

Original Research Article

Vitamin D Administration: Intramuscular versus oral route: Comparison of Effectiveness

Al-Hilali K.A.; FRCP¹, Al-Anbari H.H.; Ph.D. Clinical Pharmacology²¹Dean of Al-Safwa University College, Kerbalaa, Iraq.²Head of Pharmacy Department at Al-Safwa University College, Kerbalaa Iraq.

*Corresponding author

Dr. Haider Hamid Al-Anbari

Email: haider_alanbary@yahoo.com

Abstract: Vitamin D is a fat soluble vitamin essential for bone health. Its deficiency is highly prevalent all over the world without adequate steps or efforts to solve this problem. The aim of the study is to compare the effectiveness of orally administered versus intramuscularly administered vitamin D preparation. Sixty patients with Hypovitaminosis D participated in the study. Thirty of them (50%) preferred the oral route for taking vitamin D while the other 30 patients (50%) chose the intramuscular (I.M) injection route. Both groups used the same preparation. Two weeks later vitamin D serum level was re-checked, and a comparison of the results of the two groups was recorded. The serum level of vitamin D after (I.M) administration showed marked increment compared with results after oral way despite using the same dose in both routes, although both routes cause a significant increment. The study concluded that I.M administration of vitamin D increased its serum level more effectively than the oral route of the same dose.

Keywords: 25(OH) vitamin D, Hypovitaminosis D, oral route and intramuscular route.

INTRODUCTION:

The role of vitamin D (25 hydroxy vitamin D) in the homeostasis of calcium and bone health was appreciated in the first time in 1921 [1], and its function is the regulation of calcium and phosphorus balance for bone mineralization and remodeling. [2,3].

Vitamin D insufficiency is remarkably common all over the world [4], even in sunny climates because of cultural and social habits and life styles [5]. The daily intake of vitamin D is commonly insufficient if sunlight exposure is not performed [6], and because the amount of vitamin D present in average diet is insufficient to meet requirement [7]. Serum level between 30-50 ng/ml is regarded as sufficient, and 10-20 ng/ml as deficiency [8] (table I). Vitamin D requirement is variable e.g. up to 800 I.U per day to 50,000 units monthly is regarded adequate [9]. Opinions differ whether Vitamin D₂ (ergocalciferol) which comes from vegetable sources, or Vitamin D₃ (cholecalciferol) manufactured in the skin by the effect of sunlight ultraviolet [10], or from animal food or as already made food supplement is more efficient [11,12]. All patients with Hypovitaminosis D especially those at risk whose serum Vitamin level is severely deficient need treatment to prevent catastrophic consequences on bone and other body systems [13].

PATIENTS AND METHODS:

The total number of participants with Hypovitaminosis D was 60. Thirty six (60%) were females and 24 (40%) were males. Their ages ranged from (50) to (74) years with an average of 64 years (table II). The study was conducted by joint work of private medical clinic and the outpatient clinic of Al-Hussain medical city teaching hospital. For all patients, a full history, physical examination and some investigation were done, mainly assessment of serum vitamin D by immunoassay method (Cobas device), giving the values in ng/ml. Other tests such B-urea, S.creatinine were also done to exclude renal impairment patients. The study took 3 months work from January to April 2017. The vitamin D preparation used for treatment was in the form of one ml solution for oral / I.M administration, its trade name is (Dibase), a product of Abiogen pharma (Italy). Each ml ampoule contains 300,000 international units (i.u /ml) of cholecalciferol or vitamin D₃. According to the wish of patients, half of them preferred the intramuscular (I.M) way of administration, while the other half took it by mouth. Two weeks later, another sample of blood was taken to re-evaluate the serum level of 25 (OH) vitamin D. Ultimately the results were collected, tabulated and statistically analyzed.

STATISTICS

The results represented as the mean \pm standard deviation. Data were fed to the computer program. Statistical Package for Social Science SPSS version 16.0 under Windows Seven was used for analysis.

Shapiro-Wilk test was performed first, to assess the normality of data distribution, which yielded that the data were not normally distributed. Non-parametric tests were used, Wilcoxon Signed test (related) with p-value less than or equal 0.05 ($P \leq 0.05$) were used to compare between pre- and post-treatment values within the same group, Mann-Whitney test was used for comparing post treatment values between the groups. [14].

