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Editoriale: Aggiornamento AIFA delle Note 79 e 96 in relazione alla vitamina D: conferme e dubbi

Studio VITAL: luci e ombre

Sintesi delle nuove raccomandazioni 2022 della Società Italiana per Osteoporosi, Metabolismo Minerale e Malattie Scheletriche (SIOMMMS) per la gestione della carenza di vitamina

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EDITORIALE

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AGGIORNAMENTO AIFA DELLE NOTE 79 E 96 IN RELAZIONE ALLA VITAMINA D: CONFERME E DUBBI

In questo numero torniamo a fare il punto sul ruolo della vitamina D nei confronti del metabolismo fosfo-calcico e della salute scheletrica.

Lo facciamo pubblicando una sintesi sul corretto uso della supplementazione vitaminica D secondo le recenti raccomandazioni pubblicate dalla Società Italiana dell'Osteoporosi, del Metabolismo Minerale e delle Malattie dello Scheletro (SIOMMMS) [1].

In particolare troverete un aggiornamento, sulla base delle attuali conoscenze, relativamente alla definizione della carenza, all'identificazione dei soggetti a rischio, all'opportunità o meno del dosaggio sierico del 25(OH)D, alle condizioni che indicano l'opportunità di una supplementazione e alle modalità preferibili per praticarla in termini di posologie e tempi.

Troverete, inoltre, indicazioni su come supplementare con vitamina D in caso di insufficienza renale o epatica o di concomitanti trattamenti farmacologici che interferiscono con il metabolismo epatico della vitamina D.

Infine, trovate indicazioni su quando temere effetti tossici, come ipercalcemia e ipercalciuria.

Il tutto supportato da appropriate referenze bibliografiche, che potrete eventualmente integrare ricorrendo alle più recenti, che trovate nella ricca selezione bibliografica anche di questo numero.

Le raccomandazioni della SIOMMMS sono state recepite, anche se purtroppo solo in parte, dai recenti aggiornamenti delle Note 79 [2] e 96 [3] da parte dell'Agenzia Italiana per il Farmaco (AIFA).

NOTA 79

- ☺ Nelle "considerazioni generali" della nuova versione della Nota 79, trovate giustamente ribadita la raccomandazione a ricorrere a supplementi di calcio e vitamina D, ove dieta ed esposizione solare siano inadeguati, perché la carenza di vitamina D, in particolare, può vanificare in gran parte l'effetto dei farmaci per il trattamento dell'osteoporosi.
- ☹ Rispetto alla precedente versione della Nota, che raccomandava l'uso in particolare del colecalciferolo ed escludeva il ricorso ai metaboliti idrossilati sulla base delle precedenti linee guida pubblicate nel 2011 [3], è stato aggiunto in alternativa al colecalciferolo il calcifediolo, citando tra l'altro a presunto supporto le stesse linee guida [3] che invece indicavano il ricorso anche al calcifediolo, oltre al colecalciferolo, solo in condizioni di grave insufficienza epatica. Giustamente anche nelle "particolari avvertenze" della nuova versione della Nota 96 trovate riconosciuto che le principali prove di efficacia antifratturativa sono state conseguite utilizzando colecalciferolo, che risulta essere la molecola di riferimento per tale indicazione, mentre la documentazione clinica per gli analoghi idrossilati è molto limitata e il rischio di ipercalcemia non trascurabile.
- ☹ Nelle "particolari avvertenze" della nuova versione della Nota 79 relativamente ai pazienti con grave insufficienza renale, come nella precedente versione viene raccomandata la supplementazione con vitamina D_3, ma l'eventuale ricorso in questa condizione anche ai metaboliti 1-alfa-idrossilati della vitamina D, supportato dalle vecchie [3] e nuove

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linee guida [1], è stato sorprendentemente sostituito con il ricorso ai metaboliti 25-alfa-idrossilati, senza peraltro nessun supporto bibliografico.

NOTA 96

- ☺ Si condivide la conferma dell'inappropriatezza di uno *screening* esteso alla popolazione generale, ritenendo che la determinazione dei livelli di 25(OH)D dovrebbe essere eseguita solo in presenza di fattori di rischio per carenza e quando risulti utile per la gestione clinica dei pazienti.
- ☺ Si apprezza il nuovo riconoscimento dell'opportunità di una supplementazione in persone con grave carenza di vitamina D, anche se asintomatiche.
- ☺ Apprezzabile il recepimento da parte di AIFA dell'opportunità di innalzare la soglia minima desiderabile dei livelli sierici di 25(OH)D da 20 ng/ml (o 50 nmol/L) a 30 ng/ml (o 75 nmol/L) nei pazienti affetti da iperparatiroidismo (primario o secondario) e in quelli affetti da osteoporosi o altre osteopatie accertate, riconoscendo che la correzione del deficit di vitamina D rimane, insieme alla correzione di un carente apporto di calcio con la dieta, uno dei capisaldi della terapia per l'osteoporosi, mentre la supplementazione con vitamina D in soggetti sani e senza carenza di vitamina D appare comprensibilmente inutile, come dimostrato dai risultati tutt'altro che sorprendenti di recenti studi clinici.
- ☺ Condivisibile il *warning* sul ricorso a dosi eccessive di vitamina D, in particolare per i potenziali effetti negativi sul riassorbimento osseo come segnalato da nostri studi [5,6].
- ☺ Si apprezza la nuova inclusione tra i destinatari della prescrizione di vitamina D a carico del Servizio Sanitario Nazionale (SSN) senza necessità del dosaggio del 25(OH)D, oltre che delle persone istituzionalizzate, anche delle persone con gravi deficit motori o allettate che vivono al proprio domicilio, considerato che l'esposizione solare, come giustamente riconosciuto, rappresenta il meccanismo principale per soddisfare il fabbisogno di vitamina D.
- ☹ Manca ancora il riconoscimento di altre condizioni a rischio di ipovitaminosi D come quelle legate a forzate condizioni di ridotta esposizione solare (ad esempio per motivi lavorativi o culturali o per condizioni che controindicano l'esposizione a UVB) o quelle legate a incapacità a produrre adeguate quantità di vitamina D, nonostante l'esposizione solare, come ad esempio in età avanzata [7].
- ☹ Non sono chiare le indicazioni per i pazienti già in terapia mineralizzante associata a supplementazione con vitamina D, come raccomandato dalla Nota 79. Si ritiene che la prosecuzione della supplementazione con vitamina D vada garantita a carico del SSN indipendentemente dalla determinazione della 25(OH)D anche in questi pazienti.
- ☹ Nell'allegato 1 della Nota, relativamente alle linee guida per la prescrizione di vitamina D, vengono indicate dosi di colecalciferolo rivelatesi spesso insufficienti in alcune condizioni, come, in particolare, in età avanzata, negli obesi, in caso di grave insufficienza epatica o di terapie croniche che interferiscono con il metabolismo epatico della vitamina D o in condizioni di malassorbimento [1].
- ☹ Nello stesso allegato è indicato un trattamento alternativo al colecalciferolo con calcifediolo; quest'ultimo andrebbe indicato di seconda scelta, coerentemente con quanto riportato nella stessa Nota nelle "Particolari avvertenze" relativamente alle maggiori prove di efficacia e di sicurezza del colecalciferolo, specie se somministrato giornalmente. Anche la presunta maggiore rapidità del calcifediolo nel normalizzare i livelli di 25(OH)D è stata smentita dal nostro recente studio che ha dimostrato la possibilità di un'equivalente rapidità ricorrendo a dosi appropriate di colecalciferolo [8].
- ☹ Infine, in considerazione dei potenziali benefici extra-scheletrici della vitamina D, si condivide il fatto che allo stato attuale delle conoscenze non vi siano evidenze scientifiche certe di un beneficio della supplementazione in termini di costo/efficacia, ma si ritiene che attualmente tali benefici non si possano neppure escludere con certezza. Si veda, ad esempio, in questo numero un'analisi critica dello studio VITAL [9-11], con luci e ombre.

