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Edizione
Pacini Editore Srl
Via Gherardesca 1 • 56121 Pisa
Tel. 050 313011 • Fax 050 3130300
Info@pacinieditore.it - www.pacinieditore.it

Divisione Pacini Editore Medicina
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Redazione
Lucia Castelli
Tel. 050 3130224 • lcastelli@pacinieditore.it

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EDITORIALE

Maurizio Rossini

Dipartimento di Medicina,
Sezione di Reumatologia, Università di Verona

Cari Lettori
in questo numero troverete due importanti aggiornamenti in tema di nuove linee guida internazionali sull'uso della vitamina D e sul ruolo di quest'ultima nei confronti di diverse malattie reumatologiche infiammatorie autoimmuni.
Nel primo articolo si sintetizzano e si rivedono criticamente le recenti raccomandazioni dell'*Endocrine Society* [1]. Noterete, secondo me, il riconoscimento di quattro principi fondamentali:

1. l'inutilità di dosare la vitamina D nella popolazione sana generale, come invece spesso oggi si fa con grande spreco di risorse del Servizio Sanitario Nazionale;
2. l'opportunità di una supplementazione (definita pertanto "empirica") in alcune condizioni, come ad esempio negli anziani sopra i 75 anni, durante la gravidanza e in adulti a rischio di prediabete, senza la necessità di una valutazione preliminare dello stato vitaminico D;
3. il riconoscimento in alcune specifiche condizioni (infanzia, gravidanza, rischio di diabete, età avanzata) di benefici extra-scheletrici della vitamina D, non solo potenziali come noto da tempo, ma reali, in termini in particolare di riduzione del rischio di infezioni delle vie respiratorie, di complicanze durante la gravidanza, di progressione a diabete e di mortalità;
4. la preferenza per la posologia giornaliera della supplementazione con vitamina D_3, che ha maggiori evidenze di garantire benefici, in particolare extra-scheletrici, probabilmente perché più vicina alla fisiologia e come giustificato dal mio gruppo in un precedente numero di questa rivista [2].

Credo che queste raccomandazioni forniscano ulteriore supporto alla necessità di una revisione della nota 96 dell'Agenzia Italiana del Farmaco [3].
Nel secondo articolo si ricordano innanzitutto i motivi per i quali la vitamina D dovrebbe avere effetti immunologici. Si documenta poi che l'ipovitaminosi D, nei pazienti affetti da malattie reumatologiche infiammatorie ed autoimmunitarie (IRDs), è altamente prevalente e significativamente più frequente rispetto alla popolazione generale, ma giustamente si riconosce che l'associazione non è necessariamente espressione di un rapporto causa-effetto. Tuttavia, gli studi prospettici osservazionali hanno evidenziato una maggiore incidenza delle più comuni IRDs nella popolazione generale esposta a ipovitaminosi D e quest'ultima sembra peggiorare l'attività e il decorso clinico della malattia, sino talora a determinare un eccesso di mortalità. Infine, recentemente è stato osservato che la supplementazione con colecalciferolo (2000 UI al giorno) riduce significativamente il rischio di sviluppare alcune IRDs.
Credo che, se si riconoscono alla vitamina D effetti immunologici, in particolare in senso antinfiammatorio e immunoregolatorio, non sia saggio escluderne la potenziale utilità nel

Corrispondenza
Maurizio Rossini
maurizio.rossini@univr.it

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prevenire e nel trattare patologie autoimmuni e che sia inopportuno non screenare ed eventualmente supplementare i carenti che ne sono affetti o che sono a rischio.

Cosa ne pensate?
Buona Lettura.

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Sintesi delle nuove raccomandazioni 2024 dell'*Endocrine Society*: supplementazione vitaminica D per la prevenzione primaria

Francesco Pollastri[1], Angelo Fassio[1]
[1] UOC Reumatologia, Verona, Italia

INTRODUZIONE

L'*Endocrine Society* (ES) ha recentemente pubblicato nuove raccomandazioni sull'uso della vitamina D nella popolazione generale per la prevenzione di diverse malattie [1], da cui emergono diversi spunti interessanti che cercheremo di sviluppare in questo articolo. Queste linee guida sono state elaborate secondo la metodologia *Grading of Recommendations, Assessment, Development, and Evaluations* (GRADE), basandosi quindi su una rigorosa revisione sistematica della letteratura e su una metanalisi che raccoglie le evidenze disponibili fino a dicembre 2023 [2]. Si tratta senza dubbio del più approfondito stato dell'arte sull'argomento finora disponibile.

Il documento licenzia quattordici raccomandazioni, che rappresentano un riassunto pratico di quanto discusso nella metanalisi e che ne sintetizzano le principali evidenze. Seguendo il metodo GRADE, ciascuna raccomandazione è stata classificata in base al livello di robustezza delle prove disponibili, espresso con un numero di simboli "⊕" (da uno a quattro) (Tab. I).

Nella metanalisi, anche alla luce delle nuove evidenze maturate negli ultimi tredici anni dalla precedente [3], la ES ha identificato cinque principali scenari in cui valutare la supplementazione empirica di vitamina D (Tabb. II, III):

1. bambini e adolescenti (1-18 anni);
2. adulti (19-74 anni);
3. anziani (≥ 75 anni);
4. donne in gravidanza;
5. soggetti con prediabete ad alto rischio.

Va sottolineato come nel presente lavoro venga sempre presa in considerazione una supplementazione "empirica" di vitamina D. Questo significa che l'uso dei supplementi viene raccomandato senza una valutazione iniziale dei livelli sierici di 25-idrossi vitamina D (25(OH)D) nel soggetto. In pratica, si somministra un dosaggio di vitamina D a prescindere dallo stato basale della persona, spesso per la prevenzione o per il trattamento di una possibile carenza. Si noti inoltre che viene raccomandato principalmente il colecalciferolo (vitamina D_3) e preferibilmente con il regime giornaliero.

La presente revisione commenterà tale documento alla luce della prospettiva degli Autori e con l'integrazione di considerazioni e punti di vista di un ulteriore documento pubblicato di recente sul giornale *Endocrine Reviews* da parte di un gruppo di lavoro internazionale di esperti sull'argomento: *Consensus Statement on Vitamin D Status Assessment and Supplementation: Whys, Whens, and Hows*[4].

IL DOSAGGIO DELLA 25(OH)D NELLA POPOLAZIONE GENERALE

In linea con le raccomandazioni italiane della Società Italiana dell'Osteoporosi, del Metabolismo Minerale e delle Malattie dello Scheletro (SIOMMMS) [5], il panel di sviluppo delle linee guida della *Endocrine Society* raccomanda di non effettuare il dosaggio sistematico del 25(OH)D nella popolazione generale sana per ben note ragioni di sostenibilità e appropriatezza prescrittiva e per questo, come detto prima, si parla sempre di "supplementazione empirica".

Una novità sostanziale rispetto al 2011 [3] è il superamento (considerando la popolazione generale sana) della definizione di "sufficienza", "insufficienza" e "deficit" di 25(OH)D. Questa scelta, potenzialmente controversa, ha spinto la stessa ES a fornire un'ulteriore giustificazione in un comunicato pubblicato a luglio 2024 [6], sostenendo questa decisione sulla base della impossibilità di stabilire una soglia ideale di 25(OH)D per definire l'adeguatezza o meno di questa vitamina nel sangue. È fondamentale ricordare, e lo faremo

Corrispondenza
Angelo Fassio
Angelo.fassio@univr.it

Conflitto di interessi
L'Autore dichiara nessun conflitto di interessi.

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Tabella I. GRADE: "grado" di certezza delle evidenze e forza delle evidenze.

Livello di evidenza	Spiegazione
Alto (⊕⊕⊕⊕)	Convinzione molto alta che l'effetto reale sia vicino all'effetto stimato.
Moderato (⊕⊕⊕◯)	Convinzione moderata nell'effetto stimato; l'effetto reale è probabilmente vicino alla stima, ma vi è la possibilità che esso sia differente da essa, anche in maniera sostanziale.
Basso (⊕⊕◯◯)	Convinzione limitata nell'effetto stimato; l'effetto reale potrebbe essere differente rispetto a quello stimato, anche in maniera sostanziale.
Molto Basso (⊕◯◯)	Convinzione scarsa nell'effetto stimato; l'effetto reale è probabilmente differente rispetto a quello stimato, anche in maniera sostanziale.

Tabella II. Vitamina D per la prevenzione delle malattie.

