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EDITORIALE

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Cari Lettori,

in questo numero ospitiamo un update del prof. Peroni sul ruolo della vitamina D in età pediatrica e un update del prof. Triggiani sugli effetti della vitamina D nella prevenzione delle patologie cerebrovascolari.
Pensate: a soli due anni dai loro precedenti contributi c'è già bisogno di un update!
Entrambi gli Autori, in maniera equilibrata e obiettiva, ammettono che nonostante la vitamina D abbia degli effetti biologici riconosciuti, ben al di là di quelli scheletrici, gli studi di intervento per valutare l'effetto sulla prevenzione o sul miglioramento delle patologie che si attribuiscono a difetti di vitamina D sono spesso contraddittori, almeno per il momento e che i risultati dei trial clinici, fin qui disponibili, hanno generalmente fallito nel dimostrare un miglioramento significativo degli endpoint nel campo extra-scheletrico pediatrico e cerebrovascolare.
Entrambi gli Autori tuttavia concordano sul fatto che la contraddizione, tra quanto visto in preclinica e negli studi osservazionali di associazione e quanto risulta dai trial interventistici, piuttosto che gettare ombre, crea le premesse per un ulteriore approfondimento sul ruolo della vitamina D nella prevenzione di esiti extra-scheletrici. Concludono che è necessario acquisire nuovi dati per valutare meglio i dosaggi ottimali, la durata della supplementazione e i livelli sierici ottimali per avere degli esiti biologici e clinici positivi. L'attuale analisi dei dati di outcome dei trial non consente, infatti, di escludere il possibile effetto benefico della vitamina D in ambito extra-scheletrico. È possibile infatti identificare un quadruplice ordine di fattori responsabili dei risultati negativi, come riassunto in una recente pubblicazione della Scuola veronese [1]: popolazione di studio che non presentava un alto rischio per l'evento valutato, presenza di cofattori non adeguatamente valutati, periodo di osservazione insufficiente per valutare quell'outcome e livelli pre-supplementazione non carenziali di vitamina D, requisito quest'ultimo essenziale se si ritiene che la vitamina D agisca come nutriente, cioè sia utile supplementarla solo quando manca.
Inoltre, come recentemente ipotizzato da Colleghi francesi [2], è possibile ci sia un'altra intrigante spiegazione: l'"autacoid paradigm". Il termine "autacoid" deriva dal greco *autos* (self) e *akos* (rimedio). Questo sistema prevede che le molecole siano prodotte e agiscano localmente, a livello intracellulare o tessutale "a richiesta", mediante *signalling* autocrino o paracrino. In effetti, come sapete, a livello circolante il sistema endocrino cerca di garantire con una fine regolazione livelli costanti di 1,25$(OH)_2$D, nonostante la grande variabilità dei livelli di 25(OH)D in seguito al grado di esposizione solare o di introito alimentare o supplementare, a eccezione di condizioni di grave carenza o di estremo sovraccarico di vitamina D. Tuttavia, recentemente è stato scoperto un importante metabolismo sia 25- che 1-idrossilasico extra-epatico ed extra-renale della vitamina D, come ad esempio quello a livello cutaneo, adiposo e del sistema immune e nervoso. L'espressione in questi vari tessuti di queste attività enzimatiche e di recettori per la vitamina D rappresenta appunto l'"autacoid system". Questo sistema, a differenza di quello endocrino, è inducibile, ad esempio in seguito a stimoli infiammatori, e prevede che l'aumento locale dell'1,25$(OH)_2$D sia transitorio e autolimitante, grazie all'induzione della

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24-idrossilasi disattivante. Così le funzioni immunomodulatorie dell'1,25$(OH)_2$D sono limitate nel tempo e nello spazio nelle foci di infiammazione e non interferiscono con i livelli sierici circolanti di 1,25$(OH)_2$D. È evidente che la sintesi locale di 1,25$(OH)_2$D richiede che i suoi precursori, il 25(OH)D e soprattutto il colecalciferolo, siano localmente biodisponibili e ciò dipende sia dai loro livelli circolanti ma anche dalle loro scorte tessutali.

Questo nuovo paradigma, molto diverso quindi da quello endocrino, prevede che in particolare gli effetti extra-scheletrici della vitamina D dipendano pertanto anche dalle riserve tessutali dei metaboliti della vitamina D prodotti o inattivati localmente. Considerando questo paradigma, capite che ottenere livelli circolanti di 25(OH)D nella circolazione sistemica è necessario ma non sufficiente, se a livello tessutale per qualche motivo (Insufficiente induzione? Eccessivo catabolismo? Carenza di colecalciferolo o di metaboliti precursori?) non si ottengono adeguate concentrazioni di metaboliti attivi della vitamina D.

