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EDITORIAL

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Dear Colleagues,

The fear I expressed in my editorial for the second issue of 2019 of the Journal has unfortunately turned out to be well founded, given that there have been no occasions for an exchange with Health Board officials with regard to a cost-benefit analysis of vitamin D supplementation and for bringing operators in the health field up to date on the best ways of using it. Now, in my opinion, we run the risk that many patients will lack proper access to vitamin D treatment. As you know, faced with the exorbitant – and admittedly unjustifiable – costs for vitamin D in Italy, the national drug administration (AIFA) has indeed recently taken measures to limit prescriptions paid by the national health service (SSN) for some vitamin D-based drugs (cholecalciferol, cholecalciferol in capsules, cholecalciferol /calcium salts) for the "prevention and treatment of vitamin D deficiency in adults" (note 96, see this and future issues).

The contents of the note acknowledge the importance of vitamin D supplementation in the case of deficiency, particularly for musculoskeletal health. Yet its statements, I believe, are prone to unsure if not ambiguous interpretations, which could give rise to numerous doubts, in spite of clarifications subsequently issued by the AIFA for health workers and citizens.

The implementation of this measure will certainly reduce the costs borne by the SSN for vitamin D supplementation. Yet the Health Board will not be able to attribute these savings to an improved suitability of its use: to my mind, the note lends itself to restrictive interpretations which may negatively affect patients who should have the right to use and benefit from supplementation. Costs for the SSN may actually increase, in terms of diagnosis and above all for lack of prevention.

In my opinion, the critical parts of note 96 are as follows:

1. While recognizing that vitamin D deficiency may be asymptomatic (point 3, vitamin D chart – for citizens), its measurement is recommended only for persons with symptoms, those clearly affected by severe deficiency and above all patients with serious hypovitaminosis D complications such as osteomalacia. This recommendation seems to contradict one of the principles of the AIFA, which has always been concerned with encouraging prevention of diseases rather than the use of drugs for their treatment. Another statement, found in the measurement guidelines in Attachment 1 to the note, is likewise open to ambiguous interpretation in clinical practice: this says that determining 25(OH)D levels is not necessarily recommended in all possible risk categories. Yet does this mean that a doctor may choose to ignore those risk conditions, or, as I understand it, that in that case measuring vitamin D levels is superfluous and wasteful because it is in any case recommended for purposes of prevention?
2. Symptoms that can be attributed to hypovitaminosis D (asthenia, myalgia, diffused or localized pain, bone soreness, lumbosacral, pelvic or lower limb pain, sensory impairment, muscle weakness mainly in the quadriceps and glutes with difficulty standing up and sitting down, unsteady gait, susceptibility to falls, etc.) are varied and nonspecific. More often than not, these symptoms are attributable not to hypovitaminosis D but to many other

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conditions, some of which are more severe. Should we not believe that such a scenario might disorient doctors, leading them to overprescribe ineffective and costly doses of 25(OH)D? Should we not further imagine that unrealistic expectations will thereby be created regarding the symptomatic benefits of vitamin D supplementation, including in conditions in which a possible associated deficiency does not play a pathogenetic role?

