



# VITAMIN D

UpDates

Vol. 2 - N. 2 - 2019

 Editorial

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optimizes  
anti-osteoporotic  
medication effects

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# EDITORIAL

## Maurizio Rossini

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Dear Colleagues,

As you will see in this issue, we are featuring an article by prof. Giannini relating to a “real world” Italian experience that demonstrates the utility – in terms of preventing recurring fractures and mortality – of anti-osteoporotic pharmacological treatment in patients suffering fragility fractures, especially if such treatment is associated with calcium and vitamin D supplementation. The results confirm those from the first studies coordinated by Silvano Adami, which were conducted over ten years ago: these showed that specific treatments for osteoporosis were more reliable and even more effective when combined with calcium and vitamin D.

And to think that just in the last few days we have been subjected to media messages that deny the clinical utility of vitamin D supplementation in osteoporotic patients! In my opinion, these messages do a great disservice to the patients themselves, in addition to compromising the credibility of the prescribing doctors. Moreover, such misinformation negatively affects the National Health Service (SSN), both in terms of preventable fractures and of costs for pharmacological treatments, whose effectiveness is compromised.

As I have indeed feared for some time (see my editorial in issue no. 3/4, vol. 1/2018), the uncritical and incompetent interpretation of recent meta-analyses – plagued, as we well know, by numerous biases – have led some to make erroneous conclusions, even in good faith. Specifically, these persons believe that the clinical contribution of vitamin D vis-à-vis musculoskeletal pathologies, and in particular osteoporosis, is irrelevant; they are therefore surprised that so many of the elderly suffering from this condition use these supplements. This skepticism clearly stems from unfamiliarity with the epidemiology of vitamin D deficiency and with the physiopathology of vitamin D, phospho-calcic and bone metabolism.

As is well known, epidemiology has shown a great prevalence of vitamin D deficiency in the elderly; given their physiopathology, this deficiency is justifiable and cannot be coun-

teracted by increased exposure to sunlight, in light of the risks associated with the latter at an advanced age. Moreover, those familiar with the physiopathology of phospho-calcic and bone metabolism know that an important role is played by the frequency of vitamin D deficiency in the pathogenesis of osteoporosis in the elderly, given the related risks of secondary hyperparathyroidism and/or osteomalacia.

Now if the real aim (or prejudice) of this media campaign against vitamin D is to reduce the exorbitant expenses that we incur for vitamin D in Italy, then I am in partial agreement. Indeed I believe – as I stated in a previous editorial – that it is justifiable to attempt to reduce the present costs of vitamin D supplementation (and of monitoring its level) and even “to lower our expectations, particularly with regard to osteoporosis, by improving the suitability of the treatment...” Let me explain myself more carefully.

Lowering our expectations concerning vitamin D, in particular in treating osteoporosis, means admitting that vitamin D alone is not to be considered a suitable treatment for a developed stage of osteoporosis, especially when complicated by fragility fractures. You will certainly have noticed that over the last few years Italy has unfortunately seen a regression in the treatment of osteoporosis, in part because some doctors, for various debatable reasons, have substituted specific treatments for osteoporosis with vitamin D alone. These practitioners evidently forget that in clinical trials the former have demonstrated their clear

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2019;2(2):46-47

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superiority with respect to supplementation alone. It is sad and embarrassing to see patients in our clinics who believe they are receiving adequate treatment with vitamin D alone, even when they have already suffered two or three fractures!

Then again, even the guidelines of SIO-MMMS [1] are not completely reassuring on this point. While stating that "... an adequate supply of calcium and vitamin D represents the necessary precondition for any specific pharmacological treatment" and that "calcium and/or vitamin D deficiency is the most common cause of a failed response to pharmacological treatment of osteoporosis," they at the same time admit that "... the densitometric effects of vitamin D supplementation are nonetheless on average modest, proportional to the degree of deficiency; they have further only been

demonstrated in relation to hip fracture. The anti-fracture effect of vitamin D is modest and has been established only for hip and non-vertebral but not vertebral fractures ...".

The other field in which I believe we can (and must) improve the suitability of treatment with vitamin D is that regarding extra-skeletal pathologies. In light of current scientific evidence, its use in these cases is in fact not always justifiable: this seems to me a valid conclusion with regard, for example, to cardiometabolic disorders. This is indeed the opinion of our colleague prof. Strazzullo, author of the other feature article of this issue. Nonetheless, as is shown by the numerous references which once again support the articles of this issue, there is increasing evidence that confirms the potential beneficial effects of correcting vitamin D deficiency in extra-skeletal contexts: among other

considerations, developments in this regard justify the need for a means of keeping readers up to date, such as that provided by our Journal.

I therefore feel that it is necessary that we begin a candid debate with the Health Board Authorities on the costs and benefits of vitamin D supplementation. Otherwise, I fear that someone might "throw the baby out with the bathwater."

What do you think?

I hope you enjoy reading this issue.

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# Native vitamin D optimizes anti-osteoporotic medication effects

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## INTRODUCTION

Current treatments for osteoporosis use extremely effective drugs to reduce fracture risk [1]. It is well known, however, that in common clinical practice the expected therapeutic effect might not correspond to the one actually obtained. In fact, some patients have a suboptimal response to treatment in terms of fracture reduction and risk.