Voi cosa ne pensate ?

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Studio VITAL: luci e ombre

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INTRODUZIONE

La vitamina D è un ormone liposolubile che ha un ruolo fondamentale nella regolazione dell'assorbimento intestinale di calcio.
Il colecalciferolo è convertito dall'enzima epatico 25-idrossilasi in calcifediolo e successivamente, sotto il controllo del paratormone (PTH), dall'enzima renale 1-25-idrossilasi, nella forma biologicamente attiva, il calcitriolo.
Il calcitriolo regola direttamente l'assorbimento di calcio elementare dall'intestino ed è quindi fondamentale per garantire un adeguato substrato per la formazione dello scheletro.
In condizioni di bassi livelli di vitamina D si riduce l'assorbimento intestinale di calcio e il calcio necessario per l'omeostasi sanguigna viene prelevato dallo scheletro sotto l'influsso del PTH [1]. È noto quindi, dalla fisiologia, che la grave carenza di vitamina D porti allo sviluppo di osteomalacia (nell'adulto) e di rachitismo (nel bambino) [2].
Le prime evidenze cliniche/storiche del ruolo fondamentale della vitamina D sullo sviluppo dell'osteomalacia e nel metabolismo scheletrico provengono da antichi reperti di scheletri di soggetti con deformità e multiple fratture ossee e da evidenze empiriche.
È noto che le popolazioni che vivono al di sopra del 37° parallelo sono a più elevato rischio di sviluppare rachitismo/osteomalacia.
L'essere umano è in grado di sintetizzare vitamina D_3 tramite conversione fotochimica. Le radiazioni ultraviolette B portano alla conversione del 7-deidrocolesterolo in colecalciferolo nella cute. Tuttavia, nelle regioni nord o sud del pianeta le radiazioni di UVB della lunghezza d'onda necessaria per la sintesi della vitamina D non raggiungono la superficie.
È stato inoltre riscontrato che i bambini rachitici esposti al sole miglioravano il quadro clinico, fino alla completa guarigione.
La vitamina D può essere altresì assunta nella dieta (è presente in quantità discrete nel grasso animale). È stato dimostrato che nelle popolazioni scandinave il rischio era particolarmente elevato per i soggetti che risiedevano nell'entroterra e che pertanto avevano una dieta scarsa o addirittura priva di pesce, la fonte animale principale di vitamina D alimentare. Il fegato del merluzzo è estremamente ricco di vitamina D e ha protetto per secoli le popolazioni nordiche dallo sviluppo di osteomalacia/rachitismo.
È quindi ampiamente assodato che la vitamina D sia un nutriente/ormone di fondamentale importanza per la salute scheletrica.
Le evidenze si sono ulteriormente rafforzate negli anni più recenti. Sono stati pubblicati numerosi studi, soprattutto osservazionali ma anche interventistici, che confermano l'importanza della vitamina D e, in particolare, sottolineano l'effetto deleterio, marcato, della carenza/deficienza di vitamina D sull'osso.
È interessante notare che gli studi osservazionali condotti su popolazioni a rischio di frattura siano sostanzialmente tutti concordi nell'evidenziare il ruolo negativo della carenza di vitamina D sull'aumento del rischio di frattura. Al contrario, c'è una discreta incertezza proveniente dai dati interventistici. Alcuni trial clinici, infatti, non sono riusciti a dimostrare un effetto positivo della vitamina D sulla riduzione del rischio di frattura. Tuttavia, vanno assolutamente sottolineati i limiti di tali studi che, sebbene siano stati condotti con estremo rigore scientifico e su ampie popolazioni, non possono e non devono influenzare negativamente le nostre scelte cliniche.
In particolare, mi focalizzerò sui punti di debolezza del recente trial clinico randomizzato "VITamin D and OmegA-3 TriaL (VITAL)" di cui è stato pubblicato di recente lo studio ancillare sulle fratture da fragilità [3].

LO "STUDIO VITAMIN D AND OMEGA-3 TRIAL (VITAL)"

Lo studio VITAL è un trial clinico pragmatico randomizzato in cieco in cui venivano somministrati vitamina D, omega-3 o placebo secondo uno schema fattoriale.
In sintesi, i partecipanti (oltre 25.000 individui risiedenti negli Stati Uniti d'America) potevano ricevere una combinazione di vitamina D e omega-3 oppure vitamina D e placebo oppure omega-3 e placebo oppure una doppia compressa di placebo [4]. Lo studio, nato nel 2010 all'Università di Harvard, si prefiggeva come obiettivo principale di dimostrare un possibile effetto della vitamina D e

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degli omega-3 sull'incidenza di malattie autoimmuni e di cancro (Figg. 1, 2). Erano stati però pensati anche numerosi altri studi ancillari, tra cui anche studi mirati alla salute scheletrica e alle fratture. In una quota dei pazienti arruolati veniva anche raccolto siero per l'analisi di biomarker e venivano eseguiti degli esami strumentali per valutare la densità ossea e la fragilità.