3. The note recommends measuring 25(OH)D levels in persons with secondary hyperparathyroidism by means of a dose of parathormone (PTH), which leading international guidelines do not recommend, as it is notoriously subject to great analytic and biological variability, costly (€22) and physiopathologically altered in most elderly patients. In addition, it is known that most individuals with vitamin D deficiency do not have above average PTH concentrations.
4. The note also recommends measuring vitamin D levels in individuals affected by osteoporosis due to any cause or osteopathic diagnosed diseases that require mineralizing therapy, for which correction of hypovitaminosis should be propaedeutic for the beginning of therapy. And what about patients already undergoing therapy? And, further, why administer doses of 25(OH)D, given that even if these are above 20 ng/mL supplementation is recommended for recognized bone pathologies (as shown in the algorithm of Attachment 1)? It seems to me that the current text of the note does not clearly state what can be legitimately assumed from application of the algorithm, namely, that in all conditions of osteoporosis or of verified osteopathic diseases, including in those candidate to a mineralizing therapy, vitamin D supplementation is nonetheless recommended (as stated in note 79) and therefore reimbursed. In addition, in clinical practice, whether before or at the start of a mineralizing therapy, supplementation with higher or more generous doses of vitamin D is called for, such that measuring 25(OH)D levels is not in most cases indispensable in the clinical management of patients.
5. Given that exposure to sunlight – as has been rightly recognized – represents the principal mechanism of vitamin D production (80%), how is it that among the risk conditions for hypovitaminosis D the most frequent ones are not given? These are conditions resulting from circumstances that necessitate reduced exposure to sunlight (for example, for reasons of work, disability, cultural prohibitions or side effects linked to UVB exposure), or from those linked to an inability to produce adequate quantities of vitamin D in spite of sun exposure, such as often occurs in the elderly. It does not seem proper to limit discussion of this point to a mere acknowledgement of the risk conditions generated by long-term therapy with drugs that interfere with vitamin D metabolism or of those diseases which can result in poor absorption.
6. In my Region, testing for 25(OH)D levels in a single patient costs €17. Using cheaper pharmaceutical formulations, I can treat three patients with vitamin D for a year for this amount. Given that note 97 encourages the widespread and general usage of vitamin D – not to mention the frequent cases in which it demands it – do we not run the risk of shifting expense from prescription to diagnosis?
7. The note states that doses higher than 40 ng/ml may be associated with additional risks, among which – as is specified in the relevant clarifications – that of neoplasms. This claim is based on several reports, upon which doubt has been cast by the very source cited in the note, and which other studies have contradicted. As far as I know, so far EU regulatory agencies have not issued any alerts on the risk of oncological pathologies. In any case, exceeding the limit of 40 ng/mL can easily be caused by following commonly recommended dosages … or even by a nice sunny day. At present, this limit therefore appears to be unnecessarily alarmist, which among other things may result in doctors and patients further requesting repeated and useless tests for measuring 25(OH)D levels for fear of having exceeded them. It is known that before running the risk of the most certain side effect of vitamin D supplementation, hypercalcemia, over 100 ng/mL must be taken. In light of our current knowledge, I believe that in any case it would be more appropriate to warn of possible side effects with levels above 50 ng/mL, as stated in many guidelines.
8. The minimum threshold of 20 ng/mL of 25(OH)D is deemed sufficient in the general population, though not for some particular risk conditions: in the elderly, in patients with secondary hyperparathyroidism or in those in mineralized therapy for osteoporosis, as is in part recognized on the basis of scientific evidence in point 5 of AIFA clarifications for health workers. Some authoritative scientific societies, which are not mentioned in the background section of the note, maintain that in such conditions 25(OH)D levels above 30 ng/mL provide greater guarantees.
9. The note recommends interrupting corrective treatment once symptoms of the deficiency have disappeared, except in the case that they should resurface. But if they persist, perhaps because the conditions that expose patients to the risk of hypovitaminosis D cannot be modified, must I wait until my patient becomes ill again before treating him or her at the SSN's expense? What has happened to the appreciation for the benefits of prevention and in that sense respect for SPC recommendations for cholecalciferol?
10. All notes issued by the AIFA essentially aim to define the criteria for the reimbursement of drugs for optimal therapeutic suitability. As note 79 reminds us, prescriptions should nonetheless be written following the recommendations and warnings of the information sheets for each drug. Not only is this principle not repeated in note 96, it is even, I believe, sometimes not even respected. A possible consequence of this neglect is that it could encourage, for example, the use of some known medications even if these present side effects or are not recommended. Furthermore, Attachment 1 provides indications for the use of specific doses and not for all uses authorized by the SPC. In addition, certain studies indicate that the doses recommended in the note are insufficient for certain types of patients.
11. The note (in particular Attachment 1) recommends the need for specialist evaluation for certain conditions, such as kidney failure (I assume, by the way, that the incorrect unit of measure used for its definition is due to a typographical error); yet if fails to indicate whether there are criteria for vitamin D reimbursement in these conditions.

12. With regard now to the statement in the background section about the extra skeletal effects of vitamin D, according to which results of randomized clinical trials (RCTs) with high numbers of participants have not confirmed the hypothesis of benefits resulting from supplementation and have in particular identified areas of documented ineffectiveness in oncology and cardiology: it seems that the authors of this statement have not considered that currently available RCTs were largely conducted on non-deficient subjects and are therefore not able to exclude possible benefits in conditions of deficiency (as one could rationally expect and as has in fact been observed in some sub analyses).
And on the subject of recognized immunological effects: in this issue we feature an update from a well-known institute in Genoa on the role of vitamin D in rheumatological diseases. The authors conclude that even if the complexity of rheumatological and autoimmune diseases as well as several methodological limits of published studies significantly circumscribe the possibility of making generalizations as to the therapeutic potential of cholecalciferol in these pathologies, preliminary data from these studies, together with the safety and low cost of cholecalciferol, strongly support its use in patients affected by these diseases, considering the potential and relevant clinical benefits.

What do you think?
I hope you enjoy reading this issue.

Nota 96

Farmaci inclusi nella Nota AIFA: - colecalciferolo - colecalciferolo/Sali di calcio - calcifediolo	*La prescrizione a carico del SSN dei farmaci con indicazione "**prevenzione e trattamento della carenza di vitamina D**" nell'adulto (>18 anni) è limitata alle seguenti condizioni:* Prevenzione e trattamento della carenza di vitamina D nei seguenti scenari clinici : indipendentemente dalla determinazione della 25(OH) D • persone istituzionalizzate • donne in gravidanza o in allattamento • persone affette da osteoporosi da qualsiasi causa o osteopatie accertate non candidate a terapia remineralizzante (vedi nota 79) previa determinazione della 25(OH) D (vedi algoritmo allegato) • persone con livelli sierici di 25OHD < 20 ng/mL e sintomi attribuibili a ipovitaminosi (astenia, mialgie, dolori diffusi o localizzati, frequenti cadute immotivate) • persone con diagnosi di iperparatiroidismo secondario a ipovitaminosi D • persone affette da osteoporosi di qualsiasi causa o osteopatie accertate candidate a terapia remineralizzante per le quali la correzione dell'ipovitaminosi dovrebbe essere propedeutica all'inizio della terapia * • una terapia di lunga durata con farmaci interferenti col metabolismo della vitamina D • malattie che possono causare malassorbimento nell'adulto * Le terapie remineralizzanti dovrebbero essere iniziate dopo la correzione della ipovitaminosi D.