Ebbene attualmente noi nei trial valutiamo solo (e neppure sempre!) i livelli circolanti di 25(OH)D ma non quelli di 1,25$(OH)_2$D e tantomeno le concentrazioni tessutali, che sono quelle funzionali, in particolare per gli effetti extra-scheletrici. Capite anche che questo nuovo paradigma, scoperto un secolo dopo quello endocrino, apre la strada a nuove intriganti filoni di ricerca, quali la possibilità che talora la somministrazione locale di colecalciferolo o di 25(OH)D possa risultare un'opzione migliore alla supplementazione orale per ottenere alcuni benefici extra-scheletrici. Ad esempio, l'applicazione transcutanea di vitamina D a livello del seno potrebbe essere più efficace di quella orale nella prevenzione e nel trattamento del tumore al seno? O addirittura arriveremo a sconsigliare di coprire il seno per favorire la produzione cutanea locale di colecalciferolo?

Cosa ne pensate?
Buona Lettura

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UPDATE VITAMINA D IN PEDIATRIA

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INTRODUZIONE

La vitamina D (VD) è essenziale per l'uomo. Oltre alla nota attività sul metabolismo fosfo-calcico e sulla mineralizzazione ossea, ne conosciamo le azioni a livello extra-scheletrico, grazie alla presenza del suo recettore e dell'enzima 1α-idrossilasi in molte cellule dell'organismo. Le azioni extra-scheletriche sono rilevanti per l'organismo in via di sviluppo poiché interferiscono con i processi di maturazione anche immunologica, contribuendo allo stato di salute.

In una revisione da me preparata nel 2017 queste erano state le conclusioni sulla VD in pediatria:

- la VD sembra offrire delle prospettive in termini di prevenzione e cura di patologie croniche;
- essa può svolgere un ruolo sinergico nel mantenimento e sviluppo delle difese immunitarie del bambino;
- i valori sierici di normalità sono centrali nell'ottenimento di efficacia clinica al di là di quello che è richiesto dal metabolismo osseo. Anche se circa 1/3 della popolazione dei Paesi occidentali, Italia compresa, presenta dei livelli di VD insufficienti (livelli sierici < 20 ng/nl - 50 nmol/L), è stato suggerito che i livelli d'efficacia nel sostenere la risposta adeguata del sistema immunitario debbano essere maggiori (perlomeno o superiori a 30-40 ng/m - 75-100 nmol/L) (Fig. 1).

Si noti che queste affermazioni sono tutte condizionate (può, è possibile…). Si tratta di stabilire quale sia il ruolo della VD nelle patologie croniche, argomento molto controverso e dibattuto, dove in letteratura troviamo spesso dati discordanti e non univoci. Studi osservazionali nell'adulto hanno riportato in varie condizioni patologiche una peggiore severità nei soggetti con bassi livelli di VD. Molto spesso però studi di supplementazione hanno dato risultati negativi o controversi e hanno delineato in cardiologia e oncologia aree di documentata inefficacia. Lo studio *VITamin D and OmegA-3 TriaL* (VITAL), somministrando 2.000 UI/die di VD + acidi grassi omega 3, 1 g/die, rispetto al placebo dopo 5 anni non ha dato differenze in termini di outcome di neoplasie o patologia cardiovascolare, suggerendo come siano ben diversi i dati di associazione rispetto a quelli ottenuti con la supplementazione [1,2].

Scopo peraltro di questo aggiornamento è di dare un update ragionato su ciò che la letteratura presenta come ruolo della VD in pediatria, di come i livelli di VD assunti nella dieta siano quasi sempre insufficienti a tutte le età [3] e di come la supplementazione sia la via per ottenere livelli adeguati. Resta da chiarire se il raggiungimento di livelli adeguati si associ poi a un miglioramento clinico significativo.

La recente Nota 96, istituita dall'Agenzia Italiana del Farmaco (AIFA) per introdurre nuovi criteri regolatori sulla rimborsabilità della VD a carico del Servizio Sanitario Nazionale (SSN) nella popolazione adulta, non è applicabile ai soggetti di età pediatrica (0-18 anni), per i quali la rimborsabilità resta a carico del SSN (Nota 96, Gazzetta Ufficiale Serie Generale n. 252 del 26-10-2019). Tale disposizione potrebbe essere spiegata dalla maggiore vulnerabilità dei bambini quando lo stato vitaminico D non è adeguato, una condizione che necessita di una più vasta tolleranza prescrittiva.