PREMESSE, CONTESTO E POPOLAZIONE DELLO STUDIO VITAL

Prima di entrare nel dettaglio dello studio, è importante ricordare le motivazioni che hanno spinto gli sperimentatori a condurre questo mega-trial.

Negli Stati Uniti è estremamente frequente la somministrazione di vitamina D con preparati detti "over the counter (OTC)" che sono, per definizione, di facile reperimento nei normali supermercati.

La diffusione è nata e si è sviluppata in seguito alla credenza, fortemente radicata nella società americana, che per la salute sia essenziale un supplemento multivitaminico (spesso contenente alte dosi di vitamina D) costante e a tutte le età. L'abitudine ad assumere OTC è così radicata che il mercato è in costante aumento e ha raggiunto, negli Stati Uniti, la strabiliante cifra di 30 miliardi di dollari/anno nel 2023.

È di fondamentale importanza questa premessa per capire il contesto in cui è stato svolto lo studio VITAL.

In particolare, per comprendere che gli obiettivi dello studio VITAL erano soprattutto legati a dimostrare che l'inappropriata assunzione di vitamina D e omega-3 è, per l'appunto, inappropriata.

È inoltre importante riconoscere il contesto dello studio VITAL per comprendere al meglio le caratteristiche della popolazione in studio. Nello studio VITAL sono stati arruolati soggetti di mezza età con alcune caratteristiche peculiari. La più importante è sicuramente l'elevata scolarità: l'arruolamento, infatti, è avvenuto tramite lettera inviata al domicilio del soggetto e comprendeva questionari complessi che necessitavano di un'adeguata conoscenza medica-scientifica. Questo presupposto, insieme all'invio di brochure informative su vitamina D e omega-3, ha portato all'arruolamento di una quota notevole di pazienti che già assumevano vitamina D prima dello studio (il 42,6% dei pazienti arruolati assumevano vitamina D fuori dallo studio). Questa quota di pazienti aveva, infatti, livelli medi di 25-idrossi-vitamina D [25(OH)D] di 34,9 ng/mL prima di entrare nello studio. Nel VITAL, inoltre, era consentito continuare l'assunzione di integratori di vitamina D fino a 800 UI al giorno. È inoltre sorprendente notare che i soggetti che non assumevano vitamina D all'inizio dello studio avevano livelli medi di 25(OH)D ematici di 27,4 ng/mL, più che adeguati al mantenimento della salute scheletrica.

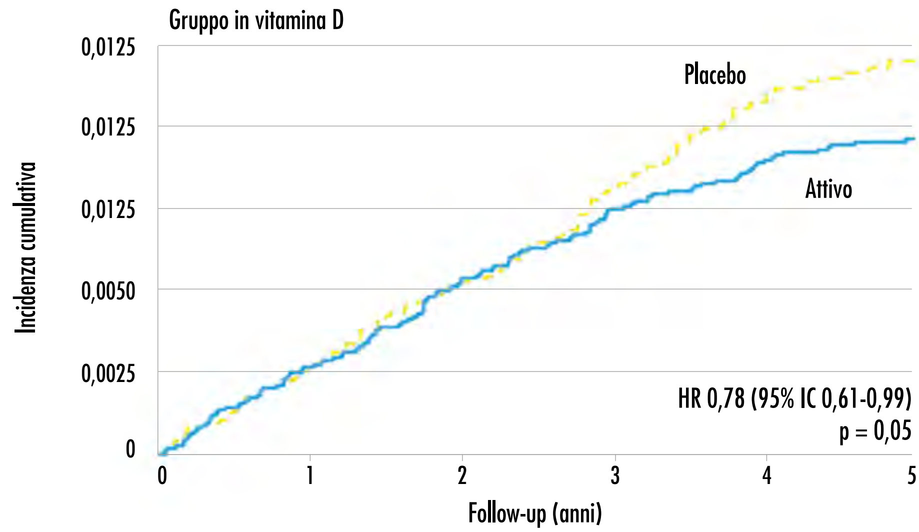
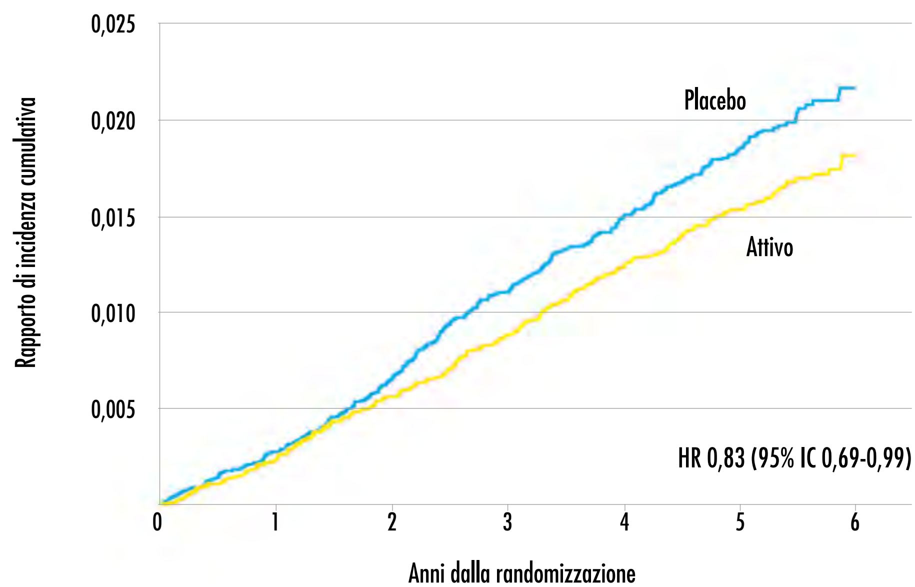


FIGURA 1.
Incidenza di malattie autoimmuni nello studio VITAL (da Hahn et al., 2022, mod.) [6].



12.927	12.738	12.543	12.341	11.992	9.557	744
12.944	12.765	12.567	12.345	11.985	9.543	746

FIGURA 2.
Incidenza di cancro avanzato nello studio VITAL (da Chandler et al., 2020, mod.) [7].