Per guidare la determinazione dei livelli di 25OH vitamina D e la conseguente prescrizione terapeutica è possibile fare riferimento alla flow-chart allegata.

Background

La vitamina D viene prodotta per effetto sulla cute dei raggi ultravioletti di tipo B (lunghezza d'onda 290 - 315 nm) che trasformano un precursore, il 7 deidrocolesterolo (la pro-vitamina D), in pre-vitamina D e successivamente in colecalciferolo (vitamina D3). La vitamina D può essere quindi depositata nel tessuto adiposo o trasformata a livello epatico in 25OH vitamina D (calcidiolo o calcifediolo) che, veicolata da una proteina vettrice, rappresenta il deposito circolante della vitamina D. Per esercitare la propria attività biologica il 25OH colecalciferolo deve essere trasformato in 1-25 $(OH)_2$ colecalciferolo o calcitriolo, ligando naturale per il recettore della vitamina D. La sede principale della 1-idrossilasi è il rene ma questo enzima è presente anche nelle paratiroidi, ed in altri tessuti epiteliali.

La funzione primaria del calcitriolo è di stimolare a livello intestinale l'assorbimento di calcio e fosforo, rendendoli disponibili per una corretta mineralizzazione dell'osso. In ambito clinico, esiste una generale concordanza sul fatto che la vitamina D promuova la salute dell'osso e, insieme al calcio (quando indicato), contribuisca a proteggere dalla demineralizzazione (in particolare negli anziani).

Il dosaggio della 25 OH vitamina D (25OHD) circolante è il parametro unanimemente riconosciuto come indicatore affidabile dello status vitaminico (Ross AC et al 2011, Holick MF et al 2011, Adami S et al 2011, NHS 2018, NICE 2016).
Diversi organismi scientifici hanno prodotto raccomandazioni per l'esecuzione del dosaggio della 25OHD.
I documenti sono per molti versi simili e partono dalla constatazione di base della inappropriatezza dello screening esteso alla popolazione generale (LeFevre ML et al 2015, LeBlanc EL et al 2015).
Le indicazioni all'esecuzione del dosaggio tuttavia differiscono tra i vari documenti di consenso. Esiste sostanziale concordanza sul concetto che la determinazione dei livelli di 25(OH)D dovrebbe essere eseguita solo quando risulti indispensabile nella gestione clinica del paziente (diagnostica differenziale o scelta della terapia).
Secondo i documenti prodotti da organismi regolatori, il dosaggio dovrebbe essere eseguito in un ristretto numero di pazienti con sintomi persistenti di profonda astenia, mialgie, dolori ossei diffusi o localizzati sospetti per osteomalacia o con PTH elevato o predisposizione alle cadute immotivate o in particolari condizioni di rischio (NHS 2018, NICE 2016). I documenti prodotti da Società Scientifiche riportano invece elenchi di categorie di persone a rischio di ipovitaminosi D tra le quali eseguire il prelievo; per esempio soggetti obesi includendo di fatto ampi strati della popolazione. (Cesareo R et al. AME 2018). Pare ragionevole limitare l'indagine a categorie ristrette notoriamente a rischio elevato come persone sintomatiche o chi assume cronicamente alcune categorie di farmaci (antiepilettici, glucocorticoidi, antiretrovirali, anti-micotici, colestiramina, orlistat etc.).
A scopo esemplificativo è stato elaborato un diagramma di flusso allegato.
Il valore di 25OHD pari a 20 ng/ml (50 nmol/l) è ritenuto, come supportato dalla letteratura scientifica, il limite oltre il quale viene garantito un adeguato assorbimento intestinale di calcio e il controllo dei livelli di paratormone nella quasi totalità della popolazione; per tale motivo esso rappresenta il livello sotto il quale iniziare una supplementazione (IOM 2011). L'intervallo dei valori compresi tra 20 e 40 ng/mL viene considerato come "*desirable range*" in base a motivazioni di efficacia, garantita oltre i 20 ng/mL, e sicurezza, non essendovi rischi aggiuntivi al di sotto dei 40 ng/mL (El-Hajj Fuleihan G et al. 2015).

