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EDITORIALE

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Cari Colleghi,

Il timore espresso nel mio editoriale del 2° numero del 2019 della Rivista si è purtroppo dimostrato fondato e in assenza di un'occasione di dibattito con le Autorità Sanitarie sul bilancio costi/benefici della supplementazione con vitamina D e di un aggiornamento degli operatori sanitari su un suo uso più appropriato… ora rischiamo, secondo me, che molti pazienti non abbiano il giusto accesso al trattamento con vitamina D. Come sapete, infatti, di fronte all'esorbitante ed effettivamente ingiustificata spesa per la vitamina D in Italia, l'Agenzia Italiana del Farmaco (AIFA) è recentemente ricorsa a una nota limitativa sulla prescrivibilità a carico del Servizio Sanitario Nazionale (SSN) di alcuni farmaci a base di vitamina D (colecalciferolo, calcifediolo nella formulazione in capsule, colecalciferolo/sali di calcio) con indicazione "prevenzione e trattamento della carenza di vitamina D" nell'adulto (nota 96, vedasi in questo numero e successiva integrazione).
Il contenuto della nota riconosce l'importanza della supplementazione di vitamina D in condizioni di carenza, in particolare per la salute muscolo-scheletrica, ma il testo si presta secondo me a incerte se non equivoche interpretazioni e lascia spazio a numerosi dubbi, nonostante i successivi chiarimenti pubblicati dalla stessa AIFA per gli operatori sanitari e i cittadini.
All'introduzione della nota conseguirà sicuramente una riduzione della spesa per la supplementazione di vitamina D a carico del SSN, ma non necessariamente attribuibile al miglioramento dell'appropriatezza d'uso, in quanto il testo si presta dal mio punto di vista a interpretazioni restrittive a scapito di pazienti che ne dovrebbero invece avere diritto e giovamento. I costi per il SSN potrebbero in realtà aumentare, in termini di diagnostica e soprattutto di mancata prevenzione.
Secondo me i punti più critici del testo della nota 96 sono i seguenti:

1. Pur riconoscendo che la carenza di vitamina D può essere del tutto asintomatica (punto 3, scheda vitamina D - cittadino) se ne raccomanda il *dosaggio solo nelle persone sintomatiche*, notoriamente affette da grave carenza e soprattutto già affette da gravi complicanze di ipovitaminosi D come l'osteomalacia; ciò sembra contrastare con uno dei principi dell'AIFA che sempre si è preoccupata di raccomandare la prevenzione delle malattie piuttosto che il ricorso ai farmaci per il loro trattamento. Anche l'affermazione contenuta nella guida alla misurazione dell'allegato 1 alla nota, secondo la quale la determinazione dei livelli di 25(OH)D non è indicata obbligatoriamente in tutte le possibili categorie a rischio, si presta a dubbia interpretazione nella pratica clinica: significa che il medico può talora ignorare quelle condizioni di rischio o, come ritiene il sottoscritto, che è in tal caso superfluo e motivo di spreco il dosaggio perché comunque raccomandata la supplementazione a scopo preventivo?
2. La *sintomatologia indicata attribuibile a ipovitaminosi D* (astenia, mialgie, dolori diffusi o localizzati, dolenza in sedi ossee, dolore lombosacrale, pelvico o agli arti inferiori, senso di impedimento fisico, debolezza muscolare soprattutto ai quadricipiti e ai glutei con difficoltà ad alzarsi da seduti, andatura ondeggiante, propensione alle cadute immotivate…) è

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largamente diffusa ed aspecifica, il più delle volte non attribuibile a ipovitaminosi D ma ad altre molteplici condizioni, spesso ben più gravi: non si ritiene che ciò possa contribuire a disorientare i medici e a indurli eccessivamente al ricorso a dosaggi della 25(OH)D inutili e costosi? Non si ritiene inoltre che in tal modo si inducano eccessive aspettative in termini di benefici sintomatici della supplementazione con vitamina D anche in condizioni nelle quali l'eventuale associata carenza non ha comunque un ruolo patogenetico?