Età 1-18 anni	Età 19-49 anni	Età 50-74 anni	Età ≥ 75 anni	Gravidanza	Prediabete
Integrazione empirica di vitamina D*	Nessuna integrazione empirica di vitamina D*	Nessuna integrazione empirica di vitamina D*	Integrazione empirica di vitamina D*	Integrazione empirica di vitamina D*	Integrazione empirica di vitamina D*
Per prevenire il rachitismo nutrizionale e per la potenziale riduzione del rischio di infezioni delle vie respiratorie.	Seguire la Dose Giornaliera Raccomandata dell'*Institute of Medicine* (USA).	Seguire la Dose Giornaliera Raccomandata dell'*Institute of Medicine* (USA).	Per la potenziale riduzione del rischio di mortalità.	Per la potenziale riduzione del rischio di pre-eclampsia, mortalità intrauterina, parto pretermine, SGA e mortalità neonatale.	Per la potenziale riduzione del rischio di progressione a diabete.

DRI: Livelli di Assunzione Dietetica Raccomandata; RDA: Dose Giornaliera Raccomandata; SGA: *Small for Gestational Age*.

Tabella III. Sommario delle nuove raccomandazioni della *Endocrine Society* sull'uso della vitamina D nella popolazione generale.

Raccomandazione	Livello di evidenza
1. Si suggerisce, in bambini e adolescenti di età tra 1 e 18 anni, di supplementare in maniera empirica la vitamina D allo scopo di prevenire il rachitismo secondario a carenza nutrizionale e potenzialmente di ridurre il rischio di infezioni delle vie respiratorie.	2|⊕⊕◯◯
2. Nella popolazione generale adulta, più giovane di 50 anni, si suggerisce di non supplementare con vitamina D, in aggiunta alle "Assunzione Dietetica di Riferimento" per questa popolazione.	2|⊕◯◯◯
3. Nella popolazione generale adulta, più giovane di 50 anni, si suggerisce di non valutare in maniera routinaria i valori di 25(OH)D.	2|⊕◯◯◯
4. Nella popolazione generale, con una età tra i 50 e i 74 anni, si suggerisce di non supplementare in maniera routinaria la vitamina D, in aggiunta alle "Assunzione Dietetica di Riferimento" per questa popolazione.	2|⊕⊕⊕◯
5. Nella popolazione generale, con una età tra i 50 e i 74 anni, si suggerisce di non valutare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯
6. Nella popolazione generale con una età pari o superiore ai 75 anni, si suggerisce di supplementare la vitamina D in maniera empirica per la potenziale riduzione del rischio di mortalità.	2|⊕⊕⊕◯
7. Nella popolazione generale con una età pari o superiore a 75 anni, si suggerisce di non valutare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯
8. Si suggerisce di supplementare in maniera empirica la vitamina D durante la gravidanza, per il fatto che riduca il rischio di pre-eclampsia, mortalità intrauterina, nascite pretermine, SGA (*Small for Gestational Age*) e di mortalità neonatale.	2|⊕⊕◯◯
9. Durante la gravidanza, si suggerisce di non dosare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯
10. Si suggerisce, negli adulti con un elevato rischio di prediabete, di supplementare in maniera empirica la vitamina D, oltre a modificare lo stile di vita, per ridurre il rischio di progressione a diabete.	2|⊕⊕⊕◯
11. Si suggerisce, negli adulti con una età di 50 anni o maggiore, a cui è stata indicata la supplementazione di vitamina D, di farlo tramite una somministrazione giornaliera a dose ridotta, invece che attraverso una somministrazione non giornaliera e con dose più elevata.	2|⊕⊕◯◯
12. Negli adulti sani, si suggerisce di non valutare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯
13. Negli adulti con carnagione scura, si suggerisce di non valutare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯
14. Negli adulti affetti da obesità, si suggerisce di non valutare in maniera routinaria i livelli di 25(OH)D.	2|⊕◯◯◯

più volte in questo articolo, che queste raccomandazioni sono rivolte esclusivamente alla popolazione generale sana, contesto in cui tale problematica non dovrebbe nemmeno porsi: essendo soggetti sani, il dosaggio della 25(OH)D non dovrebbe proprio essere richiesto.

IL CONCETTO DI "SOGLIA" PER LA 25(OH)D: UN TEMA DIBATTUTO

È ben documentata l'esistenza di una relazione tra i livelli sierici di 25(OH)D e i suoi effetti osteometabolici. Tradizionalmente, si è ritenuto che valori ≥ 30 ng/mL potessero essere considerati indicativi di adeguata replezione. Tuttavia, da anni la validità dei vari *cut-off* proposti è oggetto di dibattito. Questo vale soprattutto per l'interpretazione dei valori compresi nella cosiddetta "zona grigia" tra 20 e 30 ng/mL[6]. Infatti, nel 2011, l'*Institute of Medicine* (IOM) e la ES divergevano in maniera evidente indicando, rispettivamente, 20 ng/mL e 30 ng/mL come livelli minimi adeguati di 25(OH)D [3,6]. Le recenti linee guida della SIOMMMS stabiliscono che nella popolazione generale sana valori < 10 ng/mL indicano carenza severa, < 20 ng/mL insufficienza, mentre livelli tra 20 e 50 ng/mL sono considerati ottimali. Diversamente, nei soggetti più fragili, il *cut-off* per l'insufficienza è stato suggerito a < 30 ng/mL. Tuttavia, anche in questo caso, viene riconosciuta l'incertezza sulla reale ricaduta clinica nei soggetti sani, motivo per cui non viene raccomandato lo screening sistematico della 25(OH)D [5].

Le nuove raccomandazioni della ES prendono quindi le distanze da quelle del 2011, evitando di definire dei livelli soglia di adeguatezza per la popolazione generale sana. L'unico valore di riferimento riconosciuto è 20 ng/mL, considerato un *cut-off* negativo, ovvero il livello minimo raggiunto dalla popolazione che assume vitamina D attraverso la dieta seguendo le indicazioni delle *Dietary Reference Intakes* (DRI).

Questi valori soglia derivano da studi incentrati sul metabolismo osseo e basati su indicatori indiretti, come i livelli di paratormone (PTH) e i marcatori di turnover osseo [6]. Risulta certo straordinariamente complesso dimostrare con precisione le possibili ricadute cliniche dei diversi *cut-off* nella popolazione generale sana, una volta che abbiamo escluso la condizione di carenza grave (< 10 ng/ml).

Inoltre, la revisione sistematica della letteratura non ha individuato alcun valore soglia di 25(OH)D ideale, nemmeno per quanto riguarda i benefici extrascheletrici della supplementazione. È possibile che questi effetti positivi possano dipendere più dall'*intake* regolare di colecalciferolo che non dal raggiungimento di specifici livelli plasmatici di 25(OH)D [7].

Come già menzionato, quindi, la ES sconsiglia il dosaggio della 25(OH)D nella popolazione generale sana, non necessario e senza una reale ricaduta clinica, oltre che costoso. Per di più un utilizzo esteso di questo test (come purtroppo spesso avviene anche in Italia) potrebbe creare disparità di accesso, penalizzando coloro che non possono permettersi l'esame e che comunque gioverebbero della supplementazione "empirica".

LE POPOLAZIONI ESCLUSE DALLE RACCOMANDAZIONI

La ES si riferisce con queste raccomandazioni per lo più alla popolazione generale sana. È pertanto importante sottolineare come queste considerazioni non possano essere applicate a pazienti con patologie associate a un alterato metabolismo della vitamina D, nei quali il dosaggio della 25(OH)D può essere invece più che giustificato, sia per la diagnosi di ipovitaminosi D che per il monitoraggio della terapia. Tra questi rientrano:

- soggetti con aumentato rischio di frattura;
- pazienti con disordini del metabolismo della vitamina D, come il malassorbimento (sindrome dell'intestino corto, bypass gastrico, malattie infiammatorie intestinali);
- individui con aumentato catabolismo o ridotta attivazione della vitamina D dovuta a terapie farmacologiche;
- pazienti con aumentata perdita renale di vitamina D, come nella sindrome nefrosica.

DETTAGLI SULLE NUOVE RACCOMANDAZIONI

Le raccomandazioni che a nostro avviso hanno le maggiori ricadute pratiche sono le seguenti:

- Raccomandazione 12 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D negli adulti sani in assenza di indicazione clinica, poiché non è stato definito un livello soglia applicabile all'intera popolazione;
- Raccomandazione 3 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D negli adulti sotto i 50 anni;
- Raccomandazione 5 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D tra i 50 e i 74 anni;
- Raccomandazione 7 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D negli over 75;
- Raccomandazione 13 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D in soggetti con carnagione scura, in quanto la relazione tra melanina e produzione di vitamina D è variabile e non predicibile nel singolo individuo;
- Raccomandazione 14 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D negli individui obesi (BMI > 30 kg/m^2), data l'assenza di trial clinici che colleghino specifici livelli di 25(OH)D a un *outcome* clinico;
- Raccomandazione 9 (2|⊕◯◯◯): sconsiglia il dosaggio della 25(OH)D nelle donne in gravidanza sane, poiché non esistono valori soglia predittivi di esiti clinici rilevanti.