Evidenze disponibili

L'apporto supplementare di vitamina D è uno dei temi più dibattuti in campo medico, fonte di controversie e di convinzioni tra loro anche fortemente antitetiche.
Gli studi "storici" hanno concluso in modo decisivo a favore dell'efficacia della vitamina D nella prevenzione e nel trattamento di rachitismo ed osteomalacia (Mozolowski W 1939).
Studi più recenti e le meta-analisi che li includono, depongono a favore di una modesta riduzione del rischio di frattura delle dosi di vitamina D3 > 800 UI/die (specialmente se in associazione ad un apporto di calcio >1,2 g/die). Tra i vari studi inclusi nelle meta-analisi il peso maggiore spetta a quelli realizzati in ospiti di strutture protette mentre considerando solo popolazioni non istituzionalizzate, viventi in autonomia, la riduzione di rischio legata alla somministrazione di vitamina D risulta non significativa. (Trivedi DP et al. 2003, Bischoff-Ferrari HA et al. 2005, Bischoff-Ferrari HA et al 2012, Bolland MJ et al. 2014, Zhao JG et al 2017, USPSTF 2018, Bolland MJ et al. 2018). Tale effetto protettivo sul rischio di frattura negli ospiti delle strutture protette è la spiegazione più accreditata per giustificare il lieve effetto sulla riduzione di mortalità riscontrato in una revisione Cochrane nelle persone trattate con vitamina D (Bjelakovic G, 2014).

Diversi studi osservazionali hanno riportato in varie situazioni patologiche (cardiopatie, neoplasie, malattie degenerative, metaboliche respiratorie etc.) peggiori condizioni di salute in popolazioni con bassi livelli di vitamina D, questo ha portato a valutare con opportuni studi sperimentali l'efficacia della

supplementazione con vitamina D nella riduzione del rischio di diverse patologie (soprattutto extrascheletriche). I risultati di trial clinici randomizzati (RCT) di elevata numerosità non hanno confermato tali ipotesi e hanno delineato in oncologia e cardiologia aree di documentata inefficacia della supplementazione con vitamina D (Lappe J et al. 2017, Khaw KT et al. 2017, Zittermann A et al .2017, Manson JE et al. 2019, Urashima M et al. 2019). Nonostante l'impiego di dosi relativamente elevate (2.000 UI/die e 100.000 UI/mese) le popolazioni trattate non presentavano vantaggi in termini di eventi prevenuti rispetto ai trattati col placebo.

Particolari avvertenze

Le principali prove di efficacia antifratturativa sono state conseguite utilizzando colecalciferolo che risulta essere la molecola di riferimento per tale indicazione. La documentazione clinica in questa area di impiego per gli analoghi idrossilati è molto limitata e mostra per il calcitriolo un rischio di ipercalcemia non trascurabile. (Trivedi DP et al. 2003, Bischoff-Ferrari HA et al. 2005, Bischoff-Ferrari HA et al. 2012, Avenell A et al. 2014).

L'approccio più fisiologico della supplementazione con vitamina D è quello giornaliero col quale sono stati realizzati i principali studi che ne documentano l'efficacia; tuttavia al fine di migliorare l'aderenza al trattamento il ricorso a dosi equivalenti settimanali o mensili è giustificato da un punto di vista farmacologico (Chel V et al. 2008). In fase iniziale di terapia, qualora si ritenga opportuno ricorrere alla somministrazione di dosi elevate (boli), si raccomanda che queste non superino le 100.000 UI, perché per dosi superiori si è osservato un aumento degli indici di riassorbimento osseo, ed anche un aumento paradosso delle fratture e delle cadute (Smith H et al 2007, Sanders KM et al 2010). Una volta verificato il raggiungimento di valori di normalità essi possono essere mantenuti con dosi inferiori, eventualmente anche in schemi di somministrazione intervallati con una pausa estiva. **Il controllo sistematico dei livelli di 25OH-D non è raccomandato a meno che cambino le condizioni cliniche.**

Si rappresenta infine l'importanza della segnalazione delle reazioni avverse che si verificano dopo la somministrazione dei medicinali, al fine di consentire un monitoraggio continuo del rapporto beneficio/rischio dei medicinali stessi. Agli operatori sanitari è richiesto di segnalare, in conformità con i requisiti nazionali, qualsiasi reazione avversa sospetta tramite il sistema nazionale di farmacovigilanza all'indirizzo http://www.agenziafarmaco.gov.it/it/content/modalit%C3%A0-di-segnalazione-delle-sospette-reazioni-avverse-ai-medicinali.

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Allegato 1. Guida alla misurazione della 25OHD e alla successiva prescrizione della Vitamina D

Diagramma di flusso applicabile a persone > 18 anni per la determinazione della 25OH Vit D
La flowchart non è applicabile nelle seguenti condizioni per le quali è indicata una valutazione specialistica:

- insufficienza renale (eGFR<30 mmol/L),
- urolitiasi,
- ipercalcemia,
- sarcoidosi,
- neoplasie metastatiche, linfomi,

NB: La determinazione dei livelli di 25OHD NON deve essere intesa come procedura di screening è NON è indicata obbligatoriamente in tutte le possibili categorie di rischio.

