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 Editorial

 The role of vitamin D
in dermatological
diseases

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calcifediol?
A question of narrative!

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Rheumatology Section, University of Verona*

2023;6(3):84-85

Dear Colleagues,

In this issue, you will first find an update on the possible role of vitamin D in various dermatological diseases, as its deficiency may contribute to the pathogenesis of some skin diseases, both neoplastic and immune-mediated.

As a rheumatologist, I am particularly interested in psoriasis, the incidence and severity of which has been shown in numerous studies to be associated with vitamin D deficiency and the treatment of which has involved the use of topical vitamin D analogues for years.

The association of psoriasis with arthritic manifestations is frequent and well known. Indeed, psoriatic arthritis is classified amongst the Spondyloarthritis (SpA), representing a heterogeneous group of chronic inflammatory rheumatological diseases that share genetic, radiological and clinical characteristics, including the possible involvement of the entheses, axial skeleton and sacroiliac joints as well as peripheral joints. Copious evidence shows that specific inflammatory cytokines are involved in the pathogenesis of SpA (IL17, IL23, TNF- α , IL6). In particular, IL17 plays a pathogenetic role both in joint exertion and in entheses and bone. Recent evidence also indicates that metabolic as well as immunological factors are additionally involved in the pathogenesis of SpA, including in particular those modulating bone metabolism, such as DKK1, sclerostin and PTH, as has been shown¹⁻⁵. On such pathogenic, immunological and metabolic components, there is a scientific rationale for believing that vitamin D – often described as deficient in patients with SpA⁶⁻¹⁰ – may play an important role. Yet, in addition to playing an important role in the regulation of phosphate-calcium metabolism, including PTH control, vitamin D is also recognised for its immunomodulatory and anti-inflammatory actions¹¹. In fact, vitamin D can act by endocrine mechanism (the typical regulatory action of bone metabolism) but also autocrine-paracrine signalling, thanks to the presence within individual cells of the enzyme 1- α -hydroxylase capable of producing the active metabolite 1,25(OH)₂ vitamin D. Both the vitamin D receptor and 1- α -hydroxylase are expressed by different types of immune cells including macrophages, T-cells, dendritic cells, monocytes and B-cells. Preclinical studies indicate that vitamin D exerts biological effects on both the innate and adaptive immune systems, including on the production of proinflammatory cytokines.

It is known that vitamin D deficiency is associated with increased serum levels of pro-inflammatory mediators, including IL-6 and TNF- α , which are related to both the development and progression of inflammatory rheumatological diseases like SpA. What's more, we have recently observed that in healthy yet vitamin D-deficient subjects, supplementation with vitamin D results in a significant reduction in IL-6 and IL-17 levels¹².

The second article in this issue is dedicated to the ongoing debate on the choice between cholecalciferol and calcifediol. The authors conclude that on the basis of knowledge of physiology and current scientific evidence, cholecalciferol should be considered the therapy of first choice in the prevention and treatment of vitamin D deficiency, and that the use of calcifediol should be limited to special situations, such as malabsorption syndromes, severe obesity or liver failure.

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		% difference compared to 31 months 17 th APRIL-19 th OCTOBER (PRE NOTE 96)		31 MONTHS 19 th NOVEMBER-22 nd MAY (POST NOTE 96)	
	IN THE NOTE	ATC 5	Number of packs	Gross expenses	
Alfacalcidol	NO	A11CC03	45,9%	54,5%	
Calcitriol	NO	A11CC04	-4,8%	-3,9%	
Cholecalciferol	YES	A11CC05	-21,3%	-16,4%	
Calcifediol	YES	A11CC06	41,1%	49%	
Cholecalciferol + calcium	YES	A12AX	-27,1%	-28,9%	
TOTAL ATC IN THE NOTE			-19,6%	-15,7%	
TOTAL ATC NOT IN THE NOTE			8,5%	18,2%	

IN THE NOTE	Average gross monthly ATC POST	21,341,970
	Average gross monthly ATC ANTE	25,331,506
AVERAGE MONTHLY SAVINGS		3,989,536

IN THE NOTE	Average gross monthly ATC POST	2,027,640
	Average gross monthly ATC ANTE	1,714,870
AVERAGE MONTHLY INCREASE		312,770

Average monthly savings observed over the last 19 months in the ATC in the note: 2,807,326

FIGURE 1.

NOTE 96 – Monitoring consumption trends of the note relative to vitamin D. Office for Pharmaceutical Expenditure Monitoring and Relations with the Regions. Italian Medicines Agency (AIFA). Last analysed: May 2022. Analysis on 31 months after the introduction of the note (https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_31mesi_08.11.2022.pdf).

Also in the “Particular Warnings” of Note 96 of the Italian Medicines Agency (AIFA)¹³, it is pointed out that the main evidence of antifracturative efficacy has been conducted using cholecalciferol, which appears to be the molecule of reference for this recommendation, and that the clinical documentation in this area of use for hydroxy analogues is very limited. It should thus be a matter of concern that AIFA’s monitoring of vitamin D consumption following Note 96¹⁴, in view of expenditure savings due to the reduction in the use of cholecalciferol, shows an upswing in the consumption of calcifediol and alfacalcidol, being negligible from an economic point of view but not from a point of view of appropriateness (Fig. 1).

What do you think? Happy reading!

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The role of vitamin D in dermatological diseases

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INTRODUCTION

Vitamin D is also of great interest in dermatology. Indeed, there is a dual relationship between it and the skin. On the one hand, it is synthesised by keratinocytes in response to sun exposure and, on the other, it works actively on the skin itself. This two-way process has been named the photoendocrine system of vitamin D¹.

From a biochemical perspective, the skin synthesises the prohormone vitamin D₃ (cholecalciferol) through the interaction between 7-dehydrocholesterol and ultraviolet light. This process can meet up to 80% of our daily needs.