Such clinical picture is also known as inadequate response to anti-fracture therapy [2]. The possibility of an inadequate response to treatment seems to be correlated to multiple factors, including the advanced age of the patient, a non-optimal treatment compliance, a very high fracture risk at the beginning of treatment, and many others [2]. Nevertheless, for many years it has been known that untreated hypovitaminosis D is able to reduce the effects of osteoporotic medication in a clinically significant way.

## THE ROLE OF HYPOVITAMINOSIS D AND OF ITS CORRECTION WITHIN OSTEOPOROTIC TREATMENT

The first evidence for the prevalence of hypovitaminosis D in patients treated for osteoporosis dates back several years [3]. A study on 1500 American women with postmenopausal osteoporosis, undergoing treatment to prevent fragility fractures, indeed showed that approximately 50% of these subjects had serum levels of 25(OH)VitD < 30 ng/mL and that about 10% had levels of 25(OH)VitD < 15 ng/mL. It is known that such low levels may be responsible for a skeletal clinical picture in which osteomalacia overlaps with osteoporosis [4]. It is not surprising, then, that hypovitaminosis D, if not corrected, might represent a risk factor for possible inadequate response to treatment.

Over the years, this hypothesis has been carefully explored in several studies, most

of them conducted in Italy. Adami et al. showed that of the 900 subjects participating in the ICARO study treated with anti-osteoporotic medication, 25% had an inadequate response to treatment, which was defined as the occurrence of a new vertebral or non-vertebral fracture within 6 months from the beginning of the treatment [5]. This suboptimal response can be explained, in part, by the lack of a concomitant administration of calcium and vitamin D, an absence which could double fracture risk in these patients [5].

Another study by the same author provided even more interesting results [6]: in a population of about 1,500 women with postmenopausal osteoporosis undergoing treatment with anti-osteoporotic agents (with an adherence > 75%) for 13.1 months, the impact of vitamin D repletion was evaluated compared to its deficiency [serum 25(OH)VitD < 50 nmol/L] in terms of variations in bone density and risk of incident fractures. Less than 30% of the participating subjects in the multicentric Italian study were taking > 600 IU/day of vitamin D. Bone density increase was significantly higher in subjects with normal vitamin D serum levels and substantially absent in those with vitamin D depletion. Vitamin D depleted subjects had nearly double the risk of experiencing a new fracture compared to those with vitamin D repletion, even after adjusting for all available confounding factors [6].

Similar results were reported in a subsequent study in Spain on women with postmenopausal osteoporosis undergoing treatment with oral bisphosphonates and examined for about 12 months [7]. Even though there were no differences in the risk for new fragility fractures, patients with serum levels of 25(OH)VitD > 30 ng/mL showed an improvement in bone density, which was three times higher compared to patients with lower 25(OH)VitD levels dur-

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2019;2(2):48-51

<https://doi.org/10.30455/2611-2876-2019-03e>

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ing treatment. Almost identical results were reported in an American study conducted in the same period on 200 women with postmenopausal osteoporosis undergoing treatment with oral and intravenous bisphosphonates; in this case, the definition of inadequate response to treatment was based on bone density loss and on the occurrence of new fractures during treatment [8]. Patients with a mean 25(OH)VitD  $\geq 33$  ng/mL had approximately 4.5-fold greater odds of a favorable response to therapy compared to those with lower levels. More consistent results were seen in two subsequent studies by Spanish authors. These trials examined very large samples of subjects and included only those with high compliance to anti-osteoporosis treatment. In these cases, the definition of inadequate response to treatment was only based on the occurrence of new fractures during treatment [9, 10]. In the first study, subjects with inadequate response to treatment had lower levels of vitamin D with respect to the population that had not experienced incident fractures, and double the proportion of subjects with levels of 25(OH) VitD  $< 20$  ng/mL (49.2% vs 26.0 %, respectively) [9]. The second study screened about 7,500 subjects undergoing treatment with oral bisphosphonates [10]. Even with a compliance  $> 80\%$ , fracture risk while in treatment was 2.69 times higher in subjects with vitamin D deficiency.

Additional evidence of equal significance then led to a more refined definition of the importance of correcting hypovitaminosis D in subjects undergoing anti-osteoporosis treatment. Nurmi-Luthje et al. investigated which factors could predict mortality following hip fracture in the elderly [11]. They highlighted that osteoporosis treatment associated with calcium and vitamin D intake could reduce mortality after hip fracture in both genders. At 36 months, they observed a 43% reduction in mortality in females who used calcium and vitamin D in concomitance with anti-osteoporotic drugs. Among 23,615 patients with a mean age of roughly 78 years who had suffered hip fracture, mortality within five years after the fracture was about 25% lower in subjects treated with calcium and vitamin D (or only with vitamin D) and in subjects who underwent therapy for the prevention of osteoporotic fractures, compared to untreated patients. The reduction was roughly 28% in subjects who combined anti-osteoporotic medication with vitamin D, compared to untreated ones [12].

### THE MOST RECENT DATA FROM ITALY

Given the great interest in the data discussed here, we performed a study in order to verify whether calcium and/or vitamin D intake had an effect on anti-osteoporotic treatment in terms of the occurrence of new fractures and all-cause deaths [13]. Our investigation involved a sample of elderly persons from different Italian regions and with a prior fragility fracture.