(adattato da NICE 2018)

1. Esiste almeno un sintomo persistente fra quelli elencati suggestivo per carenza di vitamina D ?
   - Sintomi di osteomalacia come dolenzia in sedi ossee o dolore (anche pulsante) lombosacrale, pelvico o agli arti inferiori; senso di impedimento fisico; dolori o debolezza muscolare (anche di grado elevato) soprattutto ai quadricipiti ed ai glutei con difficoltà ad alzarsi da seduto o andatura ondeggiante;
   - Dolori diffusi di lunga durata;
   - Propensione alle cadute immotivate.
2. È prevista una terapia di lunga durata con farmaci interferenti col metabolismo della vitamina D (ed es. antiepilettici, glucocorticoidi, anti-retrovirali, anti-micotici, colestiramina, orlistat etc.) oppure esiste una condizione di malassorbimento (ad es. fibrosi cistica, celiachia, m. Crohn, chirurgia bariatrica, etc) ?
3. Esiste una patologia ossea accertata (osteoporosi, osteomalacia o malattia di Paget) che può beneficiare dal trattamento con vitamina D oppure necessita di terapia remineralizzante?
4. Esiste un riscontro di PTH elevato con calcemia normale o bassa?

SI → È appropriata la prescrizione di una determinazione della 25(OH) D.
Nell'interpretazione dei risultati considerare che il laboratorio potrebbe NON condividere i medesimi intervalli di normalità.

NO → La determinazione della 25(OH) D, NON è appropriata.

Livelli di 25 (OH D		
0 – 12 ng/mL (0-30 nmol/L)	13-20 ng/mL (30-50 nmol/L)	>20 ng/mL (50 nmol/L)
Prescrizione di: colecalciferolo in dose cumulativa di 300.000 UI somministrabile in un periodo massimo di 12 settimane, suddivisibili in dosi giornaliere, settimanali o mensili (non oltre le 100.000 UI/dose per motivi di sicurezza)	Prescrizione di: colecalciferolo in dose giornaliera di 750-1.000 UI o in alternativa dosi corrispondenti settimanali o mensili.	Considerare altre possibili cause dei sintomi. Con l'eccezione di patologie ossee riconosciute, la supplementazione con vitamina D non è raccomandata e pertanto non rimborsata dal SSN.
Prescrizione di: calcifediolo 1cps 2 volte al mese	Prescrizione di: calcifediolo 1cps/mese	

Verifica dei livelli della 25OH D a tre mesi nel caso non vi sia risoluzione del quadro clinico di partenza

La supplementazione con vitamina D, dopo la eventuale fase intensiva iniziale di 3 mesi, prevede:
- l'interruzione del trattamento a correzione avvenuta dei sintomi da carenza salvo ricomparsa degli stessi
- la prosecuzione per tutta la durata delle terapie remineralizzanti,
- la prosecuzione per la durata delle terapie interferenti col metabolismo della vitamina D (antiepilettici etc.)
- la prosecuzione in caso di osteomalacia, osteoporosi e malattia di Paget

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VITAMIN D
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VITAMIN D AND RHEUMATIC DISEASES

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Summary

Initially postulated by epidemiological studies, the existence of a relationship between vitamin D and rheumatic diseases has been broadly confirmed by many experimental and clinical studies. In general, the literature points to both a high incidence of hypovitaminosis D in patients with inflammatory/autoimmune rheumatic diseases and a correlation between disease activity/severity and vitamin D levels. Randomized controlled studies have tested the effect of cholecalciferol supplementation (versus placebo) in patients with rheumatic diseases: these have shown significant beneficial effects on both disease activity indices and some clinical outcomes. The complexity of the inflammatory/autoimmune rheumatic diseases and some methodological limitations of published studies to a considerable extent prevent us from making generalizations about cholecalciferol's therapeutic potential in these conditions. Nevertheless, data from preliminary studies, together with the safety and the low cost of cholecalciferol, strongly support the use of cholecalciferol in patients with these diseases, given also the potential beneficial effects on the bone metabolism.

INTRODUCTION

Traditionally, the two primary functions of vitamin D are regulation of calcium and phosphorus homeostasis and control of skeletal mineral metabolism, which are commonly defined as "skeletal effects" [1-3]. In this context, the effect of vitamin D on calcium homeostasis is important not only for bone health but also for some metabolic, cellular and neuromuscular functions.

In the last thirty years, some other functions of vitamin D have emerged, such its effect on the homeostasis/metabolism of many tissues and organs. These effects are usually defined as "extra-skeletal". It has been suggested that vitamin D has a role in cellular proliferation and differentiation, on the cardiovascular system and on the modulation of the immune system as well [1-3].

These "extra-skeletal effects", originally hypothesized on the basis of evidence from animal models [4], were subsequently confirmed by several epidemiological studies [5].

However, even though multiple and significant epidemiological studies have confirmed the correlation between appropriate levels of serum 25-hydroxy-vitamin D [25(OH)D] and a lower incidence of some pathologies, data from randomized controlled studies (RCTs) are quite heterogeneous and in some cases even contradictory [5].

The aim of this review is to describe the existing relationship between vitamin D and some inflammatory/autoimmune rheumatic diseases (IRDs) and to summarize scientific findings related to the benefits of cholecalciferol supplementation in IRDs.

VITAMIN D AND THE IMMUNE SYSTEM

Clinical observations and experimental data suggest that vitamin D plays a critical role in the modulation of immune system functions (6-8). Through its active metabolite – calcitriol [1,25(OH)2D] – vitamin D indeed seems to be able to affect the activity of most immune system cells.