AZIONE SUL TESSUTO OSSEO

Partirei dalle novità, relative, sul metabolismo osseo. In pediatria dobbiamo considerare l'azione primaria della VD nella formazione della massa ossea fin dai primi momenti della vita. Essa ha un'azione ipercalcemizzante che inizia a livello intestinale, dove promuove l'assorbimento di calcio (Ca) e fosforo (P), incrementando l'espressione dei canali di Ca sulla superficie degli enterociti. Il deficit di VD è associato a un incremento del paratormone (PTH) che determina un aumento del turnover osseo e una riduzione della densità ossea, favorendo l'insorgenza di rachitismo durante l'infanzia e di osteomalacia nell'età adolescenziale e adulta [4]. Proprio a tal proposito un articolo inglese del 2018 mette in

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Conflitto di interessi
L'Autore dichiara di non avere alcun conflitto di interessi.

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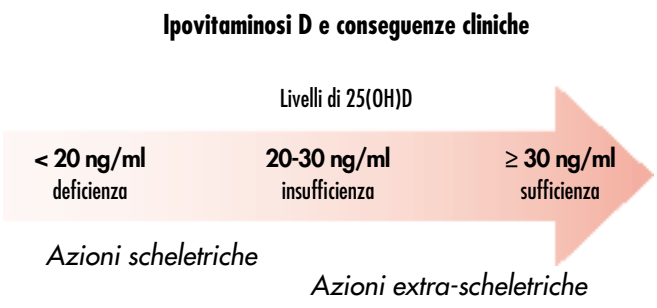

FIGURA 1.
Valori di vitamina D.

guardia sulla ripresa dell'incidenza di casi di rachitismo in quel Paese, dove la supplementazione neonatale e infantile non è mandatoria [5]. Inoltre, i casi aumentano in Inghilterra perché la sola fortificazione degli alimenti non protegge completamente da una carenza significativa. Questo, associato alla presenza di fattori di rischio per ipovitaminosi come etnia, colorito cutaneo scuro, pratiche religiose e stili di vita, comporta un aumento del rischio di cui bisogna tener conto e che ha indotto gli autori ad auspicare una variazione della politica sanitaria di prevenzione [5].

VITAMINA D IN GRAVIDANZA E ALLATTAMENTO

Sempre maggiori evidenze scientifiche confermano l'importanza di uno stato vitaminico D adeguato nella donna durante la gravidanza e l'allattamento, per gli esiti sia materni che fetali e neonatali.
La Nota 96, pubblicata da AIFA lo scorso ottobre 2019, ha introdotto nuovi criteri regolatori per la rimborsabilità a carico del SSN della VD nella popolazione adulta e ha ufficialmente riconosciuto l'importanza della VD nelle donne in gravidanza e in allattamento, includendole tra gli scenari clinici in cui la supplementazione con VD è rimborsata indipendentemente dalla determinazione della 25(OH)D.
Durante la gravidanza il metabolismo della VD si modifica per far fronte all'aumentato fabbisogno di Ca necessario per la mineralizzazione dello scheletro fetale, incrementando in maniera consistente i livelli sierici materni di $1,25(OH)_2D$. Il calcitriolo ha un ruolo fondamentale nel modulare l'omeostasi fosfo-calcica nella madre e nel feto e, quindi, nell'aumentare l'assorbimento di Ca al livello intestinale [4]. Il feto è quasi completamente dipendente dalla madre per quanto riguarda i livelli di 25(OH)D. I livelli di VD materni e neonatali sono infatti strettamente correlati, come dimostrato dall'associazione positiva tra i livelli di 25(OH)D materni valutati durante la gravidanza o in prossimità del parto e quelli cordonali o neonatali. L'elevata prevalenza di ipovitaminosi D nelle donne gravide rappresenta una condizione molto diffusa. Uno studio italiano [4] ha valutato i livelli sierici di 25(OH)D in donne gravide italiane a termine di gravidanza e ha mostrato che il 60% circa delle donne sono risultate avere livelli sierici di VD < 20 ng/ml.
Passando all'allattamento al seno, il latte materno rappresenta sicuramente l'alimento più adatto per la nutrizione del bambino, ma contiene come sappiamo scarse quantità di VD (< 50 UI/l) che risultano insufficienti secondo quanto raccomandato dalle Società Scientifiche Internazionali in questa fascia di età (400 UI/die) (Tab. I). La letteratura ha evidenziato, inoltre, che il contenuto di VD del latte correla direttamente con i livelli materni di 25(OH)D e presenta il medesimo andamento stagionale dello stato vitaminico D materno (valori più elevati durante il periodo estivo, influenzati quindi dall'esposizione solare della madre) [6]. Questi risultati confermano l'importanza della promozione di uno stato vitaminico D adeguato non soltanto nel bambino ma anche nella madre che allatta.
A tal proposito, uno studio ha mostrato che la donna che allatta presenta di per sé un rischio di carenza di VD aumentato di 4 volte rispetto alle donne che non allattano, specie se in inverno e in primavera [7].
La donna che allatta è inoltre a rischio di fratture da fragilità a causa della perdita di massa ossea. Durante la lattazione, diverse variazioni ormonali, indipendenti dall'assorbimento di calcio, possono infatti determinare la perdita del 5-10% del contenuto minerale osseo per assicurare l'apporto di calcio nel latte [8]. Le donne che allattano secernono, infatti, circa 210 mg di calcio al giorno nel latte prodotto dal seno e vivono un prolungato periodo di amenorrea *post partum* durante il quale il livello ematico di estrogeni si riduce significativamente. Durante l'allattamento, pertanto, si inducono significativi cambiamenti metabolici nello scheletro materno sia per il calcio trasmesso al bambino, sia per l'elevato turnover osseo causato dal drastico calo degli estrogeni dopo il parto.