Many factors influence the skin's ability to synthesise vitamin D. Amongst the most important are latitude, seasonality, phototype and means of sun exposure². A minority percentage of the requirement, 20%, is taken up through the food supply in the form of vitamin D₂ (ergocalciferol), found in fruit and vegetables, and vitamin D₃, contained in high amounts especially in salmon and herring. The biologically-inactive vitamin D₃ is converted in the liver into 25-hydroxy-vitamin D₃ (calcifediol), the form most commonly found in the systemic circulation. Calcifediol is again hydroxylated in the kidney into 1,25-dihydroxy-vitamin D₃ (calcitriol) which, by interacting with specific nuclear receptors called *Vitamin D Receptors* (VDRs), is the main driver of the biological effects of this molecule (Fig. 1)³.

Vitamin D plays a fundamental role for bone tissue, regulating phospho-calcium homeostasis whilst a deficiency causes osteomalacia, osteoporosis and increased susceptibility to bone fractures.

However, the effects of this vitamin are not limited to the skeleton. There is growing evidence of its ubiquitous antiproliferative and immunomodulatory properties. Vitamin D deficiency has been documented in various cardiovascular, oncological, neurological, autoimmune and infectious diseases^{2,4}.

Of particular interest are the multiple functions that vitamin D performs in the body. By acting

on the keratinocytes through an autocrine and paracrine mechanism, it controls their differentiation and proliferation whilst stimulating their production of ceramides, which are essential lipids for maintaining skin hydration¹. Vitamin D also plays an important role in the defence against skin infections by inducing the production of antimicrobial peptides, such as cathelicidin LL-37 and beta-defensin⁵. Vitamin D exerts a relevant immunomodulatory function by inhibiting antigen presentation by Langerhans cells and the proliferation of both B- and T-lymphocytes, inducing an overall shift from a Th1 response to a Th2. This inhibits the production of proinflammatory cytokines such as IL-1, -6, -8, -12, TNF-alpha and interferon-gamma, whilst inducing the production of anti-inflammatory cytokines, such as IL-10, and the differentiation of regulatory T-cells¹. The main dermatological diseases associated with vitamin D deficiency include both skin neoplasms and some of the most frequent immune-mediated diseases, like atopic dermatitis, psoriasis and vitiligo.

CUTANEOUS NEOPLASMS

Vitamin D is involved in cell differentiation, maturation and cellular senescence and has an inhibitory effect on neoangiogenesis and oncogenesis⁶. However, the association between vitamin D deficiency and skin neoplasms is controversial since data from the studies is conflicting³. Sun exposure is both a major risk factor for this type of neoplasm and the main source of cholecalciferol. For the same reason, photoprotection recommended by dermatological guidelines with the aim of preventing photoageing and photocarcinogenesis could theoretically lead to lower vitamin D production in the skin¹. Current evidence seems to suggest that this phenomenon is unlikely with common sun filters. No good studies are available that have defined the relationship between sun exposure, photoprotection, vitamin D levels and neoplasia risk². Vitamin D may be involved in the development of *Non-Melanoma Skin Cancer* (NMSC), tu-

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Conflict of interest

The author states that there are no conflicts of interest.

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80% of vitamin D requirements is provided by solar UVB irradiation (290-315 nm)

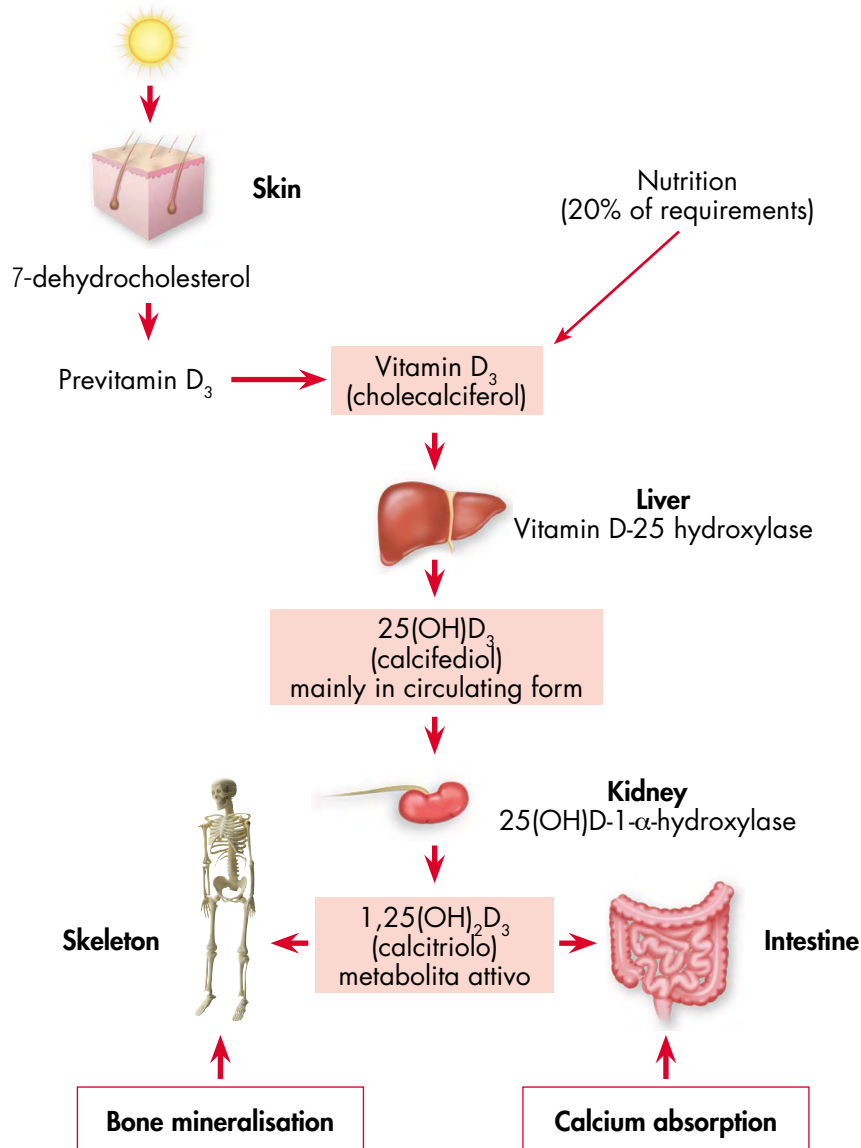


FIGURE 1. Vitamin D synthesis and metabolism ³.