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Conflict of interest
The Authors declare that they have no conflicts of interest.

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Two observations support this hypothesis: [6-8]

- the vitamin D receptor (VDR) is expressed in most immune cells, including B and T lymphocytes, monocytes, macrophages and dendritic cells;
- some immune cells seem to be able to convert 25(OH)D to 1,25(OH)2D, the active metabolite that produces the final effect of vitamin D at the cellular level.

The modulatory activity of vitamin D seems to apply both to innate and adaptive immunity [6-8].

The role of vitamin D as regulator of innate immunity has been widely characterized [6-8]. Calcitriol is able to trigger the production of antimicrobial peptides from macrophages/monocytes and to increase chemotaxis, autophagy and immune system phagolysosome fusion. In addition, 1,25(OH)2D seems able to affect gut microbiota, to reduce intestinal permeability and, more generally, to "facilitate" the barrier function of tissues against pathogens [6].

Regarding the adaptive immune system, experimental data appear more heterogeneous, even while supporting an effect on the immune function [6-8]. Calcitriol seems capable of suppressing T helper 1 (Th1) activation and to modulate activity of Th2 cells (upregulation), Th17 cells (suppression) and Treg cells (function stimulation) [6]. Moreover, 1,25(OH)2D has proved to be able to reduce the proliferation and differentiation of B lymphocytes, causing less expression of autoantibodies [6-8].

In conclusion, even though available data are not always supported by solid scientific evidence, overall they seem to indicate that vitamin D may play a protective role against pathogens and in the reduction of inflammatory/autoimmune processes, phenomena that essentially require immunomodulatory action.

HYPOVITAMINOSIS D IN INFLAMMATORY/AUTOIMMUNE RHEUMATIC DISEASES

Epidemiological studies have unequivocally confirmed a high incidence of hypovitaminosis D in several IRDs. On average, patients with rheumatoid arthritis (RA), psoriatic arthritis (PA), ankylosing spondylitis (AS), systemic sclerosis (SS) and lupus (SLE) appear to have 25(OH)D values lower by at least 8-10 ng/mL compared to those of healthy control groups [9-14].

In a post-hoc analysis of the CARMA study (Fig.1) [9], the vitamin D status of 2,234 patients with RA, PA and AS was compared with that of 667 healthy subjects. Vitamin D deficiency (< 20 ng/mL) fluctuated between 40 and 41% in patients with RA, PA and AS and was found in 27% of healthy subjects (P < 0.001). These results are even more significant if we consider that the average age of the population was well below 60 years and that patients were treated with vitamin D supplements in varying percentages. In patients affected by RA – the group with the highest percentage of patients treated with cholecalciferol (42%) – the relationship between RA and hypovitaminosis D was particularly strong in the multivariate analysis as well (OR = 1.5 - 95% CI 1.1-2.0) [9].

The high incidence of hypovitaminosis D in patients with RA was clearly confirmed by a recent meta-analysis performed on 15 observational studies (1,100 RA patients and 1,000 healthy controls) [12]. The authors observed considerably lower average 25(OH)D values in RA patients compared to those in the control group and further found that deficiency was significantly higher in patients with RA (55% in RAs vs. 33% in healthy subjects; OR = 2.5 - 95% CI 1.1-5.3). Similar studies on patients with SLE or SS produced the same results [10,11,13,14].

Recently, Islam et al. conducted a review of several studies on the prevalence of hypovitaminosis D in patients with SLE [13]. In total they analyzed 34 studies (2,265 patients with SLE and 1,846 healthy subjects). The average 25(OH)D value in SLE patients was generally about 10 ng/mL lower compared to the control group. In the absence of appropriate vitamin D supplementation, the difference between SLE patients and the control group becomes particularly important in patients treated with hydroxychloroquine, corticosteroids or other immunosuppressive medications (average difference compared to healthy subjects: 16 ng/mL) [13].

Analogous results were found in another meta-analysis conducted on data regarding SS and hypovitaminosis D (6 studies, 554 SS patients and 321 healthy subjects) [14].

The standardized average difference between patients with SS and healthy subjects was about 9 ng/mL, with some variability linked to the characteristics of the SS.

HYPOVITAMINOSIS D AND INCIDENCE OF INFLAMMATORY/AUTOIMMUNE RHEUMATIC DISEASES

Even though the data described so far clearly indicate a relationship between hypovitaminosis D and some IRDs, they are unable to define a cause-effect relationship. In other words, these data do not clarify the possible pathogenetic link between prolonged 25(OH)D deficiency and disease onset.