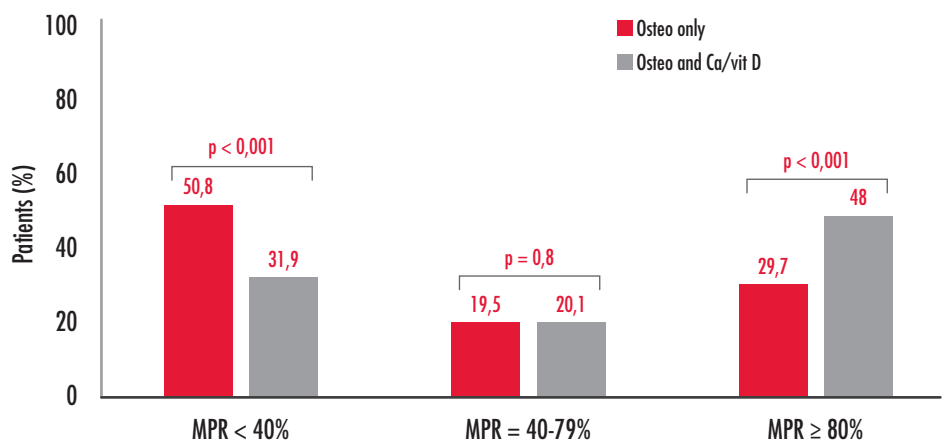
Data were obtained from administrative databases (hospital discharge forms, medical exemption certificates and use of medicines prescribed through the National Health Service) of five Italian Local Health Boards (ASLs): Naples 3 South, Pescara, Udine, Verona and Frosinone. Data analyzed involved 3.3 million patients, representing about 5% of Italy's population. The study also included 3,475 patients, age  $\geq 50$  years, with both hip or vertebral fracture and concomitant osteoporosis, who were examined between January 2011 and December 2015.

On the basis of these same databanks, patients were characterized according to whether they were undergoing any type of pharmacological treatment as well as to the presence and degree of comorbidity during the year prior to the fracture. The same patients were followed for at least one year after the occurrence of their first fracture (the reference date), with the aim of assessing the incidence of new fractures or of death by any cause.

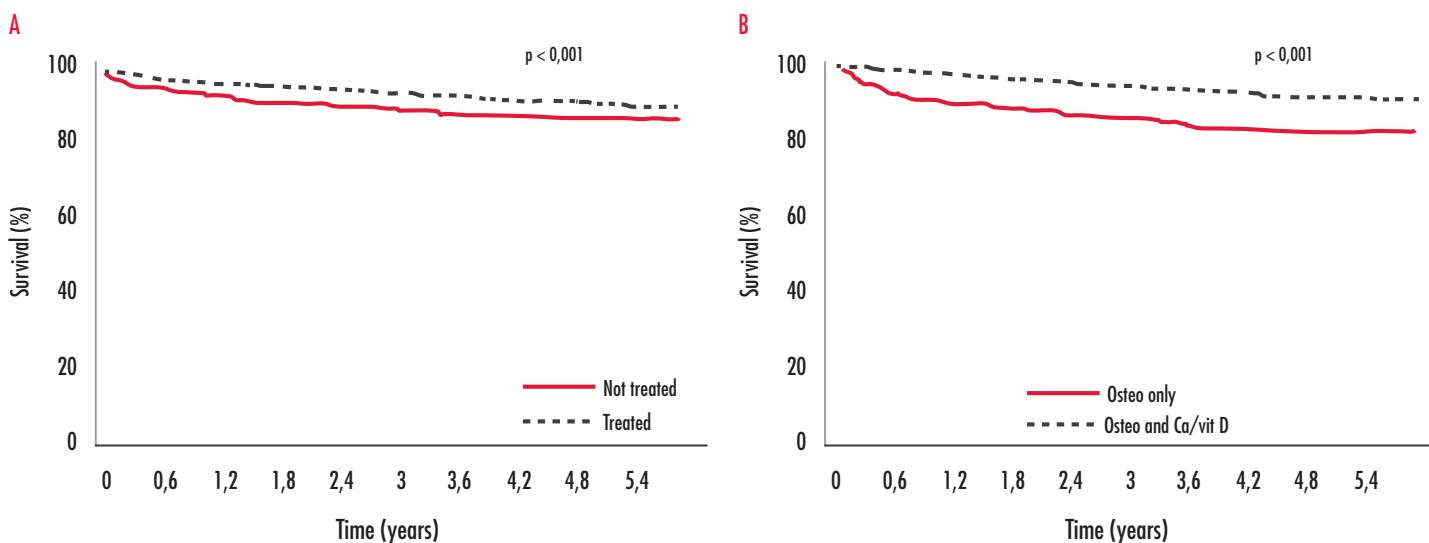
Participants in this study were elderly; after the occurrence of their first fracture, almost half (41.5%) were still untreated for osteoporosis. Patients who were untreated after their first fracture were older than treated