mours that have keratinocyte as their cell of origin and manifest as erythematous, sometimes ulcerated nodules, usually in photo-exposed areas (face, scalp, back). More specifically, it has been observed that vitamin D has the property of inhibiting the Hedgehog signalling pathway, which plays a key role in the development of basal cell carcinomas (BCC) ². Clinical data in the literature is all conflicting, sometimes positively and sometimes negatively associating serum vitamin D levels and incidence of Non-Melanoma Skin

Cancer (NMSC), both Basal Cell Carcinoma (BCC) and squamous cell carcinomas (SCCs). A positive association was even observed between NMSC and high serum levels of vitamin D, yet not between NMSC and oral supplementation ⁷. Cutaneous melanoma (Fig. 2) is a tumour that results from the neo-plastic transformation of melanocytes that, together with keratinocytes, are part of the epidermis and are responsible for producing melanin, a pigment that protects against the damaging ef-

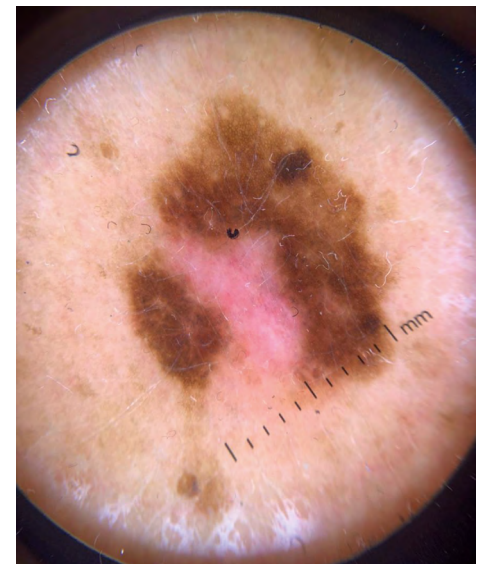


FIGURE 2. Malignant melanoma of the skin. Epiluminescence image (10X optical magnification).

fects of the sun's ultraviolet rays. With regard to melanoma, ongoing studies have shown that vitamin D and its metabolites are able to inhibit the proliferation of melanoma cells in both animal and human models ⁶. This effect appears dependent in part on the expression of VDR within neoplastic cells and the presence of specific single nucleotide polymorphisms at coding gene level ⁶. Although sometimes conflicting, the results seem to suggest a clinical association between low serum levels of vitamin D and the onset, progression and outcome of melanoma ^{8,9}. In particular, hypovitaminosis appears to play a significant role in melanomas arising in non-photo-exposed sites, which often have a worse prognosis. This result could be due not only to a diagnostic delay but also to a vitamin D-mediated protective effect on the photo-exposed areas ¹⁰.

Conclusive data on possible preventive effects of skin neoplasias by oral vitamin D supplementation is not yet available ^{1,2}.

ATOPIC DERMATITIS

Atopic Dermatitis (AD) is the most common inflammatory skin disease. It is characterised by a multifactorial aetiology including factors of genetic predisposition, altered skin barrier function, along with a filaggrin defect and Th2 immune response. Vitamin D possesses not only an immunomodulatory capacity but also the ability to stimulate filaggrin production. AD has been associated with hypovita-

minosis D in both adults and children⁵. This is consistent with the epidemiological finding that both of these conditions have a higher incidence with increasing latitude and consequently with reduced sun exposure. It has also been observed that children with AD show clinical improvement after migration to lower latitudes¹¹. Poor exposure to sunlight during the winter months may partly explain disease exacerbations that commonly occur in the cold months, whereas AD generally tends to improve in summer. Moreover, AD presents an increased risk of *Staphylococcus aureus* infections related to lower skin levels of LL-37 peptide, the synthesis of which is induced by vitamin D². In AD, oral supplementation showed an improvement in disease severity indices and also a decrease in cutaneous colonisation by *Staphylococcus aureus*⁵.

PSORIASIS

Psoriasis is a chronic inflammatory skin disease whose distinctive anatomopathological features are excessive keratinocyte proliferation, abnormal keratinocyte differentiation and the presence of a major inflammatory infiltrate (Fig. 3). These are all processes in which vitamin D plays a biologically-important role¹². Numerous studies have identified an association between low serum calcifediol levels and psoriasis with a statistically significant inverse correlation between the magnitude of the deficiency and the severity of the psoriasis^{12,13}. Other studies have found a downturn in the risk of developing psoriasis with increasing serum levels of vitamin D¹⁴. Its therapeutic effect on this disease has been known for decades, with topical vitamin D analogues such as calcipotriol and calcitriol commonly used in the local treatment of psoriasis, often in combination with a corticosteroid. These drugs have the property of not only inhibiting proliferation and increasing the differentiation of keratinocytes but also modulate the immune response, acting directly on the etiopathogenesis of plaque psoriasis on several levels¹. The evidence that oral vitamin D supplementation may be of benefit to a psoriatic patient is still debated¹².