TABELLA I.
Caratteristiche basali della popolazione arruolata nello studio VITAL (da LeBoff et al., 2022, mod.) [8].

Caratteristica	Totale (N = 25.871)	Gruppo in vitamina D (N = 12.927)	Gruppo placebo (N = 12.944)
Donne, n. (%)	13.085 (50,6)	6.547 (50,6)	6.538 (50,5)
Età, anni	67,1 ± 7,1	67,1 ± 7,0	67,1 ± 7,1
Indice di massa corporea (BMI)	28,1 ± 5,7	28,1 ± 5,7	28,1 ± 5,8
Diabete, n./totale n. (%)	3.537/25.824 (13,7)	1.804/12.900 (14,0)	1.733/12.924 (13,4)
Storia familiare di frattura di femore, n./totale n. (%)	3.704/23.979 (15,4)	1.809/11.970 (15,1)	1.895/12.009 (15,8)
Artrite reumatoide, n./totale n. (%)	1.118/25.512 (4,4)	556/12.749 (4,4)	562/12.763 (4,4)
Storia di fratture da fragilità, n./totale n. (%)	2.578/25.023 (10,3)	1.287/12.513 (10,3)	1.291/12.510 (10,3)
Cadute nell'ultimo anno, n./totale n. (%)	6.921/25.715 (26,9)	3.521/12.848 (27,4)	3.400/12.867 (26,4)
Uso di farmaci anti-osteoporotici, n./totale n. (%)	1.240/25.690 (4,8)	609/12.835 (4,7)	631/12.855 (4,9)
Fumatori, n./totale n. (%)	1.835/25.488 (7,2)	921/12.732 (7,2)	914/12.756 (7,2)
Uso di supplementi di vitamina D, n. (%)	11.030 (42,6)	5.497 (42,5)	5.533 (42,7)
Uso di glucocorticoidi, n./totale n. (%)	461/25.427 (1,8)	239/12.705 (1,9)	222/12.722 (1,7)
Introito di latte (unità)	0,71 ± 0,91	0,71 ± 0,89	0,72 ± 0,92
Livelli basali di 25(OH)D, ng/ml	30,7 ± 10,0	30,7 ± 10,0	30,7 ± 10,0
Livelli basali di calcemia, mg/dl	9,00 ± 1,61	9,00 ± 1,61	9,00 ± 1,61

In conclusione, il VITAL ha arruolato, in media, pazienti che mai avremmo trattato con dosi supplementari di vitamina D nella pratica clinica. Questa popolazione era inoltre a basso rischio di frattura già al baseline e solo 1 paziente su 10 presentava una storia di frattura da fragilità e solo 1 su 20 era trattato con farmaci per l'osteoporosi.
La Tabella I mostra le caratteristiche basali della popolazione dello studio VITAL [8].

RISULTATI DELLO STUDIO VITAL, *PRIMARY ENDOPOINT* E INCIDENZA DI FRATTURE

I soggetti arruolati nello studio VITAL, dopo essere stati randomizzati, sono stati seguiti con dei questionari annuali per oltre 5 anni e numerosi outcome sono stati valutati annualmente e al termine dello studio.
Il *primary endpoint* (incidenza di fratture da fragilità nei due gruppi di randomizzazione) non è stato raggiunto; l'incidenza di fratture era sovrapponibile nei due gruppi.
Prima di entrare nel dettaglio dei risultati dello studio ancillare sulle fratture è importante stabilire il *rate* fratturativo osservato, cioè il numero di fratture a cui i pazienti sono andati incontro durante il follow-up. Questo ci consente, ancora una volta, di comprendere meglio le caratteristiche degli individui arruolati nello studio. Sono state osservate 865 fratture da fragilità (escludendo fratture patologiche, traumatiche, periprotesiche ecc.) durante un follow-up mediano di 5,3 anni, che corrisponde a un rischio di frattura del 3,3% a 5 anni e quindi, approssimativamente, a un rischio a 10 anni del 6,6%, ampiamente sotto la soglia di trattamento farmacologico per l'osteoporosi. Similmente è stata osservata una incidenza di fratture femorali a 10 anni dello 0,8%, ancora sotto la soglia per il trattamento, solitamente posta al 3%. È quindi evidente che la popolazione arruolata era a basso rischio di frattura già prima di entrare nello studio e lo è rimasta durante tutta la durata dell'analisi.

SAFETY DELLA VITAMINA D

L'incidenza di ipercalcemia, calcolosi renale ed eventi avversi in generali era simile nei pazienti. Tuttavia, si è assistito a una riduzione degli eventi di sanguinamento gastrointestinale e di *rash* cutaneo nei pazienti trattati con vitamina D.
Il profilo di *safety* era quindi a favore del braccio in trattamento attivo con vitamina D.

ANALISI NEI SOTTOGRUPPI E LIVELLI DI VITAMINA D

In un sottogruppo della popolazione dello studio sono stati analizzati i valori di 25(OH)D dopo 2 anni (oltre che al baseline). Come atteso, i livelli di 25(OH)D sono aumentati significativamente (dal punto di vista statistico ma non clinico) nel sottogruppo trattato con vitamina D (29,2 ng/mL → 41,2 ng/mL), ma, in maniera non molto sorprendente, anche i pazienti nel braccio placebo hanno mantenuto adeguati livelli di vitamina D, raggiungendo al 2° anno valori di 29,4 ng/mL. Ancora una volta questo denota come i pazienti arruolati fossero in gran parte già in supplementazione e come questi l'avessero proseguita durante il follow-up. Sono state pertanto condotte numerose sub-analisi in base al livello basale di 25(OH)D, ma, anche in questo caso, non è stata trovata una riduzione (significativa) del rischio di frattura. Tuttavia, il dato laboratoristico era disponibile solo in una piccola porzione della coorte e, di questi, solo una minoranza aveva livelli di vitamina D insufficienti. Inoltre, nei 401 soggetti che avevano livelli di 25(OH)D sotto ai 12 ng/mL, l'incidenza di fratture è stata del 3,7% a 5 anni, estremamente simile all'intera coorte. Que-

TABELLA II.
Hazard Ratio in sottogruppi di pazienti nello studio VITAL (da LeBoff et al., 2022, mod.) [3].