ones ( $83.6 \pm 8.7$  vs  $78.2 \pm 8.7$  years,  $p < 0.001$ ). Among treated patients, 83.6% were taking those medications recommended by AIFA (the Italian state drug agency) in note 79, together with vitamin D and calcium supplementation, while only 16.4% were taking note 79 AIFA medications only. Patients following the combined therapy had a higher rate of adherence than those taking only the medications (Fig. 1). Patients treated for osteoporosis after their first fracture had a lower likelihood of new fracture occurrence than untreated subjects (Fig. 2A). Cox analysis, adjusted for all possible confounding factors, demonstrated that treated patients had a 44.4% lower risk of new fracture compared to untreated subjects (HR = 0.556, 95% CI = 0.420-0.735,  $p < 0.001$ ). Even more interesting is that subjects following the combined treatment (AIFA note 79 medications together with vitamin D and calcium supplementation) had a significantly lower risk of new fracture occurrence compared to those patients taking only the AIFA medications (Fig. 2B). The combined therapy was associated with a risk reduction of 64.4% for new fractures with respect to those patients who only used drugs for osteoporosis (HR = 0.356, 95% CI = 0.237-0.533,  $p < 0.001$ ).

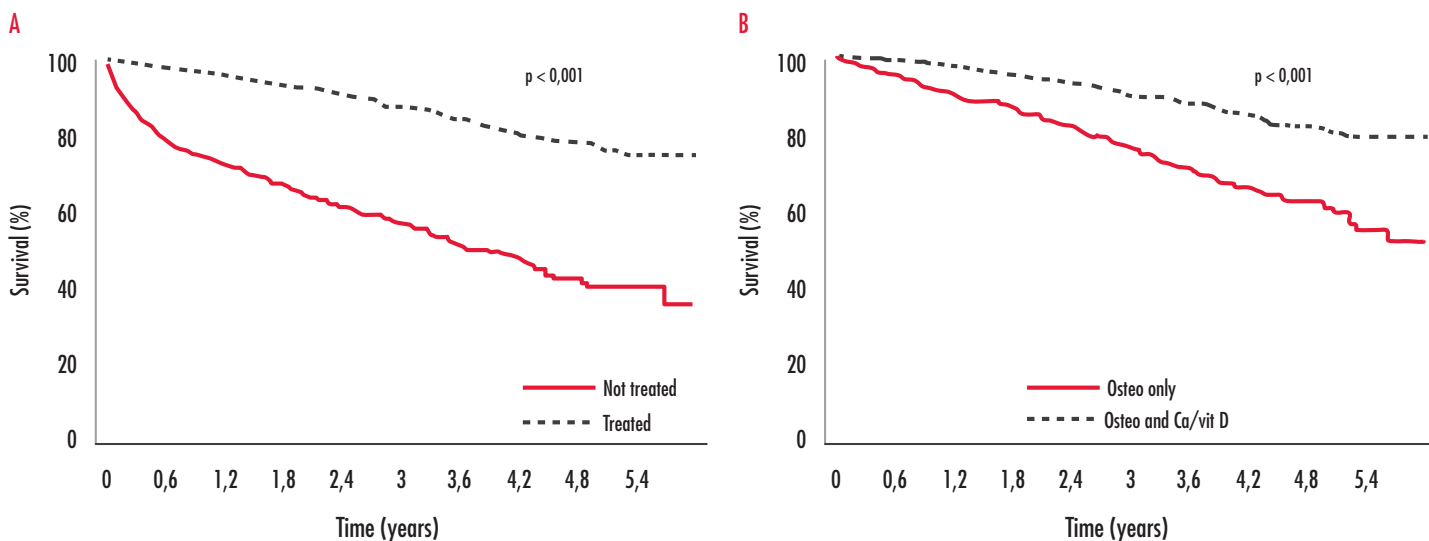
Analysis of all-cause deaths also produced interesting results. Patients treated for osteoporosis after their first fracture had a significantly lower all-cause mortality risk than those who were untreated (Fig. 3A). Cox analysis, again adjusted for all possible confounding factors, demonstrated that treated patients had a 64% lower mortality risk compared to untreated subjects (HR = 0.360, 95% CI =



**FIGURE 1.** Adherence to treatment during follow-up.

**FIGURE 2.**

Survival curves (Kaplan-Meier) without subsequent fracture in patients with previous fracture. **A)** Patients treated with osteoporosis medications vs not treated patients. **B)** Patients treated with AIFA note 79 medications only (osteoporosis only) vs patients treated with AIFA note 79 medications and calcium/vitamin D (osteoporosis and Ca/vit D).

**FIGURE 3.**

Survival curves (Kaplan-Meier) for all-cause mortality in patients with previous fracture. **A)** Patients treated with osteoporosis medications vs not treated patients. **B)** Patients treated with AIFA note 79 medications only (osteoporosis only) vs patients treated with AIFA note 79 medications and calcium/vitamin D (osteoporosis and Ca/vit D).

0.310-0.418,  $p < 0.001$ ). In addition, subjects following the combined therapy had a lower all-cause mortality risk than those patients taking only the AIFA note 79 medications (Fig. 3B). The combined treatment was associated with a 53% reduction of mortality risk with respect to those subjects who used only drugs for osteoporosis (HR = 0.471,

95% CI = 0.356-0.623,  $p < 0.001$ ).

## CONCLUSIONS

Osteoporosis treatment is without doubt associated with a significant reduction of the risk for new fractures, especially when used in high-risk individuals, such as those with previous fractures. An important additional

datum in this regard, which has forcefully emerged from real-world evidence studies, shows that death after fracture also appears to be reduced if osteoporosis therapy is used. A more recent but equally clear and important datum coming from the literature is the fact that vitamin D has a significant beneficial effect in enhancing the anti-frac-

ture effect of anti-osteoporotic drugs and contributes to further reducing mortality due to hip fracture.