VITILIGO

Vitiligo is an acquired disease of an autoimmune nature that targets epidermal melanocytes. It manifests as achromic maculae, without melanic pigment (Fig. 4). Vitamin D₃ increases tyrosinase activity and melanogen-



FIGURE 3. Erythematous-squamous plaque with clear-cut margins in a patient with psoriasis.

esis via the nuclear hormone receptor – the vitamin D receptor in melanocytes. Tyrosinase catalyses the oxidative transformation of thyroxine into dihydroxyphenylalanine, from which melanins are then formed. It has additionally been reported that the active form of vitamin D decreases apoptotic activity in melanocytes induced by ultraviolet type B radiation. Like many other autoimmune diseases, vitiligo is also associated with low levels of vitamin D, although the mechanism behind it is not yet clear^{1,15}. A direct correlation between vitamin D deficiency and the severity and/or extent of vitiligo on the body surface has not been demonstrated. Yet, it was observed that vitamin D supplementation in patients with vitiligo with a vitamin D deficiency led to a reduction in lesion size after 6 months of treatment compared to the control, so patients who only received topical cortisone therapy. Preliminary data suggests that topical application of vitamin D analogues may exert a therapeutic effect in patients with vitiligo. Indeed, it has been observed that the additional use of topical calcipotriol or tacalcitol over NB-UVB may exert a synergistic therapeutic effect on vitiligo¹⁶.

Other possible associations between cutaneous diseases and vitamin D are being in-



FIGURE 4. Sharp-edged achromic maculae on the right thigh to be attributed to vitiligo.

vestigated, such as systemic lupus erythematosus, systemic sclerosis, alopecia areata, mycosis fungoides, polymorphous light eruption and ichthyosis¹.

CONCLUSIONS

Vitamin D plays a key role in skin health and its deficiency may contribute to the pathogenesis of some skin diseases, both neoplastic and immune-mediated¹⁴.

Exposure to the sun can certainly increase vitamin D levels but is also a risk factor and thus photoprotection remains a key element in preventing skin cancer². Sun exposure is a useful tool if used correctly, through the use of sunscreens and avoiding the resulting erythema, which is a known marker of DNA damage².

Vitamin D deficiency is associated with significantly worse overall survival in melanoma patients. Five-year survival is 90% if serum vitamin D levels exceed the 10 ng/ml threshold but drops to 84% if levels fall below the threshold.

Studies with eczemas, such as AD, are also particularly interesting because they are very

common in the adult and paediatric population. High levels of vitamin D in umbilical cord blood have been associated with a reduced prevalence of eczema at/near the age of one year¹⁷. Oral vitamin D supplementation is indicated for the correction and prevention of hypovitaminosis D in the general population and in patients with skin diseases. To date, there is no established data confirming its role in the treatment of dermatological diseases in the absence of a documented deficiency¹².

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Cholecalciferol or calcifediol? A question of narrative!

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Abstract

Over the last decade, significant progress has been made in strategies for the prevention and treatment of vitamin D deficiency thanks to clinical trials and pharmaco-kinetic studies, which have also made it possible to define the pharmacological properties of cholecalciferol and calcifediol.

Although cholecalciferol and calcifediol are often considered and used equally in clinical practice, there are a number of significant differences between them, both pharmacologically and clinically, that need to be taken into account when choosing the most appropriate strategy for treating/preventing vitamin D deficiency and for the prevention of fragility fractures.

In particular, calcifediol has recently been proposed as the drug of choice as an alternative to cholecalciferol in treating vitamin D deficiency, due to a greater potency and rapidity in normalising 25-hydroxy-vitamin D serum concentration. However, a thorough evaluation of the available evidence and in particular of randomised controlled clinical trials, confirms the primacy of cholecalciferol in the prevention and treatment of vitamin D deficiency and in the primary and secondary prevention of fragility fractures in osteoporotic individuals in combination with an antiresorptive or osteoanabolic drug. Therefore, based on current evidence, the use of calcifediol should be limited to particular situations, such as malabsorption syndromes, severe obesity or liver failure.

INTRODUCTION

Epidemiological studies describe a high prevalence of hypovitaminosis D in the general adult and elderly population that is not appropriately integrated with vitamin D supplements, particularly in at-risk sub-populations such as frail or chronically ill individuals, patients suffering from malabsorption syndrome and institutionalised subjects¹⁻³.

Vitamin D, and in particular its deficiency, plays a significant role in the pathogenesis of fragility fractures, falls and numerous acute and chronic 'extra-skeletal' clinical conditions (for example, COVID-19 and infectious diseases, rheumatological diseases, neoplasms, diabetes and cardiovascular diseases)¹⁻⁷. In this clinical-epidemiological context, as expected, growing international debate has arisen on the most appropriate therapeutic strategies for the prevention and treatment of vitamin D deficiency^{7,12}. In particular, talk has recently focused on a

specific question, namely whether it is more appropriate to use calcifediol instead of the traditionally-used cholecalciferol in the treatment of hypovitaminosis D⁹⁻¹². Numerous Randomised Controlled Trials (RCTs) and pharmaco-kinetic studies have attempted to answer this question, having broadened knowledge of the pharmacological and clinical effects of these two molecules. Although the results of the most recent studies have rendered it possible to generate significant evidence with clinical impact, the numerous limitations of the published studies (such as the choice of surrogate outcomes and the extreme heterogeneity of the dosages used) have resulted in significant confusion on the subject, resulting in a narrative that is not always appropriate.

The aim of our narrative review is to summarise some of the pharmacological and non-pharmacological characteristics of cholecalciferol and calcifediol, bringing the

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narrative back to a clinical level in order to define their role in daily clinical practice.

VITAMIN D PRODUCTION AND METABOLISM

A thorough knowledge of the physiology and metabolism of vitamin D is the essential foundation and "condicio sine qua non" for settling the question of whether it is more appropriate to use cholecalciferol or calcifediol in clinical practice.

The term vitamin D normally loosely refers to both animal- and human-produced vitamin D₃ (cholecalciferol) and plant-produced vitamin D₂ (ergocalciferol)^{1,10-12}.

The main source of vitamin D for the body should be endogenous vitamin D derived from the conversion of 7-dehydrocholesterol following exposure of the skin to ultraviolet rays of a specific wavelength. This mechanism should produce the preponderant quota (approximately 80%) of vitamin D (vitamin D₃) for the body's needs, whilst smaller amounts (approximately 20%) of vitamin D₃ and vitamin D₂ can be taken in through diet¹.