RESULTS:

The serum level of vitamin D before oral administration ranged between 5-22 ng/ml with an average of 12.9 ng/ml. Two weeks after oral administration, it was increased to a range between 11-29 ng/ml with an average of 18.7 ng/ml. The range of increment after oral route was 4-10 ng/ml with an average of 5.5 ng/ml (table III). The serum level before I.M route ranged 5-17 ng/ml, with an average of 10.5 ng/ml, after I.M administration it was increased to a range between 25-45 ng/ml with an average of 31.1 ng/ml. The range of increment 15-30 ng/ml and the average 20.6 ng/ml. The average increment with oral administration 5.5 ng/ml, whereas with I.M route 20.6 ng/ml (table IV).

Table-1: Serum 25(OH) vitamin D (ng/ml) accepted by American college of cardiology (11)

Serum 25(OH) vitamin D in ng/ml	Vitamin D status
≤ 10	Severe deficiency
10-20	Deficiency
20-30	Mild-moderate deficiency
≥ 30	Sufficient
40-50	Ideal
50-150	Indeterminate data
> 150	Toxicity

Table-2: Age and sex distribution of the sample

Age group in years	No. of females	No. of males	total
50-59	8	7	15
60-69	19	12	31
70 and over	9	5	14
Total	36	24	60

Table-3: Serum level of vitamin D (ng/ml) before and 2 weeks after oral administration of vitamin D

Treatment	Range of serum level	Average
Before	5-22	12.9
After	11-29	18.7
Amount of increment	4-10	5.5

Table -4: Serum level of vitamin D (in ng/ml) before and 2 week often intramuscular injection of vitamin D.

Treatment	Range of serum level	Average
Before	5-17	10.5
After	25-45	31.1
Amount of increment	15-30	20.6

Statistical inferences revealed that a highly significant increase in serum vitamin-D level was achieved by both routes (after oral route p-value = 0.0001, after I.M route p-value = 0.000000001), with a highly significant difference between the increment after I.M route which averages 20.6 ng/ml compared with that of the oral one which averages 5.5 ng/ml (p-value = 0.0000001).

DISCUSSION:

The current adequate requirement of vitamin D can easily be met by diet /or daily multi vitamin intake, keeping in mind that sun exposure of the skin is the main source of the vitamin D. For patients with vitamin D deficiency especially if severe one, it is not enough to give them the daily requirement only. They need to be given loading doses at distant intervals. Holick et al[13] suggested that giving all adults who are vitamin D deficient 50,000 IU of vitamin D2 or

D3, Once weekly for eight weeks to achieve a blood level of 25(OH)-D above 30 ng/ml, followed by maintenance therapy of 1500-2000 IU/d oral administration is the usual way for the treatment and prevention of deficiency of vitamin D [3].

People of the third world have special circumstances, their sources of vitamin D are limited including the exposure to sunlight because of social habits e.g. clothing and veiling, also a high percentage of them are uneducated or ignorant or even noncompliant in terms of following medical guidelines, thus it is preferable to follow the choice of giving loading doses at distant intervals.

Vitamin D for (I.M) administration is not commercially available in the United States; however, it can be compounded in specialty pharmacies [14], while it is available in other countries.

In this study; more than 50% of patients were in the age group (60-69) years, with preponderance of females on males (table II).

After two weeks, using vitamin D by the oral way increased the serum values significantly but only below 20 ng/ml, i.e. within level of deficiency (table III), while after I.M administration, serum values jumped significantly higher (over 30 ng/ml, table IV), i.e. within the level of sufficiency, with a statistically significant difference between I.M and oral routes. This could be due to the fact that I.M administration reaches the blood more rapidly than the oral way.

It is unfortunate that similar international studies are unavailable for comparison, hoping that further future studies would help to discover more details and facts.

In conclusion, the current study results recommend that using vitamin-D intramuscularly achieves the intended serum levels more effectively and rapidly than the oral route for the same pharmaceutical preparation.

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