similar to another study conducted in Basrah, Iraq, from 2017-2019 which reported a prevalence of 62.5%.[12] Another study estimated the risk of vitamin D deficiency in Iraq to be 74.5%.[11] Other studies from the Middle East have reported even higher prevalence rates of 90% and 82.1% in Syria and Saudi Arabia respectively.[1,7] Despite the higher reported prevalence rates of hypovitaminosis D in the region, clinical observations indicate that a majority of individuals labeled as having hypovitaminosis D are apparently healthy and asymptomatic. The mean value of 25(OH)D in our study was 16.9 ± 14.9 ng/ml, slightly higher than the values reported in two studies from Saudi Arabia and Syria, where the mean values of 25(OH)D were 12.8 ng/ml and 8 ng/ml respectively.[1,7] The mean value of PTH in our study was 129.1 ± 110.5 pg/ml, which is relatively high compared to other studies from the region.[1,7] Up to the best of our knowledge, this study is the first and largest to determine a new cut-off value for vitamin D levels in Iraq that better reflects vitamin D status. Implementing the new suggested cut-off value in clinical practice could significantly impact public health, particularly by reducing unnecessary expenses on investigations and therapies. When fewer individuals are flagged as having hypovitaminosis D, less follow-up will be required, thereby reducing the overall burden on the healthcare system. Several limitations exist in our study. First, we did not include data on alkaline phosphatase, age, gender, and BMI, as we intended to determine the best cut-off value for the general population in Basrah, Iraq. Second, we did not consider other confounders and risk factors for osteoporosis, such as body mass index, smoking status, and physical activity, as our study was designed to determine a new cut-off value for vitamin D rather than to study the effect of vitamin D deficiency on bone health. Third, for the same reasons, a bone mineral density scan was not utilized to reflect the bone health status among the participants. Finally, as the sample was collected from Basrah city only and limited to a short time frame, this could have skewed vitamin D levels due to seasonal variation and geographic location bias.

CONCLUSIONS

The cut-off value for vitamin D deficiency needs to be redefined in areas where the disease is unexpectedly prevalent. A single cut-off value cannot be universally applied due to genetic and environmental variations. We suggest a new lower cut-off value for 25(OH)D of 12.5 ng/ml for the Iraqi population living in Basrah. The prevalence of hypovitaminosis D was high in our cohort, regardless of whether the new cut-off values were applied. However, the prevalence decreased after implementing the new suggested values. This will have a beneficial effect on current clinical practice by avoiding unnecessary expenditures on investigations and therapies and by reducing the stress associated with a hypovitaminosis D diagnosis. Further larger studies are required to establish the new suggested cut-off values.

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