The skin's production of cholecalciferol is strongly influenced by the seasons, latitude, the characteristics of the skin exposed to the sun, the use of sunscreen and by age¹. A smaller quota of vitamin D₃ can be taken from food, in particular animal fats, whilst the quota of vitamin D₂ in vegetable fats is absolutely negligible¹. In some countries, the liberal fortification of food with cholecalciferol is stored in the adipose tissue, which releases small amounts. This is also one of the reasons why obese subjects are at a higher risk of deficiency as a result of 'dilution' in a larger adipose mass^{1,11-14}. Finally, the high fat-solubility of vitamin D also results in a prolonged functional half-life, estimated to be around 2 months¹². Vitamin D remains in the bloodstream for a short time so its blood concentrations are very low (1-2 ng/ml)¹.

To become metabolically active, vitamin D must undergo two enzymatic hydroxylation processes, which occur mainly in the liver and kidney^{1,12}. During hepatic transit, vitamin D is converted to 25-hydroxy-vitamin D [25(OH)D] by the enzyme 25-hydroxylase. The process of transformation of vitamin D into 25(OH)D can occur even in the presence of a significant reduction in functioning liver tissue, although a higher prevalence of hypovitaminosis D is evident in patients with HCV-related chronic hepatitis¹.

25(OH)D, also known as calcifediol, has a high affinity for *Vitamin D Binding Protein* (VDBP) and is the main blood metabolite of vitamin D. By far, its concentrations are the most reliable index of a subject's vitamin D status¹. Serum 25(OH)D dosage is an accurate indicator of our vitamin D deposits. Therefore, the definition of a subject's vitamin D status (deficiency, insufficiency and sufficiency) is currently based exclusively on the interpretation of serum 25(OH)D levels (Tab. I).

25(OH)D (or calcifediol) is a partially hydrophilic metabolite and is only deposited in liver and muscle¹. The half-life of 25(OH)D is shorter than that of vitamin D, such that requirements are met for no more than 12-18 days^{1,8}. 25(OH)D has a low affinity for the specific Vitamin D Receptor (VDR) and thus needs to be converted into calcitriol or 1,25-dihydroxy-vitamin D [1,25(OH)₂D], in order to become metabolically active^{1,8}. It has been estimated that calcifediol, or 25(OH)D, possesses approximately 50 times less affinity for the VDR than calcitriol or 1,25(OH)₂D¹⁵. Despite the lower affinity for the VDR, recent experimental studies have shown that calcifediol can produce genomic (stimulation of gene transcription) and non-genomic (formation of cellular second messengers, phosphorylation of certain proteins) cellular effects through binding to nuclear and/or membrane receptors¹⁵.

Conversion to 1,25(OH)₂D by 1- α -hydroxylase occurs mainly in the kidney, but also can be actuated in other tissues¹. The largest share of 1,25(OH)₂D, and that which is most relevant in the control of mineral metabolism, is produced in the renal proximal tubules. The production of 1,25(OH)₂D by

1- α -hydroxylase requires the presence of Parathyroid Hormone (PTH) and is modulated by serum levels of calcium, phosphorus and FGF23^{1,12}. 1,25(OH)₂D is not deposited in the tissue and has a very short half-life^{1,8}.

Renal insufficiency progressively reduces the production of 1,25(OH)₂D¹. However, a significant deterioration in 1- α -hydroxylase activity, such as to permitted an increased dietary vitamin D intake, facilitated increased dietary vitamin D intake, although this strategy does not always optimise vitamin D intake¹.

Vitamin D is highly fat-soluble and this fat-solubility significantly influences its pharmacological characteristics. Its absorption in the gastrointestinal tract requires the presence of bile acids and takes place via the lymphatic system^{1,12}. After entering the bloodstream, vitamin D no longer be able to ensure normal hormone levels, is only detectable in the presence of significant impairment of renal function (usually stage 4-5/5D)^{1,16}. It must be emphasised, however, that even under conditions of severe compromise of renal 1- α -hydroxylase activity, 25(OH)D levels must be kept in the normal range to ensure an adequate substrate for extra-renal 1- α -hydroxylases^{1,16}.

The 1,25(OH)₂D (active metabolite) binding to a specific receptor (VDR, which is present both in the nucleus and in the cell membrane), produces the final effect of vitamin D at a cellular level¹. This effect occurs either through the stimulation of gene transcription (genomic mechanism) or through the formation of cellular second messengers or the phosphorylation of certain proteins (non-genomic mechanism)¹. Receptors for vitamin D are ubiquitous in the body.

TABLE I.

Interpretation of serum 25(OH)D levels (from Adami et al., 2011 and Rossini et al., 2016, mod.)^{1,2}.

Definition	Unit of measurement of 25(OH)D	
	nmol/L	ng/ml
Severe deficiency	< 25	< 10
Deficiency	25-50	10-20
Insufficiency	50-75	20-30
Optimum range	75-125	30-50
Excess	> 250	> 100
Intoxication	> 375	> 150

CHOLECALCIFEROL, CALCIFEDIOL AND THE LONG-STANDING ISSUE OF NORMALISING 25(OH)D CONCENTRATION

In addition to the two natural forms of vitamin D, vitamin D₃ (cholecalciferol) and vitamin D₂ (ergocalciferol, in disuse), numerous pharmaceuticals/metabolites with vitamin D activity have become available in daily clinical practice^{1,2,8}. Some have been synthesised and used prevalently in specific areas, such as the treatment of systemic disorders of mineral metabolism in chronic kidney disease or hypoparathyroidism, and thus have no relevance to the question under review. Yet, cholecalciferol and calcifediol, as already explained, are by far the two molecules most investigated and used for correcting hypovitaminosis D and for the prevention of fragility fractures in the non-nephropathic population.