Although further investigations are needed to clarify the possible effects of vitamin D on patient survival, these data consolidate and reinforce the importance of correcting hypovitaminosis D in subjects with a high risk of fragility fracture.

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# Vitamin D and cardiometabolic disorders: state of the field review

VITAMIN D  
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## INTRODUCTION

For some time it has been known that calcium and phosphate homeostasis is essential for normal cellular physiology as well as for skeletal integrity [1]. Several recent epidemiological, clinical and experimental studies have provided a very impressive series of information about new and different biological functions concerning vitamin D and the vitamin D receptor, in addition to those traditionally recognized. These functions include the ability to influence cellular growth and differentiation to modulate immune response and to control the activity of other hormonal systems [2].

As a result, it has been suggested that vitamin D deficiency favors the development of high prevalence cardiometabolic risk factors, such as diabetes, hypertension and associated cardiovascular events [3, 4].

## THE BIOLOGY OF VITAMIN D

In humans, about 80% of vitamin D (cholecalciferol) is synthesized in the skin from 7-dehydrocholesterol and the remaining 20% from diet. Vitamin D is then activated through two hydroxylation steps at positions 1 and 25, forming calcitriol (1,25-dihydroxycalciferol).

Recent studies have disproved the previous notion that biological activation of vitamin D occurred exclusively in the kidney by showing that most human tissues and cells also express the  $1\alpha$ -hydroxylase enzyme. They further indicate that the vitamin D receptor (VDR), which acts as a transcription factor, is expressed in at least 36 types of human cells, where it regulates – directly or indirectly – the expression of about 3% of the entire human genome.

In light of these findings, it appears that the vitamin D – VDR system is involved in a wide range of biological activities [2].

## VITAMIN D STATUS

The evaluation of vitamin D status is based on

circulating 25-hydroxyvitamin D [25(OH)VitD] levels [3]. In general, vitamin D deficiency is defined as levels of 25(OH)VitD < 20 ng/mL (or 50 nmol/L). However, since levels of circulating PTH are at their nadir when levels of 25(OH)VitD < 30 ng/mL, it is believed that 25(OH)VitD levels between 21 and 29 ng/mL indicates vitamin D deficiency, while levels  $\geq$  30 ng/mL (74 nmol/L) are considered adequate. Based on these criteria, about 15% of the world population, including children and adolescents, is either deficient or has vitamin D insufficiency, especially in persons who are overweight or obese. In addition, more than half of elderly subjects have suboptimal levels of 25(OH)VitD [3].

## VITAMIN D AND CARDIOMETABOLIC DISORDERS: PHYSIOPATHOLOGICAL CONNECTIONS

Based on widespread evidence showing that a high number of human tissues and cells, including cardiomyocytes and smooth and endothelial muscle cells, express both VDR and the  $1\alpha$ -hydroxylase enzyme, it has been hypothesized that the biological system of vitamin D plays a role in the pathogenesis of many cardiometabolic disorders [2]. In many studies, vitamin D deficiency and/or insufficiency led to secondary hyperparathyroidism when high levels of PTH were associated with increased cardiovascular risk. The vitamin D/VDR biological system also acts as an endocrine and paracrine negative regulator of the renin-angiotensin-aldosterone system, which plays a central role in the regulation of blood pressure, fluid volume and electrolyte metabolism. The vitamin D/VDR system also regulates insulin and insulin receptor gene expression and, through the modulation of calbindin expression, controls intracellular calcium flux in insulin cells, which in turn affects insulin release. Calcitriol synthesized in endothelial cells seems

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**VITAMIN D - UpDates**  
2019;2(2):52-57

<https://doi.org/10.30455/2611-2876-2019-04e>

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to have a contrasting effect with respect to the end-products of advanced glycation and of various pro-atherosclerotic metabolites. Furthermore, calcitriol regulates the expression of factors that promote osteoblast differentiation at the vessel wall, an action that can influence the development of vascular calcification. Calcitriol also inhibits foam cell formation and macrophage cholesterol uptake in diabetic subjects. Finally, calcitriol acts as modulator of both immune response and of cytokines biosynthesis [2, 5].

### VITAMIN D AND CARDIOMETABOLIC DISORDERS: RESULTS OF OBSERVATIONAL STUDIES (TABLE I)

Many studies have provided support for the idea that vitamin D might have an impact on the risk and possibly on the course of several metabolic and cardiovascular disorders [5]. From the analysis of 28 studies on 99,745 participants, Parker et al. found that higher levels of 25(OH)VitD were associated to a significantly lower incidence of cardiovascular diseases, diabetes and metabolic syndrome, with an odds ratio (OR) of 0.57 and a confidence interval of 95% (CI 95%: 0.48-0.68) [6].