GLI EFFETTI SCHELETRICI

Come noto, livelli ridotti di 25(OH)D si associano a una diminuzione dell'assorbimento intestinale di calcio e fosfato e possono contribuire allo sviluppo di ipocalcemia e ipofosforemia. Nei casi più pronunciati, questa condizione può favorire l'insorgenza di iperparatiroidismo secondario, con conseguente aumento del turnover osseo [4,8].

Negli ultimi anni, diversi mega-trial hanno indagato l'efficacia della supplementazione con vitamina D nella riduzione del rischio di fratture nella popolazione generale sana. Tra questi, spiccano lo studio *VITamin D and OmegA-3 TriaL* (VITAL), lo studio DO-HEALTH [9] e lo studio *Vitamin D Assessment* (ViDA) [10]. I risultati di queste ricerche hanno sollevato dubbi significativi sull'utilità della supplementazione ai fini della salute muscolo-scheletrica.

Sebbene le limitazioni metodologiche di questi studi siano state ampiamente discusse [11-13] e nonostante un beneficio della supplementazione con vitamina D – soprattutto se associata a calcio – sia stato evidenziato da una umbrella review pubblicata nel 2022 [14], alcuni aspetti della discussione rimangono ancora oggetto di dibattito. Analizzando la letteratura – riferita sempre alla popolazione generale sana, quindi a soggetti con basso o bassissimo rischio basale per gli eventi in questione – la ES ha

concluso che il beneficio della supplementazione con vitamina D sarebbe marginale. Tuttavia, alcuni risultati emersi dal materiale supplementare di questa revisione sistematica appaiono interessanti. In particolare, la *eFigure 2.5b* del documento stesso riporta una metanalisi di quindici studi, da cui emerge una riduzione del tasso di incidenza (IRR) delle cadute del 9% rispetto al placebo (IRR 0,91, 95% IC 0,81-0,99) [15]. Inoltre, la dimensione dell'effetto appare più marcata nella sub-analisi che ha incluso gli studi in cui la supplementazione prevedeva sia calcio che vitamina D (IRR 0,73, 95% IC 0,53-0,91) [15].

GLI EFFETTI EXTRA-SCHELETRICI

Le novità più rilevanti emerse dalla metanalisi riguardano i benefici della supplementazione sugli effetti extra-scheletrici. Va ricordato come circa il 3% del genoma dei mammiferi sia regolato dalla vitamina D. Inoltre, quasi tutte le cellule sono in grado di attivare la cascata metabolica che porta all'ormone attivo 1,25-diidrossivitamina D ($1,25(OH)_2D$) e il suo recettore (VDR) è ubiquitariamente espresso. Ad oggi, sono stati identificati oltre 10.000 geni target del VDR, di cui il 43% coinvolto nel metabolismo, il 19% nella formazione delle giunzioni cellulari e nell'adesione cellulare, il 10% nella differenziazione e nello sviluppo cellulare, il 9% nell'angiogenesi e il 5% nella transizione epitelio-mesenchimale, con azioni che includono anche la regolazione epigenomica [16]. È plausibile quindi attendersi un ruolo diretto della vitamina D nella regolazione di molteplici apparati, con delle potenziali implicazioni cliniche.

Numerosi dati indicano una correlazione tra la supplementazione con vitamina D (esclusivamente con regime giornaliero) e la riduzione della mortalità per cancro[17]. Allo stesso modo, diversi studi suggeriscono un possibile beneficio della vitamina D sulla salute cardiovascolare [18], anche se il *Finnish Vitamin D Trial* (FIND), progettato per dimostrarlo sulla base di eventi cardiovascolari maggiori, non è riuscito da solo a confermare questo effetto [19].

Più recentemente, sono emersi dati promettenti sulla prevalenza delle malattie autoimmuni. Nel trial VITAL è stata osservata nei soggetti sani, e peraltro neanche carenti, trattati con vitamina D, una riduzione dell'incidenza della comparsa di diverse patologie immuno-mediate [20]. Altri studi supportano il ruolo della vitamina D nella modulazione della risposta immunitaria, evidenziando un effetto protettivo sulle infezioni respiratorie sia nella popolazione pediatrica [2] che in quella adulta [21].

L'$1,25(OH)_2D$ possiede note proprietà antimicrobiche innate, esercitate attraverso l'induzione della β-defensina umana e della catelicidina [16], molecole con attività antimicrobica. In particolare, livelli sierici di 25(OH)D < 10 ng/mL sono stati associati a un maggiore rischio di polmoniti batteriche [22], un dato confermato anche da altri studi che rilevano un beneficio della supplementazione indipendentemente dai livelli basali di 25(OH)D. Diversi trial randomizzati e controllati (RCT) hanno evidenziato degli effetti positivi nei neonati e nei bambini in età prescolare, nei quali la supplementazione con vitamina D favorisce una guarigione più rapida dalle infezioni respiratorie e una ridotta insorgenza di sintomi respiratori [2,4].

Un'altra possibile correlazione è emersa anche nei confronti della severità dell'infezione da COVID-19. Livelli sierici ridotti di 25(OH)D sono stati associati a esiti peggiori di malattia, ad un aumentato rischio di long-COVID e ad una ridotta risposta alla vaccinazione. Allo stesso modo, livelli insufficienti di 25(OH)D sembrano essere associati a una maggiore frequenza di riacutizzazioni moderate o severe di broncopneumopatia cronica ostruttiva (BPCO) [4].

Oltre agli effetti immunomodulanti, la vitamina D sembra offrire un beneficio nei soggetti con prediabete o con predisposizione al diabete mellito di tipo 2. Questo effetto è stato recentemente confermato da una meta-analisi di tre ampi studi internazionali condotti negli Stati Uniti, in Norvegia e in Giappone, progettati per valutare il ruolo della vitamina D nella prevenzione della progressione da prediabete a diabete di tipo 2 [23].

Per ultimo consideriamo i dati molto interessanti relativi alla mortalità. Diverse metanalisi, condotte prevalentemente in soggetti di età superiore ai 70 anni, hanno evidenziato un beneficio significativo della supplementazione con la sola vitamina D_3, mentre non sono disponibili evidenze altrettanto solide per la vitamina D_2 [4]. Malgrado ciò sottolineiamo come le raccomandazioni della ES per la supplementazione negli anziani non distinguano tra vitamina D_2 e D_3 [4], come probabilmente sarebbe invece più appropriato fare.

LE RACCOMANDAZIONI SULLA SUPPLEMENTAZIONE

La ES fornisce raccomandazioni anche riguardo la supplementazione con vitamina D. In questo contesto, il termine supplementazione si riferisce sempre al concetto "empirico" e cioè all'apporto aggiuntivo di vitamina D, indipendentemente dall'assunzione alimentare, che si presume adeguata. Sulla base delle indicazioni della Commissione dell'IOM del 2011 [24], sono state stabilite per la popolazione generale le *Dietary Reference Intakes*, che includono le Raccomandazioni Nutrizionali Giornaliere (RDA) per la vitamina D. La Commissione ha considerato 20 ng/mL di 25(OH)D come valore target di sufficienza, stabilendo la dose giornaliera necessaria per mantenere questa soglia [6]. Di conseguenza, si considera che la popolazione tra 1 e 70 anni (comprese le donne in gravidanza) assuma circa 600 UI al giorno, mentre negli over 70 la dose raccomandata sale a 800 UI.

Pur partendo da questa premessa, l'ES riconosce che alcune categorie di popolazione possono beneficiare della supplementazione di vitamina D indipendentemente dai livelli basali di 25(OH)D.