Sottogruppo	Totale	Gruppo in vitamina D	Gruppo placebo	Hazard Ratio (95% CI)	Hazard Ratio se pazienti raddoppiati e incidenza fratture uguale
Farmaci anti-osteoporotici					
Sì	1.240	62	79	0,74 (0,53-1,03)	**0,74 (0,62- 0,97)**
No	24.450	704	697	1,01 (0,91-1,12)	1,01 (0,96-1,11)
Storia di fratture da fragilità					
Sì	2.578	146	161	0,87 (0,69-1,09)	**0,87 (0,74-0,99)**
No	22.445	598	595	1,01 (0,90-1,14)	1,01 (0,93-1,08)

sto dato, all'apparenza controintuitivo, è però spiegabile con l'ammissione di terapia vitaminica fino a 800 UI/die extra-studio. Erano inoltre ammessi dosaggi di 25(OH)D extra studio secondo la pratica clinica corrente e non è escluso che i pazienti con livelli molto bassi avessero iniziato supplementazione con vitamina D causando un bias di fondamentale importanza (esclusione di pazienti dall'analisi o aumento dei livelli di vitamina D anche nel gruppo in placebo). Da notare, inoltre, che i livelli di PTH e di calcemia nella popolazione in studio erano normali e lo erano anche nel sottogruppo con ipovitaminosi D (la presenza di iperparatiroidismo di ogni natura era un criterio di esclusione). Questo implica che i pazienti carenti di vitamina D lo erano, con ogni probabilità, da poco tempo e/o che i meccanismi di compenso omeostatico dell'asse PTH/calcemia/25(OH)D non erano ancora instaurati o del tutto evidenti. Non è stata condotta un'analisi stratificata sulla base dei valori di 25(OH)D al termine dello studio.
Sono state condotte sub-analisi in sottogruppi a particolare rischio di frattura, come i pazienti con pregresse fratture o pazienti in trattamento con farmaci per l'osteoporosi. In questi sottogruppi (comunque minoritari) il rischio di frattura non era differente tra gruppo placebo e gruppo in vitamina D. Tuttavia, si è dimostrata un'incidenza di fratture numericamente inferiore nel gruppo in trattamento attivo (Tab. II). È interessante sottolineare che la numerosità di questi sottogruppi fosse insufficiente per provare una riduzione del rischio di frattura. Inoltre, l'incidenza di fratture era non particolarmente elevata. Nei pazienti con terapia per l'osteoporosi era dell'11,3% a 5 anni (circa 22% a 10 anni) e nei soggetti con pregresse fratture era dell'11,9% a 5 anni (circa 23-24% a 10 anni). Per confronto, nell'estensione a 10 anni dello studio FREEDOM (trial clinico con denosumab) l'incidenza cumulativa a 10 anni di tutte le fratture da fragilità dei pazienti trattati con denosumab era del 16,3% contro il 26% nel braccio in placebo "virtuale", molto simile rispetto allo studio VITAL. È quindi difficile pensare che la vitamina D da sola possa avere un effetto anti-fratturativo evidente in così pochi pazienti a così basso rischio. Tuttavia, è sufficiente ipotizzare un raddoppio della numerosità della casistica (mantenendo uguali i tassi di incidenza fratturativa) in questi sottogruppi per raggiungere la significatività statistica a favore della vitamina D (Tab. II). È infatti noto che nei pazienti in trattamento con farmaci anti-osteoporotici sia ancora più fondamentale raggiungere e mantenere adeguati livelli di vitamina D (probabilmente oltre alla soglia di 20-30 ng/mL) per massimizzare l'effetto anti-fratturativo dei farmaci [5]. Questo dato è ulteriormente confermato dall'evidenza, proveniente da un'ulteriore sub-analisi sempre nello studio VITAL, di una significativa riduzione del rischio di frattura da fragilità maggiore (MOF) nei pazienti in trattamento con farmaci anti-osteoporotici [HR 0,54 (95% IC 0,29-0,99)].

CONCLUSIONI

Sebbene abbia dei limiti, il VITAL è uno studio di fondamentale importanza. Lo studio è stato condotto con rigore e su una popolazione molto ampia, seguita per un lungo periodo, e ci ha portato importanti conferme anche sui potenziali effetti extra-scheletrici della vitamina D. Tuttavia, nello studio ancillare sulle fratture da fragilità non si è assistito a una riduzione dell'incidenza di fratture nel gruppo trattato con vitamina D. Questo risultato era ampiamente prevedibile considerati gli importanti limiti dello studio e la popolazione a basso rischio arruolata. In pazienti selezionati, come ad esempio quelli affetti da osteoporosi, il trattamento con vitamina D è e rimane fondamentale per preservare la salute dello scheletro. Questa importante osservazione è stata peraltro ribadita anche dagli stessi autori dello studio VITAL, i quali suggeriscono di raggiungere e mantenere in tutti i pazienti con osteoporosi soglie di 25(OH)D ≥ 30 ng/mL [8].
In conclusione, l'effetto scheletrico della vitamina D parrebbe essere più evidente nei soggetti carenti di vitamina D a rischio di frattura o in condizioni di osteomalacia.

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Sintesi delle nuove raccomandazioni 2022 della Società Italiana per Osteoporosi, Metabolismo Minerale e Malattie Scheletriche (SIOMMMS) per la gestione della carenza di vitamina D

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INTRODUZIONE

Alla luce di nuove evidenze scientifiche la Società Italiana del Metabolismo Minerale e Malattie dello Scheletro (SIOMMMS) ha sentito la necessità di rivedere e aggiornare le sue precedenti raccomandazioni originali del 2011 circa la definizione, la prevenzione e il trattamento di carenza di vitamina D negli adulti utilizzando un approccio con sistema GRADE/PICO [1].

Negli ultimi anni le prescrizioni di determinazioni sieriche di 25(OH)D e l'utilizzo di supplementi di vitamina D sono in costante aumento.

Nel 2019 l'AIFA (Agenzia Italiana del Farmaco) con la nota 96 ne regolamenta la rimborsabilità nel tentativo di arginarne il consumo e i costi, senza una base di appropriatezza [2,3].