A meta-analysis conducted by Burgaz et al. on 18 studies ( $n = 78,028$  participants) showed that 25(OH)VitD levels were inversely associated with hypertension [7]. In addition, the more recent meta-analysis by Kunutsor et al. again demonstrated an inverse correlation between 25(OH)VitD and the risk of incident hypertension in an apparently healthy population ( $n = 283,537$ ), with a risk reduction equal to 12% for every increase of 10 ng/mL in vitamin D plasma levels [8]. Moreover, a meta-analysis of prospective studies by Song et al. (21 studies with 76,220 participants and 4,996 cases of incident type 2 diabetes) showed an inverse correlation between 25(OH)VitD and the risk of type 2 diabetes in different populations [9], with a risk reduction equal to 4% for every increase of 4 ng/mL 25(OH)VitD. In the Framingham Offspring Study, Wang et al. showed that among 1,739 participants without prior cardiovascular disease (mean baseline age = 59 years; follow-up after 5.4 years) individuals with levels of 25(OH)VitD < 15 ng/mL had a multivariable hazard ratio (HR) of 1.62 (95% CI: 1.11 to 2.36) for incident cardiovascular events, including heart attack, angina pectoris, stroke, transient ischemic attack, intermittent claudication and heart failure, com-

pared with those with 25(OH)VitD  $\geq$  15 ng/mL. This effect was only evident in participants with hypertension [10].

In addition, a recent meta-analysis of 19 prospective studies of 65,994 participants and 6,123 cardiovascular events, performed by Wang et al., showed that there was a linear inverse association between 25(OH)VitD levels in the interval between 20 and 60 nmol/L and the risk of cardiovascular disease. In particular, comparison of the 25<sup>th</sup> and 75<sup>th</sup> percentile concentrations of 25(OH)VitD showed that the multivariable relative risk was equal to 1.38 (1.21-1.57) for coronary heart disease and to 1.64 (1.27-2.10) for stroke [11].

A recent small sample study performed by Messenger et al. on 813 males (the MrOS Study, mean baseline age = 74, median follow-up of 4.4 years) did not confirm these results: yet this study looked at a low number of subjects affected by hypovitaminosis D and a small number of incident cases of cardiovascular disease [12].

Several studies have also shown that vitamin D status might affect life expectancy in the general population. Liu et al. analyzed 13,131 subjects in the NHANES III trial (age  $\geq$  35 years, median follow-up of 8 years) and found that subjects with serum levels of 25(OH)VitD < 20 ng/mL had a 2.06 (1.01-4.25) higher mortality risk for heart failure than those subjects with serum levels of 25(OH)VitD  $\geq$  30 ng/mL. Furthermore, the risk ratio for all-causes early death (< 75 years) was 1.40 (1.17-1.68) for subjects with levels of 25(OH)VitD < 20 ng/mL, and 1.11 (0.93-1.33) for subjects with values between 20 and 29 ng/mL, compared to those with serum levels  $\geq$  30 ng/mL ( $p$  for trend < 0.001) [13]. The meta-analysis conducted by Wang et al., cited above, confirmed that subjects within the lowest category of 25(OH)VitD levels had an increased risk for cardiovascular disease-specific deaths, equal to 1.42 (1.19-1.71), compared to those within the highest category [11].

A meta-analysis of 14 prospective cohort studies with 62,548 participants (5,562 deaths) by Zittermann et al. confirmed a lower mortality risk for the highest compared to the lowest percentiles of 25(OH)VitD (0.71; 0.50-0.91), with optimal concentrations between 75 and 87.5 nmol/L [14]. The mortality risk related to serum levels of vitamin D was also investigated and analyzed in specific subsets of individuals. In the

Whitehall study of quite elderly subjects ( $n = 5,409$ , mean baseline age = 77 years, follow-up of 13 years), an inverse correlation between 25(OH)VitD levels and relative risk of vascular and non-vascular mortality was observed. These data were confirmed in a meta-analysis by the same authors of 12 cohort studies with 42,565 participants [15]. In a small sample study on 289 patients with type 2 diabetes with a median follow-up of 15 years and 196 deaths (68%), severe vitamin D deficiency, with 25(OH)VitD < 13.9 nmol/L, was associated with an increased risk of cardiovascular (HR 1.95; 1.11-3.44) and all-causes mortality (HR 1.96; 1.29-2.98) [16]. Similar results were found by Dobnig et al. in patients who underwent coronary angiography [17].

### VITAMIN D AND CARDIOMETABOLIC DISORDERS: EVIDENCE FROM INTERVENTIONAL STUDIES (TABLE II)

While observational studies have almost uniformly found inverse correlations between circulating levels of 25(OH)VitD and the risk of metabolic and/or cardiovascular diseases, only recently has evidence for a correlation between vitamin D and cardiometabolic disorders been found through randomized controlled trials and relative meta-analyses.

The meta-analysis by Li et al. provided evidence for the effects of vitamin D supplementation in patients with type 2 diabetes on the most important glycol metabolic parameters [18]. Analysis of 20 randomized controlled trials over 2 to 6 months on 2,703 patients showed a significant reduction in the HOMA index of insulin resistance in patients with hypovitaminosis D, without, however, significant improvements for other variables, such as body weight, fasting blood sugar levels or glycated hemoglobin. It is important to note that the quality of the evidence provided by the above-mentioned studies was on average considered low.

Another meta-analysis by Swart et al. examined randomized controlled trials concerning vitamin D supplementation in population samples of great heterogeneity ( $n = 2,994$ ). Ranging in duration from 16 weeks to 1 year, these trials used individual data and set blood pressure and glycated hemoglobin levels as the main outcomes. Results from this meta-analysis showed that there were no significant effects of vitamin D supplementation on either of these two outcomes, while a significant reduction of LDL cholesterol levels was found [19].