RACCOMANDAZIONI CHIAVE SULLA SUPPLEMENTAZIONE CON VITAMINA D

- RACCOMANDAZIONE 1 (2|⊕⊕◯◯): si suggerisce la supplementazione empirica nei bambini e adolescenti (1-18 anni) per prevenire il rachitismo e per ridurre il rischio di infezioni respiratorie. È interessante notare che questa è l'unica raccomandazione con un outcome scheletrico. Nei vari studi considerati, il dosaggio di vitamina D varia tra 300 e 2000 UI al giorno.
- RACCOMANDAZIONE 6 (2|⊕⊕⊕◯): si suggerisce la supplementazione empirica negli anziani ≥ 75 anni, sulla base delle evidenze relative alla riduzione della mortalità per tutte le cause. Una metanalisi di 25 RCT ha stimato un effetto protettivo del 4% (riduzione del rischio relativo: 95% CI 0,90-0,99). È importante sottolineare che le evidenze a supporto di questa raccomandazione sono numerose e che l'effetto della supplementazione sembra indipendente dal livello basale di 25(OH)D. Il dosaggio di vitamina D nei vari studi varia tra 400 e 3333 UI al giorno.
- RACCOMANDAZIONE 8 (2|⊕⊕◯◯): si raccomanda la supplementazione in

gravidanza, poiché potrebbe ridurre il rischio di pre-eclampsia, mortalità intrauterina e perinatale, parto prematuro e neonati SGA (*Small for Gestational Age*). Questa raccomandazione si discosta dalle linee guida dell'Organizzazione Mondiale della Sanità (OMS) del 2016 e del 2020, che non raccomandano la supplementazione per timori di eventi avversi. Tuttavia, questi timori non trovano conferma nella revisione sistematica della letteratura. Il dosaggio di vitamina D nei diversi studi varia tra 600 e 5000 UI al giorno.

- RACCOMANDAZIONE 10 (2|⊕⊕◯): si consiglia la supplementazione nei soggetti con prediabete, per ridurre il rischio di progressione a diabete mellito di tipo 2. Anche in questo caso, la forza della raccomandazione è moderata.

COLECALCIFEROLO E SOMMINISTRAZIONE GIORNALIERA

Un aspetto particolarmente rilevante a nostro avviso riguarda la RACCOMANDAZIONE 11 (2|⊕⊕◯◯), in cui si consiglia di preferire formulazioni di vitamina D a dosaggio più basso, somministrate quotidianamente, sia per la supplementazione che per il trattamento. I benefici extra-scheletrici della vitamina D, infatti, sembrano emergere esclusivamente con la somministrazione giornaliera, senza evidenza di eventi avversi significativi.

Questa osservazione potrebbe essere spiegata dal fatto che la somministrazione quotidiana garantisce un'esposizione più costante ai composti attivi del metaboloma della vitamina D, rispetto ad altre strategie di supplementazione potenzialmente meno efficienti nel mantenere una regolazione fisiologica ottimale.

CONCLUSIONI

A cento anni dalla sua scoperta, la vitamina D continua a essere un argomento di grande interesse scientifico: solo nel 2024, su PubMed sono stati indicizzati circa 5000 articoli con vitamina D nel titolo.

Le nuove raccomandazioni della ES, a nostro avviso, segnano un cambiamento significativo nella prospettiva sulla vitamina D, ridefinendo le modalità di prescrizione e di somministrazione. L'abbandono del concetto di soglia universale per la 25(OH)D sottolinea l'inappropriatezza di uno screening di massa nella popolazione generale in assenza di chiare indicazioni cliniche. Questo spostamento di paradigma enfatizza la complessità della relazione tra salute scheletrica ed extra-scheletrica e i livelli plasmatici di 25(OH)D, un parametro difficile da modellare in maniera univoca nella popolazione generale sana a causa della presenza di numerosi fattori confondenti.

L'aspetto più interessante di queste nuove linee guida, a nostro avviso, è il maggiore focus sugli effetti extra-scheletrici della supplementazione, preferibilmente giornaliera e con colecalciferolo. Sebbene rimanga fuori discussione l'importanza di mantenere un adeguato status di vitamina D nei pazienti con patologie osteometaboliche, nelle persone sane le attuali evidenze suggeriscono che i benefici più rilevanti riguardino gli effetti extra-scheletrici, tra i quali: riduzione del rischio di infezioni respiratorie acute, prevenzione della progressione del prediabete a diabete mellito di tipo 2, riduzione delle complicanze in gravidanza, riduzione della mortalità negli anziani.

Queste considerazioni aprono nuove prospettive di ricerca, evidenziando il ruolo della vitamina D ben oltre il metabolismo osseo, con delle possibili implicazioni significative per la pratica clinica futura. Per tutto quanto finora detto, se consideriamo la popolazione sana, il problema non può e non deve più essere l'identificazione di eventuali soggetti carenti, ma al contrario il raccomandarne l'uso empirico in tutte le situazioni (ben identificate dalla ES) in cui ci siano comunque benefici clinici significativi.

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La carenza di vitamina D nelle malattie reumatiche

Andrea Giusti, Roberta Rinaldi, Federica Zoppoli, Vincenza De Iorgi, Amedeo Thneibat, Elia Maioli, Paola Modena, Guia Flego

S.C. Medicina Interna 1, Dipartimento Medico-Cardiologico, Ospedale Villa Scassi, ASL3 Genovese, Genova

Riassunto

L'ipovitaminosi D nei pazienti affetti da malattie reumatologiche infiammatorie o autoimmunitarie (IRDs) è altamente prevalente e significativamente più frequente rispetto alla popolazione generale.
Gli studi prospettici osservazionali hanno permesso di dimostrare una maggiore incidenza delle più comuni IRDs nella popolazione generale esposta all'ipovitaminosi D. Inoltre, la persistenza di uno stato vitaminico D insufficiente-deficiente sembra influenzare l'attività/severità ed il decorso clinico della malattia, interagendo con gli altri fattori prognostici negativi. Questi rilievi sembrerebbero comuni a tutte le IRDs, da quelle più frequenti come l'artrite reumatoide a quelle più "rare" ma non meno importanti come le vasculiti.
Recentemente, nel caso dei pazienti affetti da artrite reumatoide e spondilite anchilosante è stata definita anche una relazione tra ipovitaminosi D ed eccesso di mortalità.
I risultati dello studio randomizzato e controllato (RCT) VITAL, recentemente pubblicato, hanno dimostrato una minore incidenza di IRDs nei soggetti sani trattati con colecalciferolo (2000 UI al giorno) rispetto ai soggetti non trattati (placebo).
Altri RCTs, che hanno investigato l'effetto del colecalciferolo (verso placebo) in pazienti affetti da IRDs, hanno dimostrato benefici significativi della supplementazione sia sugli indici clinimetrici sia su alcuni outcomes clinici.
Sebbene la complessità delle IRDs e i limiti metodologici di alcuni studi pubblicati pongano talvolta un freno alle generalizzazioni, le evidenze disponibili, unitamente alla sicurezza e al basso costo del colecalciferolo, supportano fortemente la supplementazione con colecalciferolo nei pazienti affetti da IRDs.

INTRODUZIONE

La regolazione della omeostasi calcio-fosforo e il controllo del metabolismo minerale scheletrico sono tradizionalmente riconosciute tra le funzioni principali della vitamina D, classicamente definite "effetti scheletrici" [1-3]. Regolando l'omeostasi del calcio, la vitamina D gioca indirettamente un ruolo fondamentale anche nella regolazione di molteplici funzioni metaboliche, cellulari e neuro-muscolari, correlate direttamente ai livelli sierici di calcio.
Sebbene il riconoscimento di funzioni e di benefici "extra-scheletrici" della vitamina D risalga a più di un secolo fa – quando, per esempio, l'olio di fegato di merluzzo era impiegato per il trattamento della tubercolosi –, solo nel corso degli ultimi trent'anni sono state definite approfonditamente le funzioni della vitamina D nella omeostasi/metabolismo di numerosi tessuti e organi, che nel complesso appunto vengono qualificate come effetti "extra-scheletrici" [1-4]. Solo a titolo semplificativo (e non esaustivo), la vitamina D sembrerebbe avere un effetto sulla proliferazione e differenziazione cellulare, sul sistema cardiocircolatorio, sul sistema nervoso centrale e periferico e un effetto modulatore sul sistema immunitario [1-4]. Le evidenze sui benefici extra-scheletrici della vitamina D si basano essenzialmente sui dati derivanti da modelli animali, sulle osservazioni dei numerosi studi epidemiologici e in ultima istanza, in maniera relativamente minore, sui risultati degli studi randomizzati e controllati (RCTs).