È stata istituita un *task force* multidisciplinare per fornire linee guida cliniche con i seguenti obiettivi principali: a) rendere appropriata la gestione della carenza della vitamina D, migliorando e standardizzando la "pratica clinica"; b) offrire al paziente le indicazioni per le cure più appropriate, da seguire uniformemente a livello nazionale; e infine c) garantire un riferimento basato su prove per istituzioni e agenzie nazionali e regionali. Sono stati affrontati diversi punti chiave, alcuni dei quali suggeriscono un netto cambiamento del comportamento nella pratica clinica, tra cui una nuova definizione dello stato della vitamina D con valori di carenza e valori ottimali diversificati in base alla popolazione coinvolta [4]. Per gli aspetti metodologici legati alla ricerca delle evidenze e la stesura dei livelli di evidenza e raccomandazioni si rinvia alla pubblicazione originale [4].

QUESITO 1. DEFINIZIONE DELLO STATO VITAMINICO D: CARENZA E VALORI OTTIMALI

I livelli sierici di 25(OH)D variano ampiamente nei diversi periodi di vita, in base alla stagione, alla latitudine, al grado di esposizione alla luce solare, al fototipo e all'indice di massa corporea (IMC). Inoltre, bisogna considerare sempre anche l'elevata variabilità legata al dosaggio in immunochemiluminiscenza che oscilla tra il 10-20% intra-dosaggio e interlaboratorio. Mentre vi è accordo unanime che valori di 25(OH)D < 10 ng/mL sono una condizione di grave carenza che se protratta nel tempo porta a rachitismo e osteomalacia, un consenso per quello che può essere considerato "normalità" non esiste. SIOMMMS suggerisce un livello "ottimale" o "desiderabile", definito come il valore che si è dimostrato efficace nella prevenzione o nella correzione di patologia scheletrica come la fragilità. Si distingue, inoltre, la raccomandazione per la popolazione generale da quella per la popolazione a rischio di ipovitaminosi D o che necessita di terapia con farmaci antifratturativi. Per la popolazione generale c'è consenso sull'associazione tra valori sierici di 25(OH)D < 20 ng/mL e aumento del rischio di frattura [5]. Recenti meta-analisi hanno rivelato che per valori < 20 ng/mL (50 nmol/L) c'è un aumento del 40% del rischio di frattura femorale per ogni deviazione standard di decremento di 25(OH)D e che per valori oltre i 20 ng/ml la supplementazione non comporta un ulteriore beneficio [6]. Pertanto, nella popolazione generale si definisce: "deficiente" un livello di 25(OH) < 10 ng/ml; "insufficiente " se < 20 ng/ml e "ottimale" se compreso tra

TABELLA I.

a. Definizione dello stato della vitamina D nella popolazione generale sana

	Carenza	Insufficienza	Ottimale
Popolazione generale	< 10 ng/mL	< 20 ng/mL	Tra 20 e 50 ng/mL

b. Definizione dello stato della vitamina D nella popolazione a rischio di ipovitaminosi D o che è in terapia con farmaci per osteoporosi

	Carenza	Insufficienza	Ottimale
Popolazione a rischio di bassa vitamina D* oppure che necessita di farmaci per osteoporosi	< 10 ng/mL	< 30 ng/mL	Tra 30 e 50 ng/mL

I valori limite segnalati devono essere considerati con un margine di variabilità di ±10%, considerando l'analisi variabilità del dosaggio 25(OH)D.
Inoltre, a causa della variabilità stagionale dei livelli di 25(OH)D, è indicativo il valore determinato alla fine dell'inverno/inizio della primavera.
Da ng/mL a nmol/L: ng/mLx 2,5. * La popolazione a rischio di ipovitaminosi è indicata nella Tabella II.

TABELLA II.
Popolazione/condizione a rischio di ipovitaminosi D.

- Anziani (≥ 75 anni)
- Soggetti istituzionalizzati o condizioni associate a un'esposizione solare inadeguata
- Obesità
- Gravidanza e allattamento
- Malattie metaboliche delle ossa e altri disturbi dello scheletro
- Dieta vegana
- Anoressia nervosa
- Insufficienza renale cronica
- Cancro (in particolare mammella, prostata e colon)
- Diabete mellito tipo 2
- Malassorbimento intestinale e chirurgia bariatrica
- Farmaci che interferiscono con l'assorbimento o il metabolismo epatico della vitamina D (antiepilettici, glucocorticoidi, AIDS antivirale, agenti antimicotici, colestiramina)
- Fibrosi cistica

20-50 ng/ml [4] (Tab. Ia). Al contrario, nei pazienti con osteoporosi, specialmente se trattati con farmaci per la terapia dell'osteoporosi, così come nei soggetti a rischio di ipovitaminosi D (indicati in Tab. II), si indica un valore "ottimale" di almeno 30 ng/mL . Questo valore si associa a una riduzione significativa del rischio di fratture femorali in donne istituzionalizzate e una risposta 4,5 volte migliore nei soggetti trattati con bisfosfonati [7] (Tab. Ib).

QUESITO 2.
CHI SONO I SOGGETTI A RISCHIO DI IPOVITAMINOSI D?

Vi è una serie di condizioni cliniche e stili di vita che espongono a un rischio molto più elevato di ipovitaminosi D rispetto a quello della popolazione generale. Queste condizioni sono elencate nella Tabella II. La SIOMMMS ha aggiornato l'elenco rispetto alle classiche condizioni di rischio riportate nelle altre linee guida internazionali inserendo i soggetti con dieta vegana, quelli con anoressia nervosa, con neoplasia in particolare di mammella, prostata e colon, e i soggetti diabetici [4]. Le categorie di soggetti compresi in questa lista dovranno avere come valore "ottimale" un livello di 25(OH) D di almeno 30 ng/ml.

QUESITO 3.
È OPPORTUNO DOSARE LA 25(OH)D NELLA POPOLAZIONE GENERALE?

Il dosaggio nel siero dei livelli di 25(OH)D è aumentato drasticamente a livello mondiale nell'ultimo decennio. Questo ha chiaramente aumentato in maniera non appropriata la spesa sanitaria. Attualmente non vi è alcuna evidenza dell'utilità di uno screening "universale" dei livelli di vitamina D e nemmeno che questo sia utile per garantire un maggior successo della sua supplementazione [8,9]. Pertanto, in questa fase, in accordo con la maggioranza delle linee guida in questo campo, si raccomanda di non eseguire uno screening estensivo dei livelli di 25(OH)D nella popolazione generale, poiché non vi è ancora alcuna prova che questa rappresenti un qualche vantaggio [4].