**TABLE I.**  
Vitamin D and Cardiometabolic Disorders: results from most important observational studies.

Author [ref.]	Type of study	Characteristics	Main results
Parker [6]	Meta-analysis	28 studies (n = 99,745 participants)	Inverse association between 25(OH)D and prevalence of cardiovascular diseases, diabetes and metabolic syndrome
Burgaz [7]	Meta-analysis	18 studies (n = 78,028 participants)	Inverse association between 25(OH)D and prevalence of hypertension
Kunutsor [8]	Meta-analysis	8 prospective studies (n = 283,537; 55,816 incident cases)	Reduction of incident hypertension risk equal to 12% for each 10 ng/mL 25(OH) D increment
Song [9]	Meta-analysis	21 prospective studies (n = 76,220 participants; 4,996 incident cases)	Reduction of diabetes risk equal to 4% for each 4 ng/mL 25(OH)D increment
Wang [10]	Prospective study	<i>Framingham Offspring Study</i> (n = 1,739 clinically healthy participants, mean age 59 years, medium follow-up 5.4 years)	For levels of 25(OH)D < 15 ng/mL HR multivariate of 1.62 (CI 95% 1.11-2.36) for incident cardiovascular events vs 25(OH) D ≥ 15 ng/mL (only in subjects with hypertension)
Wang [11]	Meta-analysis	19 prospective studies (n = 65,994 participants; 6,123 events)	For lowest category of 25(OH)D compared to highest category, RR equal to 1.52 (1.30-1.77) for all cardiovascular diseases, 1.42 (1.19-1.71) for cardiovascular deaths, 1.38 (1.21-1.57) for coronary disease and 1.64 (1.27-2.10) for stroke
Messenger [12]	Prospective study	MrOS study (n = 813 males, mean age 74 years, medium follow-up 4.4 years)	No association between 25(OH)D and incidence of cardiovascular diseases
Liu [13]	Prospective study	NHANES III (n = 13,131; age ≥ 35 years, medium follow-up 8 years)	For levels of 25(OH)D < 20 ng/mL, RR of heart failure death equal to 2.06 (1.01-4.25) compared to 25(OH)D ≥ 30 ng/mL Risk ratio for all-cause premature deaths equal to 1.40 (1.17-1.68) for 25(OH)D < 20 ng/mL and 1.11 (0.93-1.33) for values between 20 and 29 ng/mL, vs 25(OH)D ≥ 30 ng/mL (p for trend < 0.001)
Zittermann [14]	Meta-analysis	14 prospective studies (n = 62,548 and 5,562 deaths)	Mortality reduced risk (0.71, 0.50-0.91) for subjects in highest category vs those in lowest category of 25(OH)D, with an optimal concentration of 25(OH)D between 75 and 87.5 nmol/L
Tomson [15]	Prospective study	Whitehall (n = 5,409, mean age 77 years, medium follow-up 13 years)	Inverse correlation between 25(OH)D and relative risk of vascular and non-vascular death
Tomson [15]	Meta-analysis	12 prospective studies (n = 42,565)	For subjects in the highest quartile of 25(OH)D, reduction of mortality for vascular causes equal to 21% (13-28%) and of all mortality equal to 28% (24-32%) vs subjects in the lowest quartile
Joergensen [16]	Prospective study	(289 patients with type 2 diabetes, medium follow-up 15 years, 196 deaths)	For levels of 25(OH)D < 10th percentile (13.9 nmol/L), HR for cardiovascular deaths equal to 1.95 (1.11-3.44) and for all-cause deaths equal to 1.96 (1.29-2.98), compared to subjects with levels of equal to 25(OH)D > 13.9 nmol/L
Dobnig [17]	Prospective study	3,258 patients, mean age 62 years, scheduled for coronary angiography, medium follow-up 7.7 years, 737 deaths	For subjects in the lowest quartile of 25(OH)D, HR for all deaths equal to 2.08 (1.60-2.70) and for cardiovascular deaths equal to 2.22 (1.57-3.13)

Another meta-analysis which included observational and interventional studies on the correlation between 25(OH)VitD levels and fat mass percentage confirmed an inverse correlation between the latter and circulating

levels of vitamin D; it did not, however, highlight any significant effect of vitamin D supplementation on fat mass percentage [20]. In another randomized controlled trial, vitamin D supplementation was given for

48 weeks to 127 type 2 diabetes patients (mean average age = 60 years) who were not selected for hypovitaminosis D and who had good glycol-metabolic control with metformin. Results did not show significant ef-