In the case of vitamin D, it is difficult to establish a cause-effect relationship: to do so would require long-term longitudinal studies performed on the general population. In this context, then, data regarding IRDs incidence

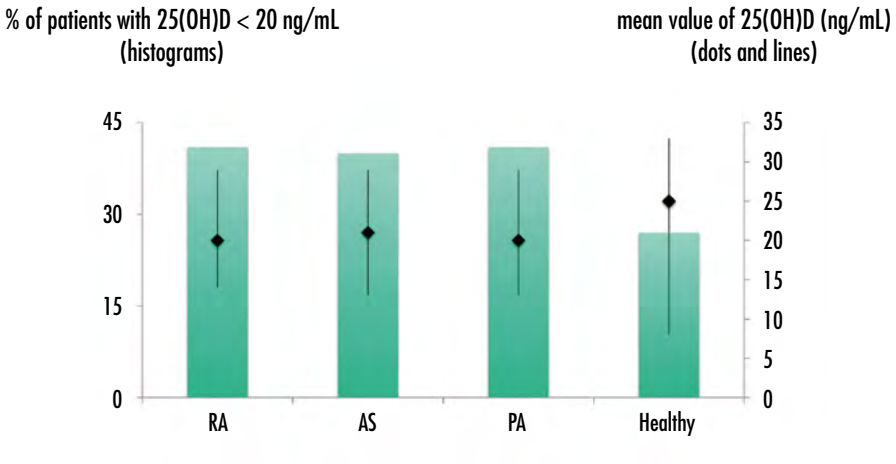

FIGURE 1.
Percentage of patients with vitamin D deficiency [25(OH)D < 20 ng/mL] (histograms) and mean value (95% CI) of 25(OH)D (ng/mL) (dots and lines) in healthy subjects and those with RA, AS and PA (CARMA study) (Urruticoechea-Arana et al., 2015) [9].

in healthy subjects as a function of either the baseline levels of 25(OH)D or of cholecalciferol intake are definitely insufficient.
Two studies have shown a correlation between exposure to UVB or intake of vitamin D3 (from food or supplements) and the risk of developing RA [15,16]. The Nurses' Health Study (NHS), conducted on a population of more than 100,000 women, showed a lower incidence of RA in subjects who had a higher cumulative average exposure to UVB compared to women who had a lower exposure (HR = 0.8, 95% CI, 0.7-0.9) [15]. These results were not confirmed in the duplicate study NHSII [15].
Results from the Iowa Women's Health Study, which investigated the incidence of RA as a function of vitamin D intake in a population of more than 29,000 women, showed that higher vitamin D intake (both via diet and supplementation) was associated with a reduced risk of RA (RR = 0.7, 95% CI, 0.4-1.0) [16].
Contrary to what has just been described, it should be noted that post-hoc analysis of these two studies and of others failed to confirm the relationship between vitamin D and RA or SLE risk [17,19]. Therefore, ad hoc studies need to be designed and carried out to further investigate the cause-effect relationship between hypovitaminosis D and IRDs occurrence.

VITAMIN D STATUS AND DISEASE ACTIVITY/SEVERITY

The existence of a relationship between vitamin D status [serum 25(OH)D] and disease activity or severity has been reported in several studies that were primarily (but not exclusively) carried out on patients with RA, SLE and SS [10-12,20-23]. Most studies that examined the relationship between 25(OH)D and disease activity in patients with RA showed an inverse correlation between vitamin D status and DAS28, VAS and/or VES [12, 20-22]. In the COMORA study, for instance, performed on 1,413 RA patients, average DAS28 values in subjects with normal vitamin D levels were considerably lower compared to subjects with hypovitaminosis D (Fig. 2) [22]. A similar relation (inverse correlation) was also found for ACPAs by Wang et al. [21].
Also for SS and SLE patients, clinical data showed an inverse correlation between 25(OH)D and disease activity or clinical outcomes (scleroderma ulcers) [10,11,23]. Regarding SS patients, for example, Caimi et al. analyzed the relationship between variation of 25(OH)D values over time and the incidence of digital ulcers in 65 SS patients. They found that a 25(OH)D reduction (in 48% of patients) during a 5-year follow-up was associated with higher risk for developing digital ulcers (OR = 16.6, 95% CI, 1.7-164.5) [11]. Another study, which investigated average 25(OH)D values as a function of disease activity measured by the SLEDAI index in 199 SLE patients, found a progressive decrease of 25(OH)D in tandem with a progressive worsening of the SLEDAI (Fig. 3) [10].

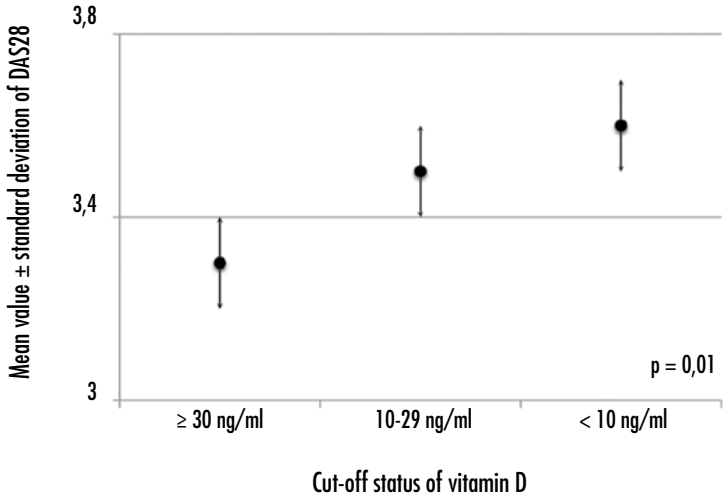

FIGURE 2.
Mean value of DAS28 ± standard deviation in patients with RA according to vitamin D status. Vitamin D cut-offs: 25(OH)D ≥ 30 ng/mL; 30 ng/mL > 25(OH)D ≥ 10 ng/mL; 25(OH)D < 10 ng/mL (Hajjaj-Hassouni et al., 2017, modified) [22].