3. Viene indicata la *determinazione della 25(OH)D in persone con iperparatiroidismo secondario*, inducendo un altro dosaggio, quello del paratormone (PTH), non raccomandato in prima linea dalle principali linee guida internazionali, notoriamente soggetto a grande variabilità analitica e biologica, costoso (22 euro) e fisiopatologicamente alterato in gran parte degli anziani; inoltre è noto che la maggior parte degli individui con carenza di vitamina D non ha concentrazioni di PTH oltre la norma.
4. Viene richiesta la *determinazione della vitamina D nelle persone affette da osteoporosi di qualsiasi causa o osteopatie accertate candidate a terapia remineralizzante*, per le quali la correzione dell'ipovitaminosi dovrebbe essere propedeutica all'inizio della terapia. E quelli che sono già in terapia? In più, perché dosare il 25(OH)D visto che poi, anche se superiore a 20 ng/ml, è raccomandata la supplementazione in caso di patologie ossee riconosciute (come indicato nell'algoritmo dell'allegato 1)? Mi pare che l'attuale testo della nota non affermi chiaramente quanto consentito dall'applicazione dell'algoritmo e cioè che in tutte le condizioni di osteoporosi o osteopatie accertate, anche in quelle candidate a terapia remineralizzante, è comunque raccomandata (come indicato dalla nota 79) e pertanto rimborsata la supplementazione con vitamina D. Inoltre nella pratica clinica comunque, preliminarmente o all'inizio di una terapia remineralizzante, è opportuna una supplementazione con dosi maggiori o più generose di vitamina D, pertanto la determinazione dei livelli di 25(OH)D nella maggior parte dei casi non risulta indispensabile nella gestione clinica del paziente.
5. Considerato che l'*esposizione solare*, come giustamente riconosciuto, rappresenta il meccanismo principale di produzione di vitamina D (80%), come mai tra le condizioni a rischio di ipovitaminosi D non sono indicate le più frequenti, cioè quelle legate a forzate condizioni di ridotta esposizione solare (ad esempio per motivi lavorativi, di disabilità o culturali o per condizioni che controindicano l'esposizione a UVB) o quelle legate a incapacità di produrre adeguate quantità di vitamina D nonostante l'esposizione solare, come ad esempio notoriamente in età avanzata ? Non mi sembra corretto limitarsi a riconoscere quali condizioni di rischio una terapia di lunga durata con farmaci interferenti col metabolismo della vitamina D o malattie che possono causare malassorbimento.
6. Il *dosaggio del 25(OH)D costa* nella mia Regione 17 euro; con questa spesa, ricorrendo alle formulazioni più economiche, posso trattare con vitamina D 3 pazienti per un anno. Considerato il largo e generico invito, se non il frequente obbligo del dosaggio previsto dalla nota 96, non si rischia di spostare la spesa dalla farmaceutica alla diagnostica?
7. Si afferma che il *dosaggio superiore ai 40 ng/ml* può essere associato a rischi aggiuntivi, tra cui, si precisa nei relativi chiarimenti, il rischio di neoplasie, sulla base di alcune segnalazioni, peraltro poste in dubbio dalla stessa fonte citata e contraddette da altri studi. Non mi risulta che le Autorità Regolatorie Europee abbiano sino a ora segnalato alert riguardanti il rischio di patologie oncologiche. Pertanto il limite dei 40 ng/ml, peraltro facilmente superabile con le comuni posologie indicate… o a causa di una bella giornata di sole…, appare attualmente un ingiustificato motivo di allarme, che peraltro esporrà il medico eil paziente a ulteriori ripetute e inutili richieste di dosaggio del 25(OH)D per il timore di averlo superato. È noto che per incorrere nel rischio del più certo effetto indesiderato della supplementazione con vitamina D, l'ipercalcemia, si devono superare i 100 ng/ml e credo comunque che alla luce delle conoscenze attuali sarebbe più adeguato segnalare possibili effetti indesiderati sopra i 50 ng/ml, come affermato in diverse linee guida.
8. La *soglia minima di 20 ng/ml* di 25(OH)D è ritenuta sufficiente nella popolazione generale, ma non in alcune condizioni di particolare rischio, negli anziani, nell'iperparatiroidismo secondario o nei pazienti in terapia remineralizzante per osteoporosi, come in parte riconosciuto in termini di evidenze scientifiche al punto 5 dei chiarimenti AIFA per l'operatore sanitario. Alcune autorevoli Società Scientifiche, ignorate nel background della nota, ritengono che in tali condizioni fornisca maggiori garanzie un livello di 25(OH)D superiore a 30 ng/ml.
9. È *prevista l'interruzione del trattamento a correzione avvenuta dei sintomi da carenza* salvo ricomparsa degli stessi: ma se persistono, magari perché non sono modificabili le condizioni che espongono al rischio di ipovitaminosi D, devo attendere che il mio paziente torni ad ammalarsi per poterlo ritrattare a carico del SSN? Dove stanno il riconoscimento dell'opportunità della prevenzione e il rispetto in tal senso dell'indicazione da RCP per il colecalciferolo?
10. Come ricordato nella nota 79, che come tutte le note AIFA è finalizzata fondamentalmente a definire i criteri di rimborsabilità dei farmaci per una migliore appropriatezza terapeutica, la prescrizione va comunque fatta nel *rispetto delle indicazioni e delle avvertenze della scheda tecnica* dei singoli farmaci. Questo principio non è ribadito e mi pare talora neppure rispettato dalla nota 96, che potrebbe ad esempio indurre l'uso di alcuni dei medicinali considerati anche quando controindicati o non indicati e che nell'allegato 1 fornisce indicazioni all'uso di specifici dosaggi e non a tutti quelli autorizzati da RCP. Inoltre vi sono studi che indicano come insufficienti per alcune tipologie di pazienti i dosaggi indicati nella nota.
11. La nota (in particolare l'allegato 1) indica la *necessità di una valutazione specialistica per alcune condizioni*, come l'insufficienza renale (peraltro immagino sia un refuso di stampa l'unità di misura scorretta usata per la sua definizione), ma non indica se vi siano o no i criteri di rimborsabilità per la vitamina D in queste condizioni.

12. Riguardo all'affermazione contenuta nel background circa gli effetti extrascheletrici della vitamina D, secondo la quale i risultati di trial clinici randomizzati (RCT) di elevata numerosità non avrebbero confermato l'ipotesi di benefici derivanti dalla supplementazione e avrebbero in particolare delineato in oncologia e cardiologia aree di documentata inefficacia …mi pare non sia stato considerato che i RCT attualmente disponibili sono stati condotti in gran parte in soggetti non carenti e quindi non sono in grado di escludere eventuali benefici in condizioni di carenza (come tra l'altro sarebbe più razionale attendersi e di fatto osservato in alcune sub-analisi).

In relazione appunto ai riconosciuti effetti immunologici, ospitiamo in questo numero un update di una nota Scuola genovese sul ruolo della vitamina D nelle malattie reumatologiche. Gli Autori concludono che sebbene la complessità delle malattie reumatologiche infiammatorie e autoimmunitarie e alcuni limiti metodologici degli studi pubblicati limitino fortemente generalizzazioni circa il potenziale terapeutico del colecalciferolo in queste patologie, i dati preliminari degli studi, unitamente alla sicurezza e al basso costo del colecalciferolo supportano fortemente l'uso del colecalciferolo in pazienti affetti da queste malattie, in considerazione dei potenziali e rilevanti benefici clinici.

Cosa ne pensate ?
Buona Lettura

ALLEGATO

Nota 96

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

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

Background

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

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

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

Evidenze disponibili

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

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

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

Particolari avvertenze

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

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

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

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

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

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

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

(adattato da NICE 2018)

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

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

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

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

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

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

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VITAMIN D
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VITAMINA D E MALATTIE REUMATICHE

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Riassunto

L'esistenza di una relazione tra vitamina D e malattie reumatologiche, inizialmente postulata sulla base degli studi epidemiologici, è stata largamente confermata attraverso studi sperimentali e clinici. In generale, la letteratura descrive un'elevata prevalenza di ipovitaminosi D nei pazienti affetti da malattie reumatologiche infiammatorie o autoimmunitarie, e una correlazione tra lo stato vitaminico D e l'attività/severità di malattia.
Gli studi randomizzati e controllati che hanno testato l'effetto della supplementazione con colecalciferolo (verso placebo) in pazienti affetti da malattie reumatologiche hanno dimostrato benefici di rilievo della vitamina D sia sugli indici clinimetrici che su alcuni outcome clinici. Sebbene la complessità delle malattie reumatologiche infiammatorie e autoimmunitarie e alcuni limiti metodologici degli studi pubblicati ostacolino in modo considerevole generalizzazioni circa il potenziale terapeutico del colecalciferolo in queste patologie, i dati preliminari degli studi, unitamente alla sicurezza e al basso costo del colecalciferolo, supportano fortemente l'uso del colecalciferolo in pazienti affetti da queste malattie, in considerazione dei potenziali e rilevanti benefici clinici.

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Conflitto di interessi
Gli Autori dichiarano di non avere alcun conflitto di interessi.

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INTRODUZIONE

Le due funzioni principali tradizionalmente riconosciute alla vitamina D sono la regolazione dell'omeostasi calcio-fosforo e il controllo del metabolismo minerale scheletrico, classicamente definite "effetti scheletrici" [1-3]. In questo contesto, l'effetto della vitamina D nell'omeostasi del calcio è rilevante non solo per le implicazioni "ossee", ma anche per alcune funzioni metaboliche cellulari e neuro-muscolari.
Nel corso degli ultimi trent'anni, sono state evidenziate alcune funzioni della vitamina D su omeostasi/metabolismo di numerosi tessuti e organi, che nel complesso sono state definite "extra-scheletriche". La vitamina D sembrerebbe avere un effetto sulla proliferazione e differenziazione cellulare e sul sistema cardiocircolatorio, e un effetto modulatore sul sistema immunitario [1-3].
Gli "effetti extra-scheletrici", inizialmente ipotizzati sulla base delle evidenze derivanti da modelli animali [4], sono stati successivamente confermati da numerosi studi epidemiologici [5]. Tuttavia, a fronte delle numerose e solide evidenze epidemiologiche che hanno confermato una correlazione tra il mantenimento di valori appropriati di 25-idrossi-vitamina D sierica [25(OH)D] e la minore incidenza di alcune patologie, i dati derivanti dagli studi randomizzati e controllati (RCT) sono piuttosto eterogenei e talvolta anche contrastanti [5].
L'obiettivo di questa revisione narrativa è descrivere la relazione esistente tra la vitamina D e alcune malattie reumatologiche infiammatorie e autoimmunitarie (IRD) e riassumere le evidenze relative ai benefici della supplementazione con colecalciferolo nelle IRD.

VITAMINA D E SISTEMA IMMUNITARIO

Le osservazioni cliniche e i dati sperimentali suggeriscono come la vitamina D giochi un ruolo critico nella modulazione della funzione immunitaria [6-8]. La vitamina D, infatti, attraverso il suo metabolita attivo, il calcitriolo [1,25$(OH)_2$D], sembrerebbe in grado di in-

fluenzare l'attività della maggioranza delle cellule del sistema immunitario.
Due osservazioni supportano questa ipotesi [6-8]:

- il recettore della vitamina D (VDR) è espresso dalla maggior parte delle cellule immunitarie, 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.

La funzione modulante della vitamina D riguarderebbe sia l'immunità innata che l'immunità adattativa [6-8].
Il ruolo della vitamina D quale regolatore dell'immunità innata è stato ampiamente caratterizzato [6-8]. 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, ridurre la permeabilità intestinale, e, più in generale, "facilitare" la funzione di barriera dei tessuti contro i patogeni [6].
Per quanto riguarda il sistema immunitario adattativo, i dati sperimentali appaiono più eterogenei, pur supportando un effetto sulla funzione immunitaria [6-8]. 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 Treg (stimolazione della funzione) [6]. Il 1,25$(OH)_2$D ha inoltre dimostrato di ridurre la proliferazione e differenziazione dei linfociti B, determinando anche una minore espressione di auto-anticorpi [6-8].
In conclusione, sebbene i dati disponibili non sempre siano supportati da solide evidenze, nel complesso sembrerebbero indicare come la vitamina D giochi un ruolo nella difesa contro agenti patogeni e nella riduzione dei processi infiammatori/autoimmunitari dell'organismo, attività che fondamentalmente richiamano a un'azione immuno-modulante.

IPOVITAMINOSI D NELLE MALATTIE REUMATOLOGICHE INFIAMMATORIE E AUTOIMMUNITARIE

Gli studi epidemiologici hanno confermato in modo univoco un'elevata prevalenza di ipovitaminosi D in numerose IRD.
In media, i pazienti affetti da artrite reumatoide (AR), artrite psoriasica (AP), spondilite anchilosante (SA), sclerosi sistemica (SS) e *lupus* (LES) sembrerebbero avere un valore di 25(OH)D inferiore di almeno 8-10 ng/ml rispetto ai rispettivi controlli sani.[9-14]
In un'analisi post-hoc dello studio CARMA (Fig. 1) [9], lo stato vitaminico D di 2.234 pazienti affetti da AR, AP e SA è stato confrontato con quello di 667 soggetti sani. La prevalenza di deficienza di vitamina D (< 20 ng/ml) oscillava tra il 40 e il 41% nei pazienti (AR, AP e SA), mentre risultava del 27% nei soggetti sani (P < 0,001). Il dato si dimostrava ancora più rilevante se si pensa che l'età media della popolazione era largamente inferiore a 60 anni e che in percentuale variabile i pazienti erano trattati con supplementi di vitamina D. Nel caso della AR, dove si riscontrava la percentuale più elevata di pazienti in terapia con colecalciferolo (42%), la relazione tra AR e ipovitaminosi D era particolarmente solida anche nell'analisi multivariata (OR = 1,5 - 95% IC 1,1-2,0) [9].
L'elevata prevalenza di ipovitaminosi D in pazienti affetti da AR è stata chiaramente confermata da una recente meta-analisi condotta su 15 studi osservazionali (1.100 AR e 1.000 controlli sani) [12]. Gli autori hanno confermato valori medi di 25(OH)D significativamente inferiori nei pazienti AR rispetto ai controlli, con una prevalenza di deficienza significativamente superiore nei pazienti AR (AR 55% *vs* sani 33%; OR = 2,5 - 95% IC 1,1-5,3).
Studi analoghi condotti in pazienti con LES o SS hanno portato alle stesse conclusioni [10,11,13,14].
Islam et al. hanno recentemente condotto una revisione degli studi che hanno investigato la prevalenza di ipovitaminosi D nel LES [13]. Complessivamente hanno analizzato 34 studi (2.265 LES e 1.846 controlli sani). Il valore medio di 25(OH)D nei pazienti LES era mediamente inferiore di circa 10 ng/ml rispetto ai controlli. La differenza tra LES e controlli diventava particolarmente rilevante nei pazienti in terapia con idrossiclorochina, corticosteroide o altro immunosoppressore, in assenza di appropriata supplementazione con vitamina D (differenza media rispetto ai soggetti sani: 16 ng/ml) [13].
Risultati analoghi sono stati descritti in un'altra meta-analisi che ha revisionato i dati relativi a SS e ipovitaminosi D (6 studi, 554 SS e 321 sani).[14] La differenza media standardizzata tra pazienti SS e soggetti sani era di circa 9 ng/ml, con una certa variabilità legata anche alle caratteristiche della SS.

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 alcune IRD, non sono in grado di definire un rapporto causa-effetto. In altre parole non chiariscono l'eventuale nesso patogenetico tra prolungata deficienza di 25(OH)D e l'insorgenza della malattia.

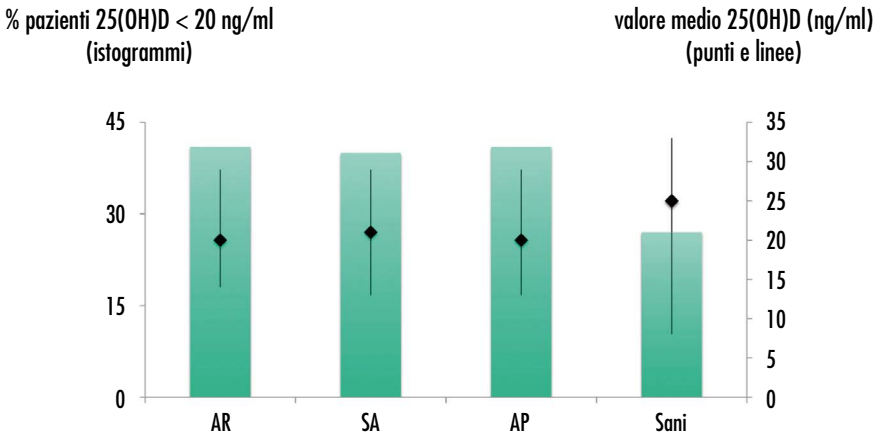

FIGURA 1.
Percentuale di pazienti con deficienza [25(OH)D < 20 ng/ml] di vitamina D (istogrammi) e valore medio (95% IC) di 25(OH)D (ng/ml) (punti e linee) in soggetti sani e affetti da AR, SA e AP (studio CARMA) (da Urruticoechea-Arana et al., 2015, mod.) [9].

Dimostrare un rapporto causa-effetto nel caso della vitamina D non è semplice, in quanto richiede studi longitudinali a lungo termine condotti sulla popolazione generale. In questo contesto, pertanto, i dati relativi all'incidenza di IRD nella popolazione sana, in funzione dei valori basali di 25(OH)D o dell'*intake* di colecalciferolo, sono assolutamente scarsi.

Due studi 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 [15,16]. 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 (HR = 0,8 - 95% IC 0,7-0,9) [15]. Questi risultati non sono stati confermati nello studio gemello NHSII [15].

Il *Iowa Women's Health Study*, 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 (attraverso sia la dieta che la supplementazione) fosse associato a un ridotto rischio di AR (RR = 0,7 - 95% IC 0,4-1,0) [16].

In contrapposizione con quanto descritto va sottolineato come post-hoc analisi dei NHS e NHSII e altri studi non abbiano confermato la relazione tra vitamina D e rischio di AR o LES [17-19], sottolineando pertanto la necessità di disegnare e condurre nuovi studi ad hoc per investigare il rapporto causa-effetto tra ipovitaminosi D e incidenza di IRD.

STATO VITAMINICO D E ATTIVITÀ/SEVERITÀ DI MALATTIA

L'esistenza di una relazione tra stato vitaminico D [25(OH)D sierica] e attività o severità di malattia è stata documentata in numerosi studi condotti prevalentemente (ma non solo) in pazienti affetti da AR, LES e SS [10-12,20-23].

La gran parte degli studi che hanno esaminato il rapporto tra 25(OH)D e attività di malattia nei pazienti affetti da AR ha evidenziato l'esistenza di una correlazione inversa tra stato vitaminico D e DAS28, VAS e/o VES [12,20-22]. Nello studio COMORA, per esempio, condotto su 1.413 pazienti AR, il valore medio di DAS28 nei soggetti normo-vitaminosici D era significativamente inferiore rispetto ai soggetti ipo-vitaminosici D (Fig. 2) [22]. Una relazione analoga (correlazione inversa) è stata descritta anche per gli ACPA da Wang et al. [21].

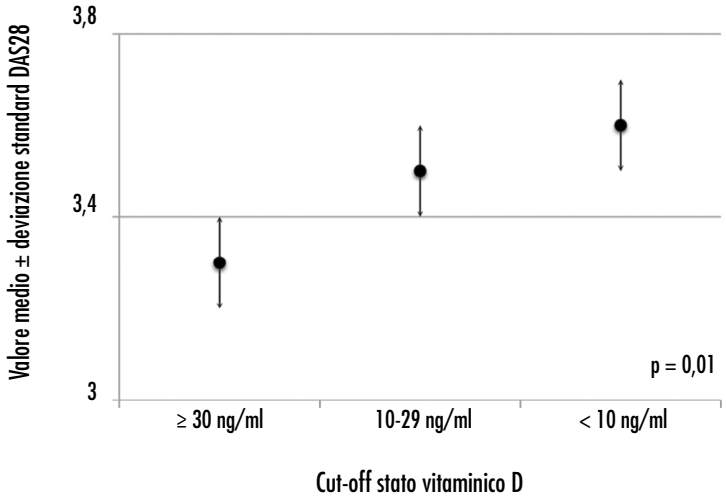

FIGURA 2.
Valore medio di DAS28 ± deviazione standard nei pazienti affetti da AR in funzione dello stato vitaminico D. Cut-off vitamina D: 25(OH)D ≥ 30 ng/ml; 30 ng/ml > 25(OH)D ≥ 10 ng/ml; 25(OH)D < 10 ng/ml (da Hajjaj-Hassouni et al., 2017, mod.) [22].

Anche nel caso della SS e del LES i dati clinici hanno evidenziato una correlazione inversa tra 25(OH)D e attività di malattia o outcome clinici (ulcere sclerodermiche e indici clinimetrici) [10,11,23]. Nel caso della SS, per esempio, Caimmi et al. hanno analizzato la relazione tra variazione del valore di 25(OH)D nel corso del tempo e incidenza di ulcere digitali in 65 pazienti SS, dimostrando come una riduzione della 25(OH)D (48% dei pazienti) nel corso dei 5 anni di follow-up fosse associata a un maggior rischio di sviluppare ulcere digitali (OR = 16,6 - 95% IC 1,7-164,5) [11]. In un altro studio, che ha confrontato il valore medio di 25(OH)D in funzione dell'attività di malattia misurata con SLEDAI in 199 pazienti LES, è stato evidenziato un progressivo decremento della 25(OH)D con il progressivo peggioramento dello SLEDAI (Fig. 3) [10].

TRATTAMENTO 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 outcome clinici, attraverso la supplementazione con colecalciferolo in pazienti con deficienza di vitamina D affetti da IRD [7].

Il potenziale terapeutico del colecalciferolo e dei suoi metaboliti nelle IRD è stato oggetto di recente revisione della letteratura in una *review* che ha descritto i principali RCT condotti in pazienti affetti da LES, AR, Morbo di Crohn, sclerosi multipla e diabete tipo 1 [7].

Nel caso del LES, sono state testate verso placebo dosi di colecalciferolo comprese tra 2.000 UI e circa 7.000 UI al giorno, in studi della durata compresa tra 3 e 12 mesi. Due di questi studi, e in particolare quello di durata più lunga (12 mesi) e quello con la dose 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 [7].

Gli studi RCT di supplementazione con colecalciferolo o suoi metaboliti nella AR hanno riportato dati meno solidi, benché estremamente incoraggianti, probabilmente anche in relazione ai numerosi limiti degli RCT (numerosità dei pazienti, durata del follow-up e valore basale di 25(OH)D relativamente alto) [7]. In generale, questi RCT hanno evi-

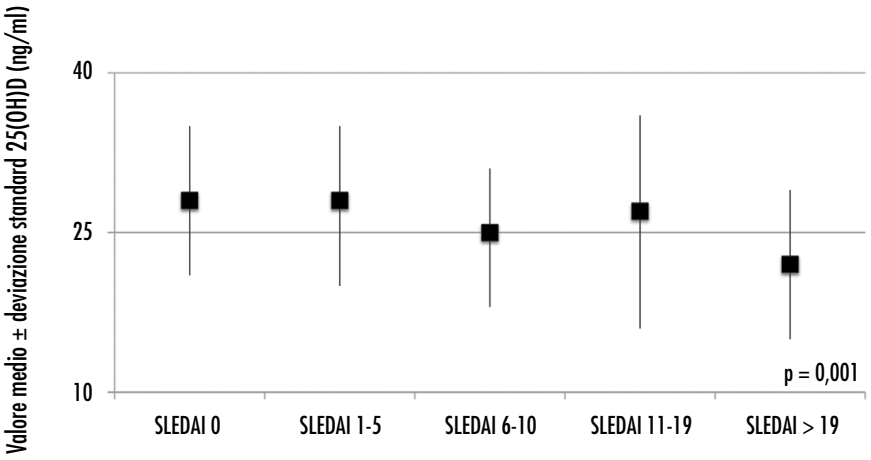

FIGURA 3.
Valori medi di 25(OH)D (ng/ml ± deviazione standard) in pazienti affetti da LES categorizzati sulla base della attività di malattia misurata con SLEDAI (da Eloi et al., 2017, mod.) [10].

denziato un trend positivo su parametri quali il DAS28, la VES e i sintomi clinici, che tuttavia non raggiungeva la significatività statistica [7].
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 [24]. 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 [24].

CONCLUSIONI

Con i limiti dovuti alla complessità ed eterogeneità delle IRD, i dati della letteratura sembrerebbero confermare in maniera univoca un ruolo della vitamina D in malattie quali AR, SS e LES. Il significato della vitamina D in altre IRD (AP e SA) sarebbe meno chiaro prevalentemente per il ridotto numero di studi pubblicati e per la modesta qualità degli stessi, ed è pertanto verosimile che anche in queste patologie la vitamina D giochi un ruolo rilevante [20]. Nel complesso si può affermare che i livelli sierici di 25(OH)D sembrerebbero influenzare l'attività e la severità di alcune IRD, e potenzialmente anche alcuni outcome clinici, mentre meno chiaro è il rapporto causa-effetto nella patogenesi delle IRD.
Sulla base dei dati derivati dai RCT, la supplementazione con colecalciferolo dovrebbe essere offerta a tutti i pazienti affetti da IRD 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 IRD normo-vitaminosici D finalizzato a migliorare il decorso clinico e gli outcome della malattia dovrà invece essere oggetto di RCT disegnati ad hoc e condotti su casistiche appropriate.

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