Corrispondenza
Andrea Giusti
andreagiusti6613@gmail.com

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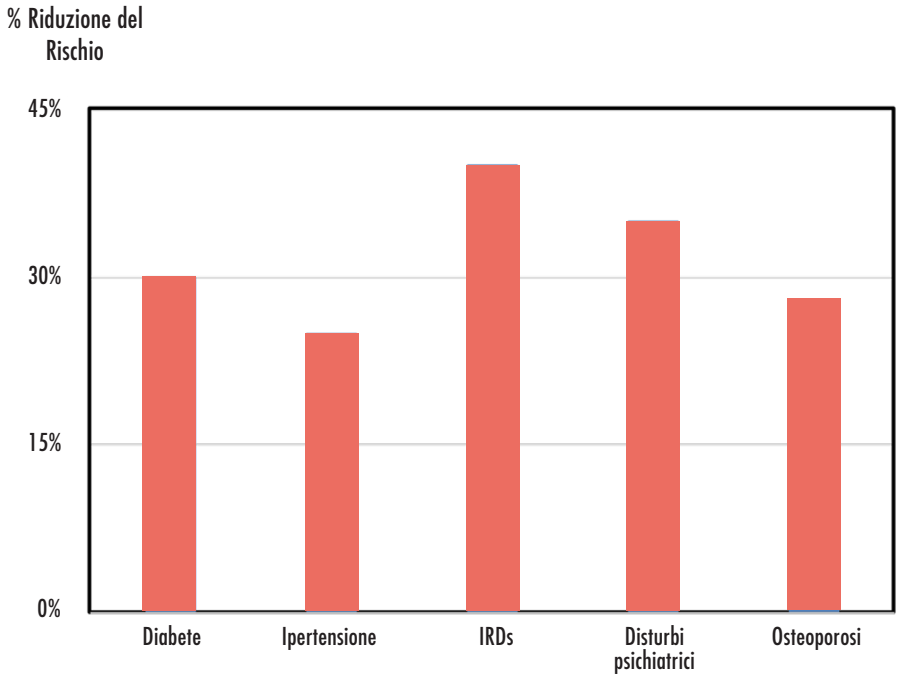

FIGURA 1.
Riduzione (%) del rischio di sviluppare malattie reumatologiche (IRDs), diabete, ipertensione, osteoporosi o disturbi psichiatrici in soggetti con livelli sierici di 25(OH)D nella norma rispetto a soggetti ipovitaminosici. I valori di *Odds Ratio* risultavano rispettivamente 1,5 per diabete, 1,3 per ipertensione, 2,0 per IRDs, 1,8 per disturbi psichiatrici e 1,6 per osteoporosi (da Dumbre et al., 2025, mod.) [7].

Complessivamente, evidenze sostanziali supportano l'esistenza di una correlazione tra il mantenimento di valori appropriati di 25-idrossivitamina D sierica [25(OH)D] e la minore incidenza e severità di alcune patologie acute e croniche [4-6].
Tra le malattie non trasmissibili, le malattie reumatologiche infiammatorie e autoimmunitarie (IRDs) sembrerebbero quelle maggiormente correlate e più fortemente influenzate dai livelli di 25(OH)D, come emerge da una recente metanalisi che ha analizzato l'impatto dello stato vitaminico D sul rischio di sviluppare cinque tipologie/categorie diverse di malattie non trasmissibili: IRDs, diabete, ipertensione, osteoporosi e disturbi psichiatrici [7]. Livelli di 25(OH)D appropriati sarebbero in grado di ridurre il rischio di IRDs, disturbi psichiatrici e diabete rispettivamente del 40%, 35% e 30% (Fig. 1).

L'obiettivo di questa revisione narrativa è quello di descrivere la relazione esistente tra la vitamina D e alcune IRDs e di riassumere le evidenze relative ai benefici della supplementazione con colecalciferolo nelle IRDs stesse.

VITAMINA D E SISTEMA IMMUNITARIO

Che la vitamina D possa essere a tutti gli effetti considerata un "potente" immunomodulatore emerge da dati sperimentali e da studi clinici, che hanno univocamente dimostrato come il suo metabolita attivo, il calcitriolo [1,25$(OH)_2$D], possa influenzare l'attività delle cellule del sistema immunitario [4,8-11]. Numerose sono le osservazioni sperimentali che supportano l'effetto immunomodulatore della vitamina D. Due rilievi meritano sicuramente di essere citati [9-11]:

- il recettore della vitamina D (VDR) è espresso dalla maggior parte delle cellule del sistema immunitario, tra cui linfociti B e T, monociti, macrofagi e cellule dendritiche;
- alcune cellule del sistema immunitario sarebbero in grado di convertire la 25(OH)D in 1,25$(OH)_2$D, il metabolita attivo che produce l'effetto finale della vitamina D a livello cellulare, agendo pertanto con modalità autocrina/paracrina nei confronti della conversione della 25(OH)D.

La funzione modulante della vitamina D riguarderebbe sia l'immunità innata che l'immunità adattativa (Tab. I) [4].
Il ruolo della vitamina D quale regolatore dell'immunità innata è stato ampiamente caratterizzato [4,9-11]. Il calcitriolo è in grado di stimolare la produzione di peptidi antimicrobici da parte dei macrofagi/monociti e di incrementare la chemiotassi, l'autofagia e la fusione fagolisosomiale delle cellule del sistema immunitario. Il 1,25$(OH)_2$D sarebbe in grado anche di influenzare la composizione del microbiota intestinale, di ridurre la permeabilità intestinale e, più in generale, di "facilitare" la funzione di barriera dei tessuti contro i patogeni [9-11]. La vitamina D sarebbe inoltre responsabile di una riduzione della maturazione delle cellule dendritiche e della presentazione antigenica [4].
Per quanto riguarda il sistema immunitario adattativo, i dati sperimentali appaiono più eterogenei, pur supportando un effetto modulante anche rispetto alla funzione immunitaria adattativa [9-11]. Il calcitriolo sarebbe in grado di sopprimere l'attivazione dei T helper 1 (Th1) e di modulare l'attività delle cellule Th2 (upregolazione), Th17 (soppressione) e T-regs (stimolazione della funzione) [9-11]. Questi effetti si tradurrebbero direttamente in una riduzione delle citochine Th1, in un incremento delle citochine Th2, in una riduzione della differenziazione dei Th17 e in un incremento della differenziazione dei T-regs [4].
Il 1,25$(OH)_2$D ha infine dimostrato di ridurre la proliferazione e la differenziazione dei linfociti B e di inibire la secrezione di immunoglobuline, determinando anche una minore espressione di auto-anticorpi [4,9-11].
In conclusione, è quindi evidente come se da un lato la vitamina D gioca un ruolo rilevante nella difesa contro agenti patogeni, dall'altro è implicata significativamente nella riduzione dei

TABELLA I.
Principali effetti della vitamina D sull'immunità innata e adattativa (da Giannini et al., 2022, mod.) [4].

Funzione/Cellula	Effetto
Immunità innata	
Differenziazione macrofagica	Incrementata
Funzione battericida	Incrementata
Maturazione delle cellule dendritiche	Ridotta
Presentazione antigenica	Ridotta
Immunità adattativa	
Citochine Th1	Ridotte
Citochine Th2	Incrementate
Differenziazione Th17	Ridotta
Differenziazione T-regs	Incrementata
Proliferazione linfociti B	Ridotta
Secrezione immunoglobuline linfociti B	Ridotta

processi autoinfiammatori e autoimmunitari dell'organismo, attraverso un'azione immunomodulante.

PREVALENZA DI IPOVITAMINOSI D NELLE MALATTIE REUMATOLOGICHE INFIAMMATORIE E AUTOIMMUNITARIE

Gli studi epidemiologici hanno sistematicamente confermato un'elevata prevalenza di ipovitaminosi D nelle cinque principali IRDs [artrite reumatoide (AR), artrite psoriasica (APs), spondilite anchilosante (SpA), sclerosi sistemica (SSc), e lupus (LES)], con valori medi di 25(OH)D mediamente inferiori di 8-16 ng/ml rispetto a controlli sani [12-17]. Per esempio, lo studio CARMA (Fig. 2) [12], che ha analizzato lo stato vitaminico D di 2234 pazienti affetti da AR, APs e SpA e di 667 soggetti sani, ha dimostrato una prevalenza di deficienza di vitamina D (<20 ng/ml) di circa il 40% nei pazienti affetti da IRDs, a fronte di una significativamente minore prevalenza (27%) nei soggetti sani.
I dati derivati dalla coorte ESPOIR [18] hanno confermato l'elevata prevalenza di ipovitaminosi D nei pazienti affetti da AR, evidenziando una prevalenza di severa deficienza (<10 ng/ml) pari al 18% e una prevalenza combinata di insufficienza-deficienza (<30 ng/ml) pari al 82%. Questi dati appaiono particolarmente significativi se si considera che l'età media della coorte era di 49 anni. L'elevata prevalenza di ipovitaminosi D nei soggetti affetti da AR è stata definitivamente avvalorata da una metanalisi condotta su 15 studi osservazionali (1100 AR e 1000 controlli sani), che ha evidenziato una prevalenza del 55% nei pazienti affetti da AR contro una prevalenza del 33% nei soggetti sani [*Odds Ratio* (OR) 2,5; 95% *Confidence Interval* (95% CI) 1,1-5,3] [15].
Studi analoghi, condotti in pazienti con APs, LES o SSc, hanno portato alle stesse conclusioni [13,14,16,17,19,20]. Rotondo et al. hanno descritto, in una corte di 233 pazienti affetti da APs, una prevalenza di deficienza (<20 ng/ml) pari al 39%, che incrementava al 65% nei soggetti con interessamento assiale, ed una prevalenza combinata insufficienza-deficienza pari al 64% [19]. In una recente metanalisi condotta su quattro studi, che complessivamente avevano arruolato 264 pazienti APs e 287 soggetti sani, i valori medi di 25(OH)D risultavano significativamente ridotti nei pazienti APs rispetto ai controlli: differenza media -6,4 ng/ml (95% CI -8,31, -4,53) [20].
Coerentemente, revisioni sistematiche della letteratura e metanalisi che hanno confrontato soggetti affetti da LES o SSc con soggetti sani hanno confermato come il valore medio della 25(OH)D nei primi fosse mediamente inferiore di 9-16 ng/ml rispetto ai controlli sani, con una certa variabilità legata alle caratteristiche specifiche dei pazienti [16,17]:

- LES – 34 studi con 2265 LES e 1846 controlli: differenza media pari a 10 ng/ml (in assenza di supplementazione con vitamina D la differenza media era pari a 16 ng/ml) [16];
- SSc – 6 studi con 554 SSc e 321 controlli sani: differenza media pari a 9 ng/ml [17].

È interessante osservare come più recentemente l'attenzione alla relazione tra vitamina D e IRDs si sia estesa anche ad altre IRDs, relativamente più "rare" sebbene non meno importanti (es. vasculiti e polimialgia reumatica) [21-24]. In questo contesto vale la pena citare il lavoro recentemente pubblicato da Korkmaz et al., che ha analizzato i valori medi di 25(OH)D in pazienti affetti da vasculite sistemica (VS) dei piccoli-medi vasi, in pazienti affetti da AR e in soggetti sani [22]. I pazienti VS presentavano una prevalenza di deficienza (<20 ng/ml) o insufficienza-deficienza (<30 ng/ml) significativamente superiore rispetto ai sani: 25(OH)D <20 ng/ml 51% (VS) *versus* 22% (sani); 25(OH)D <30 ng/ml 75% (VS) *versus* 34% (sani). Nei pazienti AR la prevalenza risultava sovrapponibile ai pazienti VS. Se invece si analizzavano i valori medi di 25(OH)D nei tre gruppi, si rilevavano valori di 25(OH)D sovrapponibili nei pazienti VS e AR, che risultavano significativamente inferiori rispetto ai soggetti sani, con una differenza media di circa 12 ng/ml. Non sono pochi gli studi che hanno evidenziato

un'elevata prevalenza di ipovitaminosi D nelle vasculiti, dimostrando come questo reperto sia comune a tutte le vasculiti esaminate (incluse per esempio Takayasu, Behcet, ANCA-associate) [22-24].
In conclusione, questa breve revisione narrativa della letteratura sembra confermare come l'ipovitaminosi D sia un reperto comune in tutte le IRDs e come l'entità di questa deficienza (rispetto ai soggetti sani) sia assolutamente simile tra le varie IRDs.

IPOVITAMINOSI D E INCIDENZA DI MALATTIE REUMATOLOGICHE INFIAMMATORIE E AUTOIMMUNITARIE

I dati fino ad ora descritti, pur identificando chiaramente una relazione tra ipovitaminosi D e IRDs, non sono in grado di definire un rapporto causa-effetto. In altre parole, non chiariscono l'eventuale nesso patogenetico tra una prolungata esposizione a ridotte concentrazioni di 25(OH)D e l'insorgenza della malattia.
Dimostrare un rapporto causa-effetto nel caso della vitamina D non è semplice, in quanto richiede degli studi longitudinali a lungo termine condotti sulla popolazione generale. In questo contesto, un certo numero di studi prospettici osservazionali e un RCT (descritto successivamente con gli studi di intervento terapeutico) hanno valutato l'incidenza di IRDs nella popolazione sana, in funzione dei valori basali di 25(OH)D o dell'*intake* (alimentazione ed esposizione ai raggi UVB) di colecalciferolo.
Due studi osservazionali hanno dimostrato una correlazione tra esposizione ai raggi UVB o *intake* di vitamina D_3 (alimentare o con supplementi) e il rischio di sviluppare AR [25,26]. Lo studio *Nurses' Health Study* (NHS), condotto su una popolazione di più di 100 mila donne, ha dimostrato una minore incidenza di AR nei soggetti con maggiore esposizione cumulativa media agli UVB rispetto alle donne con la minore esposizione [*Hazard Ratio* (HR) 0,8; 95% CI 0,7-0,9] [25]. Questi risultati non sono stati confermati nello studio gemello NHSII [25].
Il *Iowa Women's Health Study* (IWH), analizzando l'incidenza di AR in funzione dell'*intake* di vitamina D in una popolazione di più di 29.000 donne, ha evidenziato come un maggiore *intake* di vitamina D (sia attraverso la dieta sia attraverso la supplementazione) fosse associato ad un ridotto rischio di AR [*Relative Risk* (RR) 0,7; 95% CI 0,4-1,0] [26].
I dati del NHS e IWH sulla AR sono stati confermati da uno studio prospettico *population-based* che ha descritto, su 12.555 individui con valutazione basale della 25(OH)D e monitorati per un tempo medio di 10,8 anni, una riduzione del rischio relativo di sviluppate una IRDs incidente nei soggetti con più elevata 25(OH)D: per un incremento di 10 ng/ml HR 0,94 (95% CI 0,90-0,98) [27].
Complessivamente, analizzando anche i report con risultati negativi, si può sostenere l'esistenza di un rapporto di causa-effetto tra prolungata esposizione a ridotti livelli di 25(OH)D e incidenza di IRDs nella popolazione generale [25-32]. Poiché il livello delle evidenze risulta più solido e significativo per l'artrite reumatoide rispetto