QUESITO 4 .
È OPPORTUNO UN DOSAGGIO DEI LIVELLI DI 25(OH)D NELLA POPOLAZIONE A RISCHIO PER IPOVITAMINOSI O IN CHI DEVE INIZIARE UNA TERAPIA CON FARMACI PER L'OSTEOPOROSI?

Sebbene la maggioranza delle linee guida indichi la misurazione dei livelli sierici 25(OH)D nei soggetti definiti a rischio di ipovitaminosi D come altamente raccomandabile, non vi è nessuna prova diretta a sostegno di questa raccomandazione [4]. Inoltre, non esistono evidenze che la valutazione basale del 25(OH)D sia un predittore del rischio di tossicità durante l'integrazione o che serva per stabilire la posologia di vitamina D da somministrare [10]. Allo stesso tempo, molti studi hanno dimostrato che l'integrazione con dosi elevate di vitamina D è sicura anche in soggetti con 25(OH)D > 20 ng/mL . Si suggerisce quindi di non misurare indiscriminatamente i livelli di 25(OH)D in pazienti con condizioni/patologie a rischio di ipovitaminosi D. Si suggerisce, inoltre, di non misurare i livelli basale di 25(OH)D di routine in pazienti candidati per il trattamento farmacologico per la fragilità scheletrica, in quanto mandatoria a prescindere dai valori basali. Semmai sarà utile la verifica del raggiungimento dei livelli "ottimali" 25(OH)D dopo aver iniziato la supplementazione [4].

QUESITO 5.
COME SUPPLEMENTARE LA VITAMINA D?

Non esiste una singola dose fissa di integrazione per tutti i soggetti che ne necessitano. Si consiglia una dose di integrazione per via orale di colecalciferolo tra 800 UI e 2.000 UI/die [11].

Si suggerisce uno schema di supplementazione che potrà essere quotidiano, settimanale o mensile, adeguando la dose da somministrare all'intervallo temporale della schedula adottata.

Si consiglia di non usare dosi refratte oltre i 30 giorni. Non andrebbe superata la dose in bolo in un giorno di 100.000 UI di colecalciferolo (nello schema mensile).

In soggetti obesi la posologia del colecalciferolo dovrebbe essere aumentata di circa il 30% rispetto alla dose utilizzata in individui con BMI normale.

Un adeguato apporto di calcio (800-1.000 mg/die) con la dieta o con supplementi deve essere sempre garantito. In pazienti che necessitano una rapida normalizzazione dei livelli di vitamina D (oste-

TABELLA III.
Sinossi delle raccomandazioni, grado di evidenza e forza di raccomandazione.

Quesito e Raccomandazione	Livello di evidenza
1. La valutazione biochimica dei livelli sierici 25(OH)D dovrebbe essere condotta nella popolazione generale?	
Si raccomanda di non eseguire la misura 25(OH)D nella popolazione generale	⊕
2 .Dovrebbe essere fatta una determinazione dei livelli sierici 25(OH)D nella popolazione a rischio di ipovitaminosi D?	
Si suggerisce di non misurare indiscriminatamente i livelli di 25(OH)D in pazienti con condizioni/patologie a rischio di ipovitaminosi D **Si raccomanda** di misurare i livelli di 25(OH)D solo quando è ritenuto necessario per la gestione clinica del paziente (cioè, quando si sospetta osteomalacia)	⊕⊕ ⊕⊕
3. Dovrebbe essere fatta una determinazione dei livelli sierici 25(OH)D nelle categorie specifiche di soggetti/pazienti a rischio (Tab. II)?	
Si suggerisce che i livelli di base di 25(OH)D non dovrebbero essere di routine valutati in pazienti candidati per il trattamento farmacologico per osteoporosi o altri disturbi metabolici delle ossa (che sono obbligatoriamente associati a supplementazione di vitamina D), a meno che non si sospetti l'osteomalacia	⊕⊕
4. Come dovrebbe essere integrata la vitamina D in soggetti con ipovitaminosi D o candidati a trattamento farmacologico con farmaci antifratturativi?	
Si suggerisce una dose di integrazione di colecalciferolo tra 800 UI/die e 2.000 UI/die. Non esiste una singola dose fissa per tutti i soggetti da integrare **Si suggerisce** uno schema quotidiano, settimanale, mensile basato sulla dose somministrata. La dose massima singola giornaliera da somministrare non deve superare 100.000 UI. Un adeguato apporto di calcio (800-10.00 mg/die) deve essere sempre garantito **Si suggerisce** l'uso di una dose iniziale di carico, seguita da dose di mantenimento in pazienti con osteomalacia sintomatica e/o livelli di 25(OH)D < 10 ng/mL o in pazienti che iniziano terapia con bisfosfonati endovenosi o denosumab con 25(OH)D < 20 ng/mL **Si suggerisce**, come dose di carico, colecalciferolo 3.000-10.000 UI/die (media 5.000 UI/die) per 1-2 mesi, o colecalciferolo in una singola dose di 60.000 a 150.000 UI seguita dalla dose di mantenimento (2.000 UI/die) Si suggerisce in alternativa calcifediolo 20-40 mcg/die (4-8 gtt/die) per 20-30 giorni, prima di passare alla dose di mantenimento con colecalciferolo*	⊕ ⊕ ⊕⊕⊕ ⊕⊕⊕
5. Nella popolazione generale va integrata la vitamina D?	
Si raccomanda di non somministrare supplementi di vitamina D nella popolazione generale, dal momento che non vi è alcuna prova certa di un rapporto costo/efficacia favorevole, sia sulla mortalità che su effetti scheletrici ed extra-scheletrici	⊕⊕⊕
6. Come dovrebbe essere integrata la vitamina D in pazienti con funzionalità renale compromessa?	
Si raccomanda nel paziente con CKD-MBD di correggere ipovitaminosi D con colecalciferolo e con le stesse modalità utilizzate nella popolazione generale con funzione renale normale **Si raccomanda** di limitare l'uso di composti attivi della vitamina D (calcitriolo o analoghi sintetici) a soggetti in dialisi o in stadio G4-G5 CKD con iperparatiroidismo grave e progressivo	⊕⊕⊕⊕
7. Come dovrebbe essere integrata la vitamina D nei soggetti che soffrono da grave insufficienza epatica o da terapie che interferiscono con il metabolismo epatico di vitamina D?	
Si suggerisce l'integrazione con almeno 2.000 UI/die di colecalciferolo in pazienti con grave insufficienza epatica o in caso di terapie croniche che interferiscono con il metabolismo della vitamina D epatica. L'uso del calcifediolo è una possibile alternativa	⊕