Cholecalciferol

Cholecalciferol (D₃) is the natural vitamin D compound of animal/human origin. As described, cholecalciferol is a prohormone, precursor of the two hydroxylated forms (25(OH)D and 1,25(OH)₂D) of vitamin D and thus needs to undergo two natural hydroxylation processes to be transformed into its metabolically active form^{1,8}.

Cholecalciferol is strongly lipophilic. In connection with this characteristic, gastrointestinal absorption is influenced by the presence of bile acids, occurring via the lymphatic system and can be significantly impaired in the case of malabsorption.¹² Also by virtue of its lipophilicity, cholecalciferol is normally stored in adipose tissue, where it creates deposits from which it is slowly released. Precisely for this reason, it has a rather short blood half-life (estimated T_{1/2} of 19–25 hours) but a much longer functional half-life (several weeks)⁸. The high functional half-life of cholecalciferol is one of its main strengths in clinical use, making it an extremely flexible and adaptable product in practice, allowing for intermittent administration regimes^{1,2}. Therefore, if on the one hand, high lipophilicity represents an advantage in relation to the functional half-life, on the other it can constitute a disadvantage – as mentioned – in obese subjects (high dilution) and in patients suffering from malabsorption (reduced intestinal absorption). Cholecalciferol is available in formulations

for oral and intramuscular use. With the exception of particular clinical conditions (malabsorption syndromes), oral administration is preferable due to being superior in terms of efficacy in raising serum 25(OH)D concentration compared to the intramuscular formulation^{17,18}.

In the RCTs designed to identify the most appropriate dosage and treatment regimen for normalising and maintaining optimal 25(OH)D concentration (30–50 ng/ml), cholecalciferol has been used in broadly varying dosages and administration regimens, going from doses of 400–4,000 IU per day to doses of 25,000–50,000 IU per month, also utilising therapeutic “bolus” doses of up to 600,000 IU (not recommended). In terms of increased 25(OH)D concentration, the RCTs have generally shown great heterogeneity in the response to supplementation with standard doses of cholecalciferol. This significant heterogeneity, which makes the dose-response to treatment less predictable, would appear to be linked to numerous factors (some of which are not fully elucidated), such as the basal 25(OH)D value, the Body Mass Index and factors affecting intestinal absorption and metabolism^{12–14,19,20}.

Taking into account the interfering factors illustrated and considering the results of the main RCTs, however, it can be stated that when used at appropriate dosages and treatment regimens, cholecalciferol is able to effectively normalise and maintain concentrations of 25(OH)D within the optimal/desirable range (30–50 ng/ml). For severe hypovitaminosis D (<10 ng/ml), the most appropriate approach, being broadly supported by the Italian guidelines, requires the administration of a therapeutic dose of 3,000–10,000 IU per day for 1–2 months, followed by a maintenance dose of approximately 2,000 IU per day^{1,2,21}. In subjects with less severe hypovitaminosis D and in patients who are candidates for remineralising therapy (anti-resorptive or osteoanabolic), the most recent Italian guidelines suggest daily doses (or cumulative equivalents) of between 800 IU and 2,000 IU per day (with a single maximum dose not exceeding 100,000 IU)²¹.

The main concern raised with respect to the use of cholecalciferol and the treatment regimes illustrated is the “relative slowness” of cholecalciferol in normalising 25(OH)D concentration in absolute terms and with respect to calcifediol^{11–14}. As we

shall see, this aspect is one of the main battle horses for advocates of the use of calcifediol in clinical practice. In this context, we thus feel it is important to emphasise the results of a recent RCT, published by Fassio et al., which challenged the aforementioned assumption²². The drug-kinetics study by Fassio et al.²², investigating the effect of three different cholecalciferol treatment regimens (10,000 IU per day for 8 weeks followed by 1,000 IU per day for 4 weeks; 50,000 IU per week for 12 weeks; 100,000 IU every 2 weeks for 12 weeks), showed that supplementation with 10,000 IU cholecalciferol per day for 8 weeks, followed by 1,000 IU per day for 4 weeks in healthy subjects with hypovitaminosis (baseline 25(OH)D value averaging 14 ng/ml), was able to result in achieving the target concentration of 25(OH)D >20 ng/ml in all subjects in just two weeks. Similar results have been described for the other two treatment regimens. Furthermore, after four weeks of treatment, almost all subjects had achieved a value of 25(OH)D >30 ng/ml. This treatment regimen proved to be safe since there were no cases in which the concentration of serum 25(OH)D exceeded the safety limit of 100 ng/ml (Tab. I). In conclusion, based on the evidence described, cholecalciferol must be considered as the therapy of choice in the treatment and prevention of hypovitaminosis D.

Calcifediol

Calcifediol [25(OH)D] is the hepatic metabolite of vitamin D and can roughly be said to differ from cholecalciferol due to the presence of a hydroxyl group at position C-25¹². Thus, along the vitamin D metabolism pathway, calcifediol is a step up from cholecalciferol to the biologically-active form (calcitriol)¹².

25-hydroxylation confers certain properties to calcifediol that underlie its different pharmacokinetics and pharmacodynamics, being the prerequisite for proposing it as an alternative to cholecalciferol. Being more hydrophilic, calcifediol is absorbed directly into the portal system and not through the lymphatic system, so does not undergo ‘dilution’ in adipose tissue. Furthermore, although with less affinity than calcitriol, it is able to bind to the VDR and potentially have cellular effects that are genomic (stimulation of gene transcription) and non-genomic (formation of cellular

second messengers, phosphorylation of certain proteins)¹⁵.