USE OF VITAMIN D TO TREAT INFLAMMATORY/AUTOIMMUNE RHEUMATIC DISEASES

Overall, the epidemiological and clinical findings described here have opened the way toward the hypothesis that reduction of disease activity and perhaps even improved clinical results can be attained by using cholecalciferol supplementation in IRDs patients with vitamin D deficiency [7].
A recent literature review describing the main RCTs performed on patients with SLE, RA, Crohn's Disease, multiple sclerosis and type I diabetes has highlighted the therapeutic potential of cholecalciferol and its metabolites with regard to IRDs [7].
In the case of SLE patients, studies were conducted using cholecalciferol doses between 2,000 IU and roughly 7,000 IU daily for 3 to 12 months versus placebo. Two of these studies, namely that with the greatest duration (12 months) and that in which the highest doses of cholecalciferol were given (50,000 IU per week), clearly showed beneficial effects of cholecalciferol on disease activity (SLEDAI and ECLAM), on VES and on clinical symptoms. The only study which did not confirm these results was compromised by various shortcomings, such as the short period in which supplementation was given and the inclusion of patients in which the disease was not active [7].
Less solid though very promising data were obtained from RCT studies that used cholecalciferol supplementation or its metabolites in RA patients. The weakness of the data in these cases is probably due to several limitations of the RCTs (number of patients, duration of the follow-up and relatively high baseline 25(OH)D values) [7].
In general, these RCT studies highlighted positive trends regarding DAS28, VES and clinical symptoms; yet these did not achieve statistically significant results [7].
On the other hand, a more recent prospective study that administered cholecalciferol 100,000 IU per month in RA patients showed beneficial effects on VAS and DAS28 [24]. The most important point of this study is that it demonstrated different effects of cholecalciferol on DAS28 and VAS depending on baseline 25(OH)D levels: the most beneficial effects of cholecalciferol on

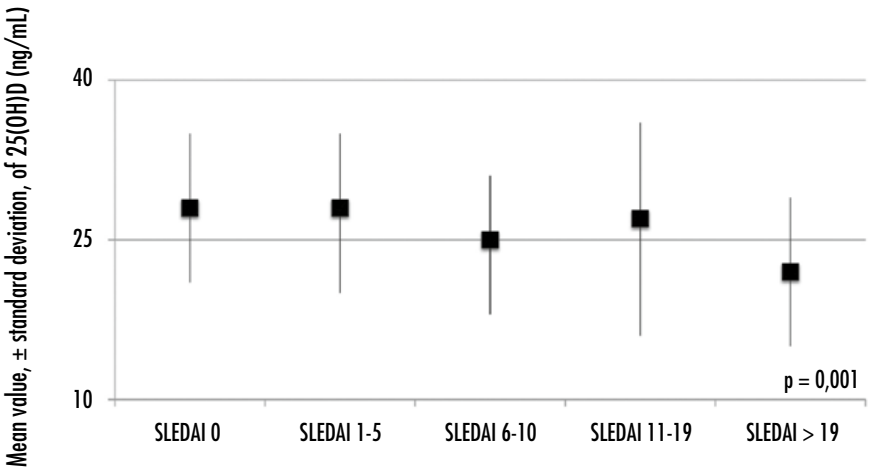

FIGURE 3.
Mean values of 25(OH)D (ng/mL ± standard deviation) in patients with SLE classified on basis of disease activity measured by SLEDAI (Eloi et al., 2017) [10].

DAS28 were found in patients with baseline 25(OH)D > 20 ng/mL, while its greatest effects on VAS were in patients with baseline 25(OH)D < 20 ng/mL [24].

CONCLUSIONS

Within the limits dictated by the complexity and heterogeneity of the IRDs, data from the literature appear to unambiguously confirm a role of vitamin D in diseases such as RA, SS and SLE. Its effect with regard to other IRDs (PA and AS) seems less clear, mainly because of the scarcity of published studies and their modest quality. It is therefore possible that vitamin D plays a relevant role in these diseases as well [20]. In general, we can state that serum 25(OH)D levels seem to influence the activity and severity of some IRDs and can possibly also have an effect on certain clinical outcomes; less clear is the cause-effect relationship in IRDs pathogenesis.

Based on data from RCTs, cholecalciferol supplementation should be offered to all patients with IRDs who do not have optimal 25(OH)D baseline values. Meanwhile, for IRDs patients with normal vitamin D values, well-designed RCTs conducted on specific populations will be necessary to determine the possible use of cholecalciferol, with the aim of improving the clinical evolution and outcome of the disease.

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