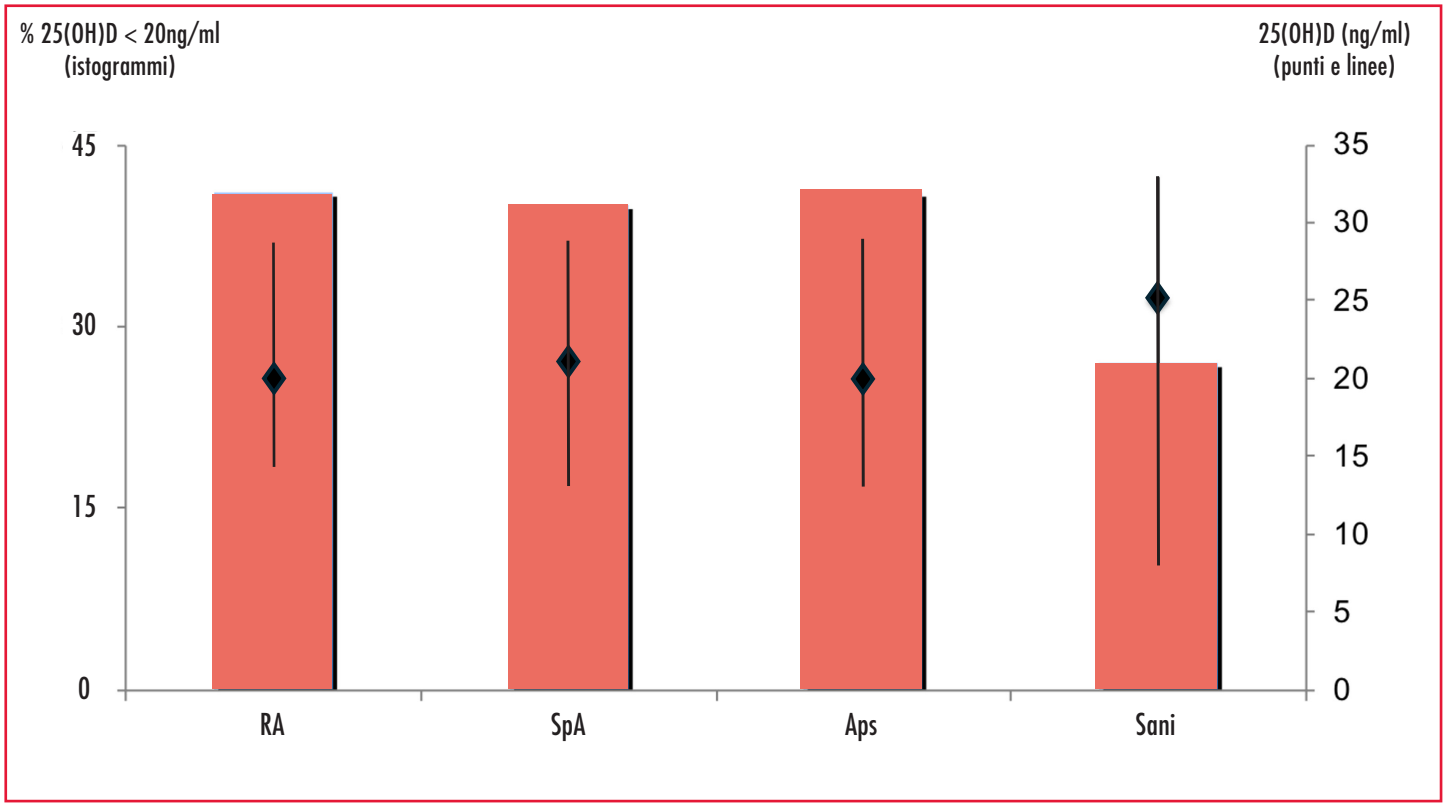

FIGURA 2.
Percentuale di pazienti con deficienza [25(OH)D <20 ng/ml] di vitamina D (istogrammi) e valore medio di 25(OH)D (ng/ml) ± deviazione standard (punti e linee) in soggetti sani e affetti da AR, SpA e APs – studio CARMA (da Urruticoechea-Arana et al., 2015, mod.) [12].

ad altre IRDs, nuovi studi disegnati *ad hoc* dovranno approfondire il rapporto causa-effetto tra l'ipovitaminosi D e l'incidenza di IRDs, per patologie quali il LES, APs, SSc, SpA e vasculiti.

STATO VITAMINICO D E ATTIVITÀ/SEVERITÀ DI MALATTIA

L'esistenza di una relazione tra lo stato vitaminico D [25(OH)D] e l'attività/severità di malattia è stata documentata in numerosi studi condotti prevalentemente (ma non solo) in pazienti affetti da AR, LES e SSc, e non è pertanto più considerabile oggetto di controversia, stante l'omogeneità dei risultati publicati [13,14,32-36].

Per quanto riguarda i pazienti con AR, le evidenze depongono per una correlazione inversa tra stato vitaminico D e indicatori di severità/attività di malattia quali DAS28, VAS, VES e ACPA, come emerge dallo studio COMORA (1413 pazienti) e da un altro lavoro pubblicato da Wang et al. [33-34].

I dati (già descritti) della coorte ESPOIR hanno confermato come nei pazienti con AR la presenza di una severa deficienza di 25(OH)D (<10 ng/ml) sia associata ad una maggiore attività/severità di malattia alla valutazione basale, dimostrando inoltre *outcomes* funzionali e di progressione radiografica peggiori nei pazienti con 25(OH)D <10 ng/ml [18]. I dati delle analisi multivariate evidenziavano infatti un maggior rischio di disabilità a sei mesi (HAQ-DI score ≥0,5 – OR 1,70; 95% CI 1,05-2,75) e progressione radiologica a 12 mesi (progressione mTSS – OR 1,76; 95% CI 1,01-3,06) nei pazienti AR con 25(OH)D inferiore a 10 ng/ml rispetto ai soggetti con valori superiori. Questi risultati sembrerebbero in parte convalidati anche nei pazienti con *early* RA [36].

Anche nel caso della SSc, della SpA e del LES i dati clinici depongono per una correlazione inversa tra 25(OH)D e attività di malattia o *outcomes* clinici (es. ulcere sclerodermiche, interstiziopatia polmonare e indici clinimetrici) [13,14,35-40]. Nel caso della SSc, per esempio, Caimmi et al. hanno analizzato la relazione tra la variazione del valore di 25(OH)D nel corso del tempo e l'incidenza di ulcere digitali in 65 pazienti SSc, dimostrando come una riduzione della 25(OH)D (48% dei pazienti) nel corso dei 5 anni di *follow-up* fosse associata ad un maggior rischio di sviluppare ulcere digitali (OR 16,6 – 95% CI 1,7-164,5) [14]. Questi risultati sono stati confermati in almeno un altro studio [37]. In termini più generali la letteratura sembrerebbe suggerire come lo stato vitaminico D (unitamente ad altre variabili prognostiche) sia in grado di avere un impatto sul fenotipo nei pazienti SSc [37]. Nello specifico soggetti affetti da SSc ipovitaminosici D presenterebbero una malattia più aggressiva, con coinvolgimento multiorgano più severo, specialmente a livello polmonare e cardiaco [37,38].

Una recente revisione sistematica della letteratura con metanalisi ha portato alla conclusione che anche nel caso del LES lo stato vitaminico D è inversamente correlato con l'attività/severità di malattia [39]. Per esempio, confrontando il valore medio di 25(OH)D in funzione dell'attività di malattia misurata con SLEDAI in 199 pazienti LES, Eloi et al. hanno evidenziato un progressivo peggioramento dello

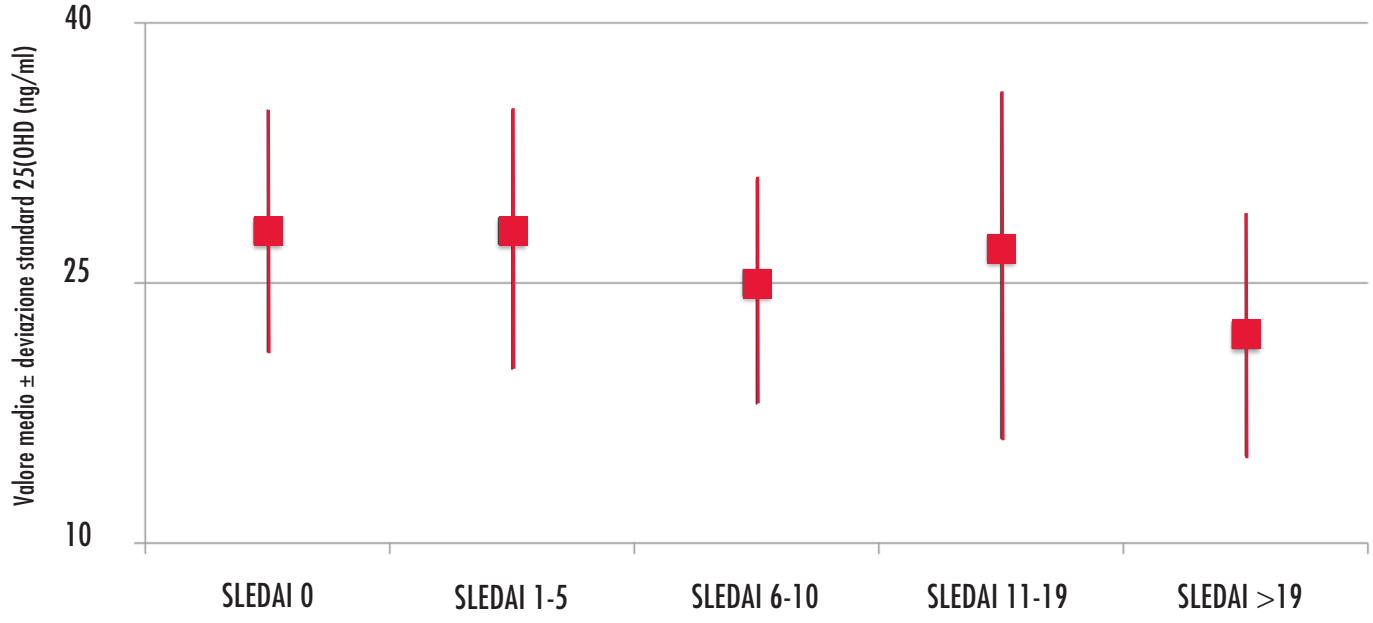

FIGURA 3.
Valori medi di 25(OH)D (ng/ml ± deviazione standard) in pazienti affetti da LES categorizzati sulla base dell'attività di malattia misurata con SLEDAI (da Eloi et al., 2017, mod.) [13].

SLEDAI con il progressivo decremento della 25(OH)D (Fig. 3) [13].
Sebbene meno numerosi, anche nel caso della SpA la deficienza di vitamina D si è dimostrata avere un effetto sfavorevole sull'attività di malattia, sulla disabilità, sulla severità radiografia e, non meno importante, sulla massa ossea [40].
Nel loro complesso, le evidenze descritte, coerenti con i dati sperimentali sull'effetto immunomodulante della vitamina D, definiscono l'esistenza di una relazione/interazione tra 25(OH)D e attività/severità di malattia nei pazienti con IRDs, indipendente dai fattori prognostici e di rischio più comunemente accettati.

STATO VITAMINICO D E MORTALITÀ NELLE MALATTIE REUMATOLOGICHE INFIAMMATORIE E AUTOIMMUNITARIE

L'esistenza di una relazione tra ipovitaminosi D e mortalità nella popolazione generale e nei soggetti con malattie croniche è ormai accertata da più di vent'anni [6,41]. Sono tuttavia recentissime le evidenze che confermano questa relazione anche nei pazienti affetti da IRDs, ed in particolare nei soggetti con AR [42-46]. Due lavori estremamente significativi [42,43], che hanno analizzato la relazione tra 25(OH)D e mortalità nei pazienti AR utilizzando i dati del *National Health and Nutrition Examination Survey* (più noto come NHANES), sono arrivati alle stesse conclusioni: l'ipovitaminosi D aumenta il rischio di mortalità, mortalità per cause cardiovascolari e mortalità per neoplasia nei pazienti affetti da AR, e questo effetto sarebbe particolarmente significativo nei soggetti di età superiore ai 60 anni e in quelli con fattori di rischio per malattie cardiovascolari (BMI, ipertensione e diabete). L'impatto di questi risultati nella pratica clinica è particolarmente rilevante se si considera che le due analisi hanno permesso di definire il valore limite di 25(OH)D al di sopra del quale si hanno benefici sulla mortalità (in termini di riduzione), stimato tra 20 ng/ml e 25 ng/ml. L'analisi dei dati NHANES è stata ulteriormente avvalorata da un grosso studio condotto su un database di origine diversa (*UK Biobank*, Gran Bretagna).
Analoghi risultati sono stati descritti anche nella SpA. In un'analisi retrospettica di una coorte israeliana è stata dimostrata una relazione tra valori di 25(OH)D <30 ng/ml e la mortalità nei pazienti affetti da SA, con un effetto proporzionale al grado di ipovitaminosi D e più spiccato nei soggetti di genere maschile [46].
Sebbene siano decisamente meno rilevanti le evidenze su altre IRDs, indirettamente un effetto della vitamina D sulla mortalità nella SSc o nel LES dovrebbe essere atteso in considerazione del rapporto tra ipovitaminosi D e complicanze internistiche in queste popolazioni, precedentemente descritto.

SUPPLEMENTAZIONE CON VITAMINA D NELLE MALATTIE REUMATOLOGICHE INFIAMMATORIE E AUTOIMMUNITARIE

Nel complesso, le evidenze epidemiologiche e cliniche descritte hanno aperto la strada verso l'ipotesi di poter ridurre l'attività di malattia ed eventualmente migliorare gli *outcomes* clinici attraverso la supplementazione con colecalciferolo in pazienti con deficienza di vitamina D affetti da IRDs [10]. I dati osservazionali prospettici (popolazione generale), così come per altre patologie croniche non trasmissibili, hanno inoltre ammesso la possibilità di ridurre la stessa incidenza delle IRDs nella popolazione sana attraverso dei protocolli di supplementazione [6,7].
Il potenziale terapeutico del colecalciferolo e dei suoi metaboliti nelle IRDs è stato investigato in un certo numero di RCTs, oggetto di una recente revisione [10].
Nel caso del LES, sono state testate verso placebo dosi di colecalciferolo comprese tra 2000 UI e circa 7000 UI al giorno, in studi della durata compresa tra 3 mesi e 12 mesi condotti in pazienti con ipovitaminosi D. Due di questi studi – ed in particolare quello di durata più lunga (12 mesi) e quello con la dose cumulativa giornaliera di colecalciferolo più elevata (50.000 UI a settimana) – hanno chiaramente evidenziato un effetto benefico del colecalciferolo sull'attività di malattia (SLEDAI e ECLAM), sulla VES e sui sintomi clinici. L'unico studio che non ha confermato questi dati presentava numerose criticità, tra cui la breve durata della supplementazione e l'inclusione di pazienti con malattia non attiva [10].
I dati conclusivi dei primi RCTs condotti in pazienti affetti da AR sono risultati meno solidi, benché estremamente incoraggianti, probabilmente anche in relazione ai numerosi limiti degli RCTs (numerosità dei pazienti, durata del *follow-up* e AR in remissione in uno studio) [10]. In generale, questi RCTs, condotti in pazienti affetti da AR che presentavano ipovitaminosi D, hanno evidenziato un trend positivo su parametri quali il DAS28, la VES e i sintomi clinici, che tuttavia non raggiungeva la significatività statistica [10].
Più recentemente, tuttavia, uno studio prospettico di supplementazione con 100.000 UI di colecalciferolo al mese in pazienti AR ha evidenziato un effetto benefico sulla VAS e sul DAS28 [47]. Uno degli aspetti più rilevanti di questo studio è la dimostrazione di effetti differenti del colecalciferolo sul DAS28 e sulla VAS in funzione del valore basale della 25(OH)D: maggiori benefici del colecalciferolo sul DAS28 nei pazienti con 25(OH)D basale >20 ng/ml e maggiori benefici del colecalciferolo sulla VAS nei pazienti con 25(OH)D basale <20 ng/ml [47].
Un supporto all'interpretazione dei risultati degli studi di supplementazione nella AR arriva da una recente metanalisi, che ha confermato l'importanza della dose e della durata della terapia sull'effetto benefico del colecalciferolo nei pazienti con AR: VAS e DAS28 dimostravano di migliorare nei soggetti trattati con colecalciferolo (rispetto a quelli non trattati) con dosi più elevate e per più lungo tempo [48].
La pubblicazione nel 2022 dei dati dello studio VITAL ha spazzato via ogni dubbio e controversia circa l'effetto benefico della supplementazione con colecalciferolo (2000 UI al giorno) nelle malattie autoimmunitarie [49]. Il VITAL è sicuramente il più grande RCT pubblicato sull'argomento, avendo arruolato 25.871 soggetti monitorati per circa 5 anni. Obiettivo dell'analisi, in questo caso, era valutare l'impatto della supplementazione con vitamina D sull'incidenza di IRDs nella popolazione generale. In questo caso i pazienti arruolati non sono stati selezionati in funzione della carenza di vitamina D e la maggioranza presentava un valore di vitamina D nella norma. I risultati dello studio hanno permesso di dimostrare come la supplementazione di colecalciferolo fosse in grado di ridurre del 22% l'incidenza di malattie autoimmunitarie [49]. L'effetto risultava ancora più significativo e rilevante (39%) quando si escludevano dall'analisi i primi due anni di *follow-up* (per ovvi motivi di plausibilità biologica) [49].

CONCLUSIONI

Con i limiti dovuti alla complessità ed eterogeneità delle IRDs, i dati della letteratura sembrerebbero confermare in maniera univoca un ruolo della vitamina D (patogenesi, severità e *outcomes*) in malattie quali AR, SSc, LES, APs, SpA.

Il significato della vitamina D in altre IRDs (es. vasculiti) sarebbe meno chiaro, prevalentemente per il ridotto numero di studi pubblicati e per la modesta qualità degli stessi, ma è tuttavia verosimile che anche in queste patologie la vitamina D giochi un ruolo rilevante.

Nel complesso si può affermare che:

- il mantenimento di appropriati livelli di 25(OH)D attraverso la supplementazione con colecalciferolo nella popolazione generale possa ridurre l'incidenza di numerose IRDs, unitamente ad altri interventi preventivi;
- il mantenimento di appropriati livelli di 25(OH)D attraverso la supplementazione con colecalciferolo in pazienti affetti da IRDs possa ridurre l'attività/severità di malattia, alcune complicanze e, nel caso della AR e SpA, anche la mortalità.

Sulla base dei dati derivati dai RCTs, la supplementazione con colecalciferolo a dosi appropriate dovrebbe pertanto essere offerta a tutti i pazienti affetti da IRDs che non presentino un valore basale di 25(OH)D ottimale, sia per le implicazioni reumatologiche che per quelle "scheletriche". L'eventuale utilizzo del colecalciferolo nei pazienti IRDs normo-vitaminosici D finalizzato a migliorare il decorso clinico e gli *outcomes* della malattia (ora ritenuto plausibile) dovrà invece essere oggetto di ulteriori RCTs condotti su casistiche appropriate.

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