Therefore, calcifediol would present some strongly emphasised pharmacological and clinical advantages, which can be summed up in five points: 1) Greater rapidity and potency (compared to cholecalciferol) in increasing serum 25(OH)D concentration; 2) More linear and predictable dose-response curve compared to cholecalciferol, independent of basal 25(OH)D concentration and other factors; 3) Efficacy even in the presence of liver function impairment, due to not requiring hepatic hydroxylation; 4) Greater efficacy (compared to cholecalciferol) in obese subjects, not being sequestered from adipose tissue; 5) Greater efficacy in subjects suffering from malabsorption syndrome, in relation to the different intestinal absorption mechanism (compared to cholecalciferol)¹². Overall, these aspects – which can be summarised as the greater potency and speed of calcifediol – have been corroborated by the results of several RCTs comparing the efficacy of cholecalciferol and calcifediol in normalising serum 25(OH)D concentration in subjects with hypovitaminosis D^{9-14,23-25}.

As a whole, the studies would demonstrate that at “defined comparable” doses, calcifediol would be able to produce a faster and greater increase in 25(OH)D concentration than cholecalciferol. What's more, calcifediol would have a relative potency compared to cholecalciferol that is around 2–8 times greater. The extreme variability in the estimate of relative potency would be attributable to the doses used, the basal value of the serum 25(OH)D concentration (which can influence the cholecalciferol response) and the non-linear dose-response curve of cholecalciferol (higher 25(OH)D increase for very low basal 25(OH)D values and vice-versa)^{11,12}. Therefore, when observing the growth curves of 25(OH)D concentration during therapy with cholecalciferol and calcifediol, the greater speed and potency of calcifediol is evident. These findings were also confirmed in studies conducted in elderly or overweight/obese subjects and in patients suffering from malabsorption syndrome^{13-14,26}.

Based on these results, recent Italian guidelines have included calcifediol in therapeutic strategies for the management of hypovitaminosis D²¹. In particular, in subjects with osteomalacia or with a serum concentration of 25(OH)D <10 ng/ml, calcifediol (as

an alternative to cholecalciferol) has been suggested at a dose of 20-40 mcg per day for 20-30 days, before switching to a maintenance dose²¹. This recommendation has been proposed limited to specific conditions where a rapid normalisation of serum 25(OH)D concentration is deemed necessary. From the time of Aesop through to “The Canterbury Tales” and “The Merchant of Venice”, the proverb “*all that glitters is not gold*” has been a well-known expression that takes on particular relevance in this context.

Indeed, the interpretation of comparative studies between cholecalciferol and calcifediol deserves to be supplemented with some considerations aimed at correcting the narrative, as is also emphasised by the Italian guidelines and some literature reviews^{10,11,21}. The limited half-life of calcifediol (12-18 days as opposed to several weeks for cholecalciferol) and the fact that it is not able to lead to a repletion of vitamin D stores (depositing only in liver and muscle) may be a problem in the event of reduced adherence or persistence to treatment^{1,8}. Although there are few published studies on the negative effects of reduced adherence/persistence to treatment, a very recent study conducted in patients initially hypovitaminous with calcifediol supplementation showed that after discontinuation of calcifediol treatment, there was already evidence of a progressive and significant reduction in serum 25(OH)D concentration in the first few weeks, which restabilised to within the deficiency range between 8 and 12 months²³. In relation to hydroxylation, calcifediol is a step up from cholecalciferol and is thus partially released from the physiological control mechanisms of vitamin D metabolism^{10,21}. Although reports of intoxication (hypercalcaemia) are relatively few and mostly related to inappropriately high dosages due to intake errors, the use of calcifediol is strictly limited to defined doses and may in some circumstances require frequent monitoring of serum 25(OH)D and calcium values in order to identify intoxication and hypercalcaemia at an early stage^{10,21,27}. Based on literature data, this risk is inexistent with cholecalciferol, just as no serological monitoring is deemed necessary during treatment with vitamin D₃^{10,21}.

At a pharmacodynamic level, few studies

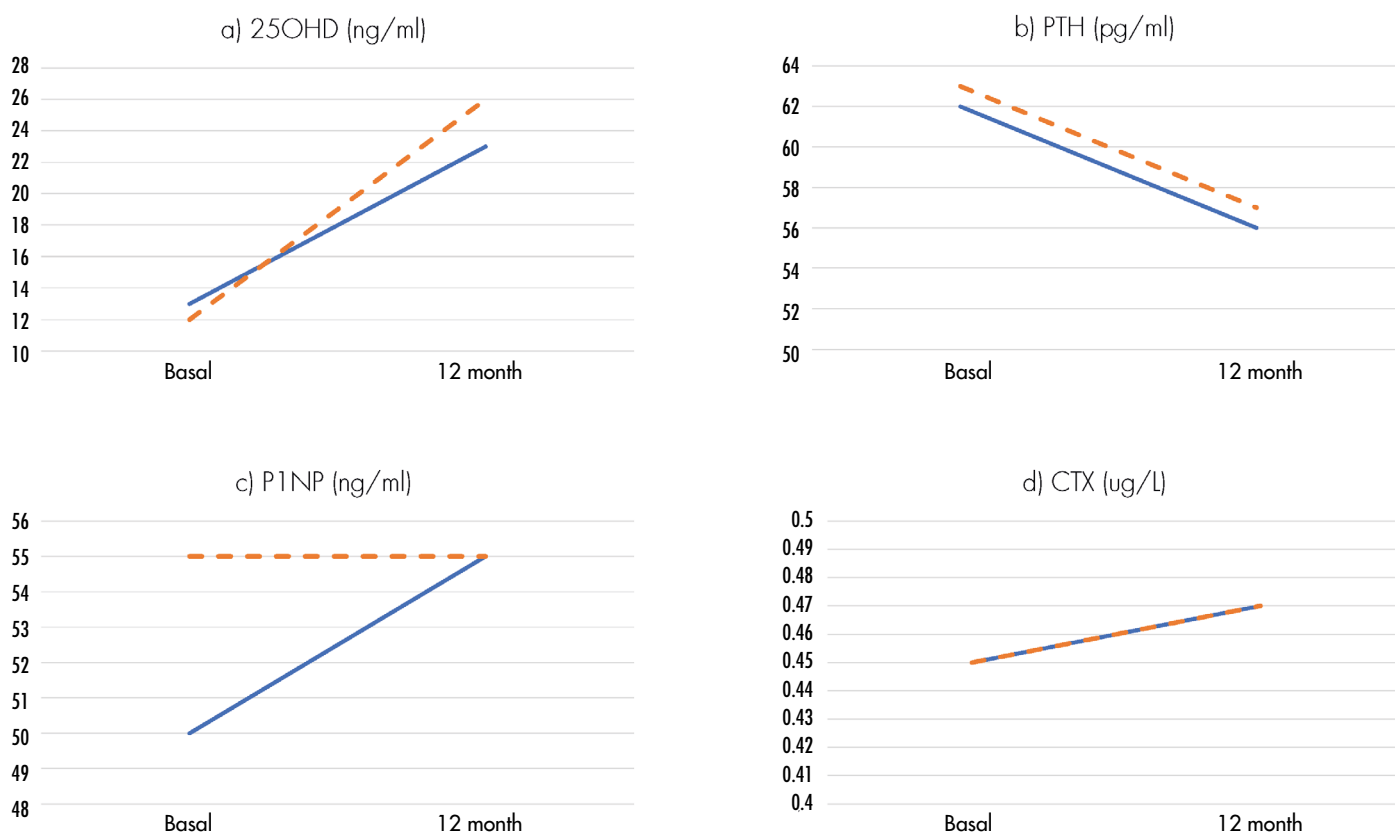
have investigated the effect of cholecalciferol and calcifediol on vitamin D metabolites, regulators of calcium and phosphorus homeostasis, markers of bone removal and inhibitors of the Wnt system²⁸. Without going into too much detail, it should be pointed out that with respect to the effects on parathyroid hormone (decrease) or bone remodelling markers, the results of the comparison studies are not univocal in establishing a superiority of calcifediol over cholecalciferol (Fig. 1)^{23,24,26}. In this context, however, the most critical issue with respect to the use of calcifediol is the absence of evidence in terms of antifracture efficacy^{10,11,21}.

CHOLECALCIFEROL AND CALCIFEDIOL IN FRACTURE PREVENTION

In the introduction to our review, we mentioned the importance of narrative in settling the matter of whether cholecalciferol is superior to calcifediol or vice-versa. Indeed, reviewing the literature makes it extremely clear that the RCTs have only focused on the certainly important outcome of normalising the serum concentration of 25(OH)D, whilst systematically failing to investigate one of the most important endpoints of vitamin D treatment, namely a reduction in the incidence of fragility fractures, not to mention the effect on falls and potential extra-skeletal impacts.

No extensive literature research is required to support the anti-fracture efficacy of cholecalciferol in at-risk, vitamin D-deficient populations when used in appropriate doses (and in combination with calcium supplementation)^{10,11,29}.

In view of overwhelming evidence in support of the anti-fracture efficacy of cholecalciferol supplementation, the contribution of the RCTs conducted with calcifediol is decidedly limited. A recent Cochrane meta-analysis, which reviewed RCTs of therapeutic intervention (fracture risk reduction) conducted with vitamin D and its metabolites, identified only two studies with calcifediol, which were deemed pertinent on the basis of the quality of the experimental design²⁹. It should be noted that in both studies, the risk of ‘bias’ could not be assessed. On the basis of the results of these two studies, it can be said that there is currently insufficient scientific evidence to support the anti-fracture efficacy of calcifediol^{29,30}. In the most recent RCT published by Peacock et al., for example, the incidence

**FIGURE 1.**

The baseline and 12-month mean value of 25(OH)D (a), PTH (b), P1NP (c) and CTX (d) concentrations in patients treated with cholecalciferol (blue solid line) or calcifediol (orange dashed line) (Pérez-Castrillón et al., 2023, mod.)²³.

of new vertebral and non-vertebral fractures was similar in subjects treated for 4 years with calcium (750 mg daily), calcifediol (15 ug daily) or a placebo³⁰.

To support the correct narrative referring to a reduction in fracture risk, what is perhaps the most relevant aspect of this narrative, namely the fact that in all of the most successful RCTs registering pharmaceuticals for fracture prevention, it should be noted that patients were supplemented with cholecalciferol (and calcium) in varying dosages. Therefore, the anti-fracturing efficacy of bisphosphonates, teriparatide, denosumab and romosozumab has been demonstrated in the presence of supplementation with cholecalciferol and calcium^{10,11,21}. It can be concluded, therefore, that robust evidence unequivocally demonstrating an effect of calcifediol on fracture reduction is lacking.

CONCLUSIONS

In conclusion, in daily clinical practice, cholecalciferol should be considered the therapy of choice in the prevention and treatment of vitamin D deficiency, as well as in the primary and secondary prevention of fragility fractures in osteoporotic individuals in combination with an anti-resorptive or osteoanabolic drug. Calcifediol may offer some advantages in terms of its possible increased speed and potency in raising and normalising serum 25(OH)D concentration, although this claim needs further investigation in view of the recent work published by Fassio et al.²². In this regard, it is also worth emphasising that the extent that this different drug-kinetics may lead to greater clinical benefits (such as a reduction in the risk of fracture) has not been clarified, in view of a lack of clinical data from RCTs.

It thus seems inappropriate, as is also stated

in the Italian guidelines, to recommend calcifediol, a drug of choice and alternative to cholecalciferol in the prevention/treatment of hypovitaminosis D and/or in the prevention of fragility fractures in osteoporotic patients in combination with an antiresorptive or osteoanabolic^{1,2,21}. As recently suggested, calcifediol may be considered as a therapy of choice in particular clinical situations such as obesity, advanced chronic hepatopathy and malabsorption syndrome^{1,2,21}.

Randomised, controlled clinical trials will be necessary to define the efficacy of calcifediol in different clinical settings, in terms of skeletal and extra-skeletal benefits.

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