**TABLE II.**  
Vitamin D and Cardiometabolic Disorders: results from most important observational studies.

Author [ref.]	Type of study	Characteristics	Main results
Li [18]	Meta-analysis	20 randomized controlled trials of vitamin D supplementation (n = 2,703 patients with type 2 diabetes, for a period of 2-6 months)	Supplementation with vitamin D followed by reduction of insulin-resistance HOMA index, particularly in patients with hypovitaminosis D, without, though, improvements in body weight, fasting blood sugar and glycated hemoglobin.
Swart [19]	Meta-analysis	12 randomized controlled trials of vitamin D supplementation (n = 2,994, length of therapy between 16 weeks and 1 year)	Ineffective supplementation for two main outcomes (blood pressure and glycated hemoglobin) Reduction of cholesterol LDL
Golzarand [20]	Meta-analysis	Observational studies and controlled clinical trials on relation between vitamin D supplementation and percentage of body fat.	Inverse correlation between levels of 25(OH)D and percentage of body fat, but no relation between vitamin D and percentage of body fat
Angellotti [21]	RCT	Randomized controlled trial on vitamin D supplementation for 48 weeks (n = 127 patients with type 2 diabetes, mean age 60 years, not selected for hypovitaminosis D and with good glycol metabolic control with metformin)	No effect on glycated hemoglobin and insulin secretion velocity
Cefalo [22]	RCT	Randomized controlled trial on 18 overweight, nondiabetic, vitamin D deficient volunteers following hypocaloric regime and vitamin D supplementation for 3 months	Increase of insulin sensitivity measured using hyperinsulinemic-euglycemic clamp in treated subjects but not in control group, with equal weight loss in both groups
Bislev [23]	RCT	Randomized controlled trial with vitamin D supplementation (n = 81 females in post-menopausal age with hypovitaminosis D and secondary hyperparathyroidism for 12 weeks)	Reduced PTH levels but no reduction in renin-angiotensin-aldosterone system activity or in levels of blood pressure, glycated hemoglobin, plasma lipids or vascular stiffness
Sluyter [24]	RCT	ViDA Study Randomized controlled trial with vitamin D supplementation (n = 517 adult subjects, for 1.1 years)	No significant effect on blood pressure parameters for all subjects, but significant favorable changes in vascular stiffness and central blood pressure parameters among a subset of participants with severe vitamin D deficiency
Manson [25]	RCT	VITAL Study ( <i>Vitamin D and Omega 3 Trial</i> ) Randomized controlled trial with vitamin D supplementation and/or omega 3 fatty acids (n = 25,871 subjects, age > 50 years, for over 5 years)	No significant effects on the incidence of overall or specific cardiovascular events, even in participants with levels of 25(OH)D < 20 ng/mL

fects on either glycated hemoglobin levels or on insulin secretion velocity, in spite of the significantly higher levels of circulating 25(OH)VitD [21].

In another clinical trial, 18 nondiabetic volunteers with both obesity and vitamin D deficiency were fed a hypocaloric diet combined with either a weekly administration of 25,000 IU of 25(OH)-hydroxycholecalciferol or a placebo for three months. A significant rise in vitamin D concentrations was

associated with a considerable increase in insulin sensitivity, measured using a hyperinsulinemic-euglycemic clamp in subjects under active treatment compared to the placebo group. Body weight in both groups decreased equally [22].

In a controlled clinical trial on 81 postmenopausal women with hypovitaminosis D and secondary hyperparathyroidism, treatment with vitamin D for 12 weeks reduced PTH levels but did not reduce renin-angioten-

sin-aldosterone system activity or lower levels of blood pressure, glycated hemoglobin, lipids, lipoproteins or vascular stiffness [23]. As part of the ViDA Study, a total of 517 adults were recruited to receive, for 1.1 years, either an initial dose of 200,000 IU of vitamin D3 followed by monthly 100,000 IU doses, or a placebo. Results showed no significant changes in hemodynamic parameters in the total sample; among a subset of participants with severe vitamin D deficien-

cy, however, statistically significant favorable changes in vascular stiffness and central blood pressure parameters were observed [24].

Recently, results from VITAL (Vitamin D and Omega 3 Trial) have been published, a trial investigating the effects of daily vitamin D3 administration (2,000 IU) and/or omega 3 fatty acids (1 g) in 25,871 subjects for a period of over 5 years; the group studied was composed of men 50 years of age or older and women 55 or older. The primary endpoints were the incidence of cancer and of major cardiovascular events. These results showed that vitamin D supplementation was not associated with a lower risk of either of the primary or secondary endpoints (the latter represented by specific forms of cancer and cardiovascular events), even in the subset of participants with baseline values of 25(OH)VitD < 20 ng/mL [25].

## CONCLUSIONS

Most observational studies, both transversal and prospective, suggest that there is an inverse correlation between vitamin D status (expressed as plasma levels of 25-hydroxycholecalciferol), on one hand, and cardiometabolic risk factors and cardiovascular morbidity and mortality, on the other, both in samples of the general population and in high risk patients (such as the elderly and patients with diabetes, hypertension and/or chronic kidney disease).

Results from several experimental studies provide biological plausibility for such statistical and epidemiological associations and for the hypothesis of the metabolic and cardiovascular effects of vitamin D.

Recently, many randomized controlled studies have been performed in the attempt to confirm this hypothesis. Some of these trials examined samples of people taken from the general population while others examined smaller groups of patients affected by specific morbid conditions. While on one hand some of these studies corroborated the possible positive effect of vitamin D supplementation in subjects with vitamin D deficiency relative to some risk factors (particularly high blood pressure and insulin resistance), on the other hand the largest trials did not confirm the positive effect of vitamin D supplementation on cardiovascular morbidity and mortality. At the same time, some possibility of a positive effect of vitamin D cannot be completely excluded for specific subsets of patients, or in therapeutic treatments of longer

duration based on innovative approaches. At present, then, there is a clear need for further experimental research and for more controlled studies with specific aims.

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