* La raccomandazione è limitata a una normalizzazione più rapida dei livelli sierici di 25(OH)D.
Forza della Raccomandazione: si suggerisce di/di non...: positiva/negativa debole; si raccomanda di/di non...: positiva/negativa forte.
Livello di evidenza: ⊕ molto bassa, ⊕⊕ bassa, ⊕⊕⊕ moderata, ⊕⊕⊕⊕ alta.

omalacia sintomatica o in chi deve iniziare acido zoledronico o denosumab) si consiglia l'uso di una dose iniziale di carico, seguita da dose di mantenimento. Come dose di carico, si consiglia colecalciferolo 3.000-10.000 UI/die (media 5.000 UI/die) per 1-2 mesi, o colecalciferolo in una singola dose da 60.000 a 150.000 UI seguita dalla dose di mantenimento (2.000 UI/die) [4,12]. In alternativa si potrà considerare l'utilizzo del calcifediolo 20-40 mcg/die (4-8 gtt/die) per 20-30 giorni, prima di passare alla dose di mantenimento con colecalciferolo.

QUESITO 6. LA POPOLAZIONE GENERALE ANDREBBE SUPPLEMENTATA?

Il razionale per una potenziale integrazione con colecalciferolo di tutti i soggetti si basa sul considerare "carenti" i soggetti con valori < 30 ng/mL, su potenziali effetti

extrascheletrici, sul profilo di sicurezza e i bassi costi.
Tuttavia, attualmente in base alle recenti evidenze non è possibile trarre conclusioni sufficienti per un vantaggio nella supplementazione della popolazione generale (in soggetti esclusi dalla Tab. II) [13]. Per cui si raccomanda di non supplementare la popolazione generale non a rischio di ipovitaminosi.

QUESITO 7. I SOGGETTI CON INSUFFICIENZA RENALE VANNO SUPPLEMENTATI CON VITAMINA D E COME?

Nell'insufficienza renale ridotti livelli di 25(OH)D limitano la disponibilità del substrato per l'idrossilazione renale a calcitriolo, aggravando così gli effetti della ridotta capacità di idrossilazione a 1,25(OH)$_2$D. Ciò determina un iperparatiroidismo secondario. L'integrazione con vitamina D è in grado di normalizzare i livelli di 25(OH)D e ridurre i livelli di PTH e migliorare la mineralizzazione ossea nell'insufficienza renale. Per la supplementazione si suggerisce di adottare le stesse indicazioni suggerite per la popolazione generale [14].
Si raccomanda di utilizzare il colecalciferolo, mentre per il calcifediolo le evidenze sono limitate [14]. Si raccomanda di limitare l'uso di composti attivi della vitamina D (calcitriolo o analoghi sintetici) a soggetti in dialisi o in fase G4-G5 con iperparatiroidismo grave e progressivo [14].

QUESITO 8. COME SUPPLEMENTARE SOGGETTI CON INSUFFICIENZA EPATICA O IN TERAPIA CON FARMACI CHE INTERFERISCONO CON IL METABOLISMO EPATICO DELLA VITAMINA D?

Ridotti livelli di 25(OH)D sono comuni in pazienti con malattie epatiche croniche non solo per un deficit di 25-idrossilazione o un aumento del catabolismo del calcifediolo, ma per molteplici atri, tra cui malnutrizione, ridotta esposizione al sole, malassorbimento, sintesi ridotta della *D-Binding Protein* [4]. L'importanza della riduzione della 25-idrossilazione sembra limitata agli stadi più avanzati di insufficienza epatica [15]. L'integrazione con vitamina D è inoltre necessaria in caso di molti farmaci che interagiscono con il metabolismo epatico della vitamina D, come gli antiepilettici (carbamazepina, fenobarbital,dintoina), ma anche glucocorticoidi, agenti anti-neoplastici, antiretrovirali, antibiotici anti-tubercolari. Si consiglia l'integrazione con almeno 2.000 UI/die di colecalciferolo in pazienti con grave insufficienza epatica o in caso di terapie croniche che interferiscono con il metabolismo epatico della vitamina D. L'uso del calcifediolo è una possibile alternativa anche se le evidenze di un vantaggio sono limitate [4].

QUESITO 9. QUAL È IL PROFILO DI SICUREZZA E IL LIVELLO DI TOSSICITÀ?

Le "classiche" manifestazioni di intossicazione da vitamina D, come l'ipercalcemia e l'ipercalciuria, sono da considerarsi eccezionali con la somministrazione di colecalciferolo e possono verificarsi solo in caso di livelli di 25(OH)D intorno o superiori a 150-200 ng/mL [16]. La tossicità può verificarsi più frequentemente, anche con i dosaggi raccomandati, con calcitriolo o alfa-calcidiolo (come da RCP). Tra gli effetti di tossicità "non-classici" è stato riportato da alcuni studi il rischio di caduta. I dati sono contraddittori e limitati a dosi elevate in bolo e in soggetti instituzionalizzati, anche se in quelli carenti di vitamina D l'effetto di una normalizzazione (a 30 ng/ml) sembra essere protettivo sulle cadute [17].

CONCLUSIONI

Queste raccomandazioni sul *management* del deficit di vitamina D in Italia sono fondate sulla base scientifica più solida al momento, mediante l'uso di una metodica rigorosa, e sono indirizzate principalmente ai medici perché affrontino questo problema molto diffuso con appropriatezza basata sull'evidenza, offrendo un miglioramento dello standard di approccio al problema. Alcune raccomandazioni sono in linea con altre linee guida ma alcuni punti offrono un nuovo approccio, come la personalizzazione dei livelli ottimali. Le raccomandazioni si concentrano sugli effetti scheletrici della vitamina D in popolazioni a rischio. Non sono stati deliberatamente affrontati gli effetti extra-scheletrici, mentre si conferma per ora l'assenza di un evidente beneficio nella supplementazione della popolazione sana.

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