AZIONI EXTRA-SCHELETRICHE

Negli ultimi anni sono state individuate molte azioni della VD definite extra-scheletriche. Tra queste un ruolo di primo piano è svolto dalla regolazione della risposta immunitaria. Da anni è noto come la VD eserciti importanti funzioni sulle diverse cellule dell'immunità innata e adattativa. Produce defensine e catelicidina che contribuiscono a fornire delle difese pronte per il bambino, orienta le cellule dendritiche (DC) verso una maggiore tollerogenicità, presenta un'azione antinfiammatoria, sopprimendo i linfociti Th17 e incrementando la quota dei linfociti T regolari (Treg). Riduce la produzione di citochine proinfiammatorie dai linfociti Th1. È in grado di regolare anche la barriera intestinale che nel neonato è ancora immatura, aumentando la maturazione delle cellule epiteliali, promuovendo la formazione delle *tight-junctions* e facendo maturare le cellule del sistema immunitario presenti nell'intestino.

RUOLO NELLE INFEZIONI

Molti studi hanno rilevato una relazione tra stato vitaminico e infezioni respiratorie; in particolare, nei bambini affetti da rachitismo si riscontra una maggior incidenza di infezioni respiratorie. Camargo et al. hanno riscontrato un rischio maggiore di infezioni respiratorie a 3 mesi di età nei neonati con valori di VD < 10 ng/ml nel sangue cordonale rispetto ai neonati con valori > 30 ng/ml [9]. Alle stesse conclusioni sono giunti Belderbos et al. riguardo a una maggior incidenza di bronchiolite nei neonati con deficit vitaminico [10].

RUOLO NEL *WHEEZING* E NELL'ASMA

Nella prevenzione, autori danesi hanno dimostrato che alte dosi di VD dalla 24ª settimana di gestazione non si associavano a una riduzione del rischio di asma dei nati a 6 anni di vita [11], anche se altri studi hanno evidenziato un effetto positivo della supplementazione sulla funzionalità polmonare del neonato. Molti studi hanno dimostrato che il deficit di VD correla in età pediatrica a un maggior numero di infezioni respi-

TABELLA I.
Trattamenti proposti dalle Società Scientifiche Internazionali per la profilassi e la terapia del deficit di vitamina D.

	Profilassi con D_3 o D_2	Trattamento con D_3 o D_2
0-12 mesi	400-1.000 UI/die indipendentemente dal tipo di allattamento	2.000 UI/die per 6 settimane oppure 50.000 UI/settimana per 6 settimane < 1 mese: 1.000 UI/die per 1-3 mesi 1-12 mesi: 1.000-3.000 UI/die (in base al peso) per 1-3 mesi
Pretermine con PN < 1.500 g	200-400 UI/die	
Pretermine con PN > 1.500 g	400-600 UI/die	
1-18 anni	600-1.000 UI/die, almeno nei mesi con bassa insolazione; si consigliano dosi raddoppiate-triplicate nei soggetti con fattori di rischio	2.000 UI/die per 6-8 settimane oppure 50.000 UI/settimana per 6-8 settimane
1-18 anni con fattori di rischio: obesità, patologie epatiche, malassorbimento intestinale [malattia infiammatoria intestinale (IBD), celiachia, fibrosi cistica], terapie con farmaci anticomiziali, corticosteroidi, antiretrovirali o antifungini	1.000-1.500 UI/die, almeno nei mesi con bassa insolazione	4.000-6.000 UI/die

ratorie e quindi di accessi ospedalieri, di ricoveri e di utilizzo di cicli di terapia con corticosteroidi orali [12].
Che la supplementazione di VD ad alte dosi sia in grado di ridurre la frequenza delle riesacerbazioni asmatiche e favorire un miglior controllo della patologia verrà probabilmente chiarito da studi come quello in corso (studio DIVA) [12]: studio multicentrico canadese in bambini prescolari con *wheezing* scatenato da infezioni virali, che riceveranno due dosi di VD ad alte dosi 100.000 UI a distanza di 2 mesi e una dose giornaliera di 400 UI per il periodo invernale *vs* placebo. Le attuali evidenze dimostrano che la supplementazione ha diminuito il rischio di riesacerbazioni (meno steroidi sistemici, meno visite in Pronto Soccorso), ma con meno efficacia sulla severità dell'asma [13]. Una metanalisi ha indicato che il maggior beneficio si ha nei pazienti con livelli di partenza di 25(OH)D molto bassi (< 10 ng/mL) e in chi effettuava una terapia a dosi giornaliere o settimanali [14]. Gli effetti sono però meno evidenti nei bambini da 1 a 5 anni, dove forse la patologia respiratoria ostruttiva ha cause e una fisiopatologia diverse.

RUOLO NELLE MALATTIE AUTOIMMUNI

Molti studi hanno individuato una correlazione tra la presenza di ipovitaminosi D e il rischio di sviluppare patologie autoimmuni quali diabete tipo 1 (DM1), morbo di Chron e artrite reumatoide (AR). Infatti, un apporto adeguato di VD durante i primi anni di vita è associato a una riduzione del rischio di sviluppare DM1 negli anni successivi, in modo direttamente proporzionale alla dose somministrata [15,16]. In particolare, con un effetto protettivo del 27% in Inghilterra, anche se altri studi non hanno dato esito positivo in termini di protezione del rischio. Questo sia che la supplementazione fosse effettuata durante la gravidanza oppure durante l'infanzia. Gli studi randomizzati controllati però sono pochi.
Nella AR la prevalenza della malattia aumenta in caso di ipovitaminosi D. Per quanto riguarda la supplementazione i risultati sono ancora una volta controversi: la supplementazione potrebbe avere un impatto sulla severità della malattia specie se i livelli sono bassi, anche se nuovi studi in questo settore sono necessari.

OBESITÀ E SINDROME METABOLICA

I dati disponibili indicano che c'è un'associazione tra obesità e ipovitaminosi D (valori insufficienti > 50% dei bambini obesi). Comunque, l'effetto biologico del difetto di VD su insulino-resistenza, ipertensione, iperlipidemia e progressione a diabete tipo 2 è probabilmente poco rilevante. Per questo i risultati della supplementazione non sono univoci [3].

CONCLUSIONI

In conclusione, la VD ha degli effetti biologici ben al di là di quelli scheletrici. Se è importante mantenere dei livelli adeguati di VD per mantenere un ottimale stato di salute osseo, questo può essere d'utilità anche per una varietà di sistemi e organi diversi. Comunque, studi di intervento per valutare l'effetto sulla prevenzione o sul miglioramento delle patologie che si attribuiscono a difetti di VD sono stati spesso contraddittori, almeno per il momento. Maggiori dati dalla ricerca sono necessari per valutare dosaggi ottimali, durata della terapia, e i livelli sierici indicativi per avere degli esiti clinici o biologici positivi.

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VITAMIN D
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LA VITAMINA D NELLA PREVENZIONE DELLE PATOLOGIE CEREBROVASCOLARI: I RISULTATI DEI NUOVI TRIAL CLINICI TRA IMPREVISTI E PROBABILITÀ

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INTRODUZIONE

L'ictus ischemico è la principale causa di disabilità a lungo termine e la quarta causa di mortalità a livello mondiale. L'Organizzazione Mondiale della Sanità (OMS) ha stimato che ogni anno si verificano circa 15 milioni di nuovi casi di ictus, dei quali 5 milioni con esito fatale, mentre in altri 5 milioni di casi si verificherà una disabilità grave e permanente con rilevanti costi sociali. Si ritiene che nei prossimi anni l'invecchiamento della popolazione e la riduzione della mortalità per ictus determineranno un progressivo aumento della prevalenza. I ricercatori hanno cercato di creare sistemi validati di calcolo del rischio al fine di identificare i pazienti ad alto rischio per ridurre la possibilità di insorgenza dell'ictus e di identificare soglie di rischio che consentano di impostare una terapia preventiva efficace [1,2].

Accanto allo studio di fattori di rischio noti per le patologie cerebrovascolari – ipertensione, diabete, dislipidemie, fumo, fibrillazione atriale – una particolare attenzione è stata rivolta negli ultimi anni all'identificazione di nuovi potenziali fattori di rischio, tra i quali hanno assunto particolare rilevanza i fattori nutrizionali e dietetici.

La vitamina D, ampiamente utilizzata per la prevenzione e il trattamento delle patologie ossee [3], è stata introdotta negli anni recenti anche per la possibile prevenzione delle malattie cerebrovascolari. Da oltre un decennio negli Stati Uniti le vendite di vitamina D sono cresciute esponenzialmente, rendendola uno degli integratori più ampiamente utilizzati [4,5]. I suoi potenziali benefici sono stati sostenuti da studi ecologici, di laboratorio e osservazionali, ma tali dati sono risultati inconsistenti e insufficienti per stabilire un nesso di causalità [3,6,7]. Gli studi sull'utilità della vitamina D nella prevenzione delle malattie cerebrovascolari, condotti con analisi secondarie o post hoc, hanno offerto risultati largamente nulli. Ma tutti presentavano limitazioni dovute alla bassa dose, a un potere inadeguato dello studio, a una breve durata e a un accertamento subottimale degli endpoint [3]. Non esistevano studi condotti su vasta scala, con dosi significativamente alte di vitamina D, aventi quale endpoint primario la prevenzione delle malattie cerebrovascolari. Pertanto, l'*Institute of Medicine* [3] e la *Preventive Services Task Force* degli Stati Uniti [8] giunsero alla conclusione che i dati disponibili non consentivano un accertamento definitivo dell'efficacia e della valutazione del rapporto rischio/beneficio dell'uso della vitamina D per questo scopo. L'*Institute of Medicine* invitò la comunità scientifica a intraprendere trial clinici con alti dosaggi di vitamina D (almeno doppi rispetto alla dose giornaliera raccomandata di 600-800 UI/die per la salute ossea) in popolazioni differenti, compresi gli afroamericani che tendono ad avere una minore sintesi cutanea di vitamina D con l'esposizione alla luce solare rispetto ai membri di altri gruppi etnici [9].

I NUOVI TRIAL CLINICI (Tab. I)

Il *VITamin D and OmegA-3 TriaL* (VITAL) è stato il primo trial su vasta scala [10,11]. Condotto negli Stati Uniti, è un trial randomizzato, in doppio cieco, *vs* placebo, che ha valutato i benefici e i rischi di un'integrazione dietetica di vitamina D_3 (2.000 UI/die) e acidi grassi omega-3 (1 g/die di Omacor® capsule di olio di pesce con 840 mg di acidi grassi omega-3, comprendenti acido eicosapentaenoico [EPA,

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460 mg] + acido docosaexaenoico [DHA, 380 mg]) per la prevenzione primaria del cancro e delle patologie cerebrovascolari in 25.871 uomini e donne degli USA, di età ≥ 50 e ≥ 55 rispettivamente. Il disegno dello studio prevedeva un numero simile di uomini e donne e un ampio campione di afroamericani. Lo studio ha avuto una durata di 5,3 anni. I risultati del VITAL hanno dimostrato che la vitamina D non determina una riduzione dell'endpoint co-primario di patologie cerebrovascolari (composto da infarto del miocardio, ictus e mortalità cerebrovascolare; HR = 0,97 [0,86-1,08]). Inoltre, non riduce gli endpoint cardiovascolari secondari prespecificati, comprendenti un composito espanso di eventi cerebrovascolari maggiori più rivascolarizzazione coronarica (HR = 0,96 [0,86-1,08]), o infarto miocardico (HR = 0,96 [0,78-1,19]), ictus (HR = 0,95 [0,76-1,20]) e mortalità cerebrovascolare (HR = 1,11 [0,88-1,40]) considerati individualmente. La vitamina D non ha effetto su tutte le cause di mortalità (HR = 0,99 [0,87-1,12]). Simili risultati sono stati visti in analisi che hanno escluso il primo o i primi due anni di follow-up o hanno eliminato la non compliance. Non sono stati rilevati significativi incrementi, associati al trattamento, del rischio di ipercalcemia, calcolosi renale o sintomi gastrointestinali. La vitamina D non influenza i cambiamenti a un anno dei marker lipidici o infiammatori. L'associazione tra vitamina D e rischio di endpoint cerebrovascolari o mortalità per tutte le cause non differisce significativamente per razza o gruppo etnico, fattori di rischio cardiovascolari, livelli sierici di 25(OH)D, simultanea randomizzazione per acidi grassi omega-3 o altre caratteristiche prespecificate come potenziali effetti modificanti, la vitamina D non riduce significativamente questi endpoint in nessun sottogruppo.

Il *Vitamin D Assessment Study* (ViDA) è un trial randomizzato, in doppio cieco, *vs* placebo, condotto in Nuova Zelanda [12]. I 5.110 partecipanti sono stati suddivisi in due gruppi che hanno ricevuto vitamina D_3 (n = 2.558) alla dose iniziale di 200.000 UI seguita, dopo un mese, da una dose mensile di 100.000 UI o placebo (n = 2.552) per una mediana di 3,3 anni (range 2,5-4,2 anni). Non è stata rilevata alcuna differenza significativa nella percentuale di tutti gli eventi combinati cerebrovascolari fra il gruppo della vitamina D (11,8%) e quello del placebo (11,5%) (HR = 1,02 [0,87-1,20]). Anche la sottoanalisi per infarto miocardico (RR = 0,90 [0,54-1,50]) e ictus (RR = 0,95 [0,55-1,62]) non ha prodotto risultati significativi. Gli stessi risultati sono stati ottenuti nel sottogruppo di partecipanti con deficit di vitamina D (HR = 1,00 [0,74-1,35]) e quando i partecipanti erano suddivisi per precedenti eventi vascolari. Non è stata rilevata alcuna differenza tra i gruppi di vitamina D e placebo al momento del primo evento vascolare o nella frequenza di outcome secondari patologia-specifici. Anche il ViDA, come lo studio VITAL, ha rilevato che la vitamina D non riduce il rischio di mortalità per tutte le cause.

La breve durata dello studio e la somministrazione di vitamina D in bolo (100.000 UI/mese) costituiscono limiti importanti di questo trial.

Lo studio *Women's Health Initiative* (WHI) è un trial randomizzato, in doppio cieco, *vs* placebo, nel quale sono state arruolate 36.282 donne in postmenopausa, con età compresa tra 51 e 82 anni, provenienti da 40 centri clinici degli Stati Uniti [13]. Le partecipanti sono state suddivise in due gruppi che hanno ricevuto rispettivamente 1.000 mg di calcio carbonato + 400 UI di vitamina D_3/die oppure il placebo. Il periodo medio di follow-up è stato di 7 anni. I risultati di questo studio per patologia coronarica (HR = 1,04 [0,92-1,18]), ictus (HR = 0,95 [0,82-1,10]) e morte per cause vascolari (HR = 0,92 [0,77-1,10]) non sono risultati statisticamente significativi.

Il *RECORD Trial* (*Randomized Placebo-Controlled Trial of Vitamin D3 and/or Calcium*) è uno studio pragmatico, randomizzato, fattoriale, *vs* placebo, dell'integrazione con calcio e/o vitamina D_3 per la prevenzione secondaria di fratture da fragilità ossea [14]. La ricerca è stata condotta su 5.292 soggetti con un'età media di 77 anni. La durata media del follow-up è stata di 6,2 anni. I partecipanti presentavano una carenza di vitamina D all'ingresso nel trial e sono stati suddivisi in quattro gruppi: vitamina D_3 (800 UI/die), calcio (1.000 mg/die), entrambi, placebo. Gli outcome principali erano costituiti dalla mortalità per tutte le cause, mortalità per patologie vascolari, mortalità per neoplasie e incidenza di neoplasie. Gli *Hazard Ratio* per infarto miocardico (HR = 0,97 [0,75-1,26]), ictus (HR = 1,06 [0,85-1,32]), e mortalità vascolare HR = 0,91 [0,79-1,05]) non sono risultati significativi. In un'analisi statistica *post hoc* aggiustata per la compliance e, quindi, con un minore numero di partecipanti, i trend per una ridotta mortalità nel gruppo trattato con la vitamina D e un'aumentata mortalità nel gruppo che aveva assunto solo il calcio risultavano accentuati, anche se tutti i risultati non hanno raggiunto la significatività statistica.

Trivedi et al. hanno condotto uno studio per determinare l'effetto dell'integrazione ogni 4 mesi di vitamina D sul tasso di fratture in uomini e donne di età ≥ 65 anni [15]. Il trial era randomizzato, in doppio cieco e prevedeva la somministrazione di 100.000 UI/die di vitamina D_3 o di placebo ogni 4 mesi per un periodo di 5 anni. Sono stati inclusi 2.686 soggetti (2037 uomini e 649 donne) di età compresa tra 65 e 85 anni. Gli *Hazard Ratio* per l'incidenza di patologia coronarica (HR = 0,94 [0,77-1,15]), mortalità cardiaca (HR = 0,84 [0,56-1,27]), incidenza di patologia cerebrovascolare (HR = 0,90 [0,77-1,06]), e mortalità vascolare (HR = 0,84 [0,65-1,10]), non hanno raggiunto la significatività statistica.

Il *Finnish Vitamin D Trial* (FIND) per la prevenzione primaria delle neoplasie e delle patologie cerebrovascolari, con una durata di studio di 5 anni, ha previsto l'arruolamento di 2.495 soggetti (uomini con età ≥ 60 anni e donne con età ≥ 65 anni) [16]. I partecipanti sono stati suddivisi in tre gruppi che hanno ricevuto rispettivamente 1.600 o 3.200 UI/die di vitamina D o placebo. Era stato previsto inizialmente di arruolare 18.000 partecipanti ma lo studio è stato successivamente ridimensionato per difficoltà di reclutamento e per mancanza di fondi. Gli outcome primari comprendono l'incidenza di neoplasie e patologie vascolari. I risultati del trial, attesi per giugno 2018, non sono ancora stati pubblicati.

Lo studio VITAL resta finora l'unico trial condotto su un ampio campione di popolazione avente come endpoint primari il cancro e le patologie cerebrovascolari. Infatti, gli ulteriori due studi su vasta scala: il *D-Health* australiano [17] e il *Vitamin D and Longevity* (VIDAL) britannico [18], che prevedono rispettivamente l'arruolamento di 25.000 e di 20.000 individui, hanno come loro endpoint la mortalità totale e l'incidenza di neoplasie. Soltanto il *D-Health* prevede l'esame dell'incidenza di patologie cerebrovascolari, i risultati del trial sono attesi per il 2021.

Una recente metanalisi di trial sulla vitamina D [19], che ha incluso anche gli studi VITAL e ViDA, ha dimostrato che la vitamina D non riduce il rischio di eventi avversi cardiovascolari maggiori (10 trial,

TABELLA I. I nuovi trial clinici.

Trial	Campione	Range età	Durata (anni)	Dose vit. D	Outcome
Vitamin D and Omega-3 Trial (VITAL), USA	25.875	≥ 50 uomini ≥ 55 donne	5	2.000 UI/die	Neoplasie, patologie vascolari
Vitamin D Assessment Study (ViDA), Nuova Zelanda	5.110	50-84	3.3 (mediana)	100.000 UI/mese	Patologie vascolari
Women's Health Initiative (WHI)	36.282	51-82	7 (media)	400 UI/die	Frattura del femore, altre fratture, cancro del colon-retto, mortalità totale e per cause
Randomized Placebo-Controlled Trial of Vitamin D_3 and/or Calcium (RECORD)	5.292	77 (media)	6.2 (media)	800 UI/die	Mortalità totale, per cause vascolari e per neoplasie, incidenza neoplasie
Trivedi et al.	2.686	65-85	5	100.000 UI ogni 4 mesi	Incidenza fratture, mortalità totale
Finnish Vitamin D Trial (FIND), Finlandia	2.495	≥ 60 uomini ≥ 65 donne	5	1.600 UI/die o 3.200 UI/die	Neoplasie, patologie vascolari
D-Health, Australia	21.315	60-84	5	60.000 UI/mese	Mortalità totale, neoplasie
Vitamin D and Longevity (VIDAL), Gran Bretagna	20.000	65-84	5	100.000 UI/mese	Mortalità totale, neoplasie

6.243 eventi, 79.111 partecipanti; RR = 1,00 [0,95-1,06]), di infarto del miocardio (18 trial, 2.550 eventi, 82.576 partecipanti; RR = 1,00 [0,93-1,08]), ictus (15 trial, 2.354 eventi, 82.239 partecipanti; RR = 1,06 [0,98-1,15]), o mortalità cardiovascolare (10 trial, 2.202 eventi, 76.783 partecipanti; RR = 0,98 [0,90-1,07]).

CONCLUSIONI

I risultati di studi sperimentali in vitro e in vivo suggeriscono che l'1,25(OH)$_2$D inibisce la proliferazione delle cellule muscolari lisce vascolari e la calcificazione vascolare, influisce favorevolmente sull'omeostasi del volume e della pressione sanguigna mediante la regolazione del sistema renina-angiotensina-aldosterone, riduce l'infiammazione e migliora la sensibilità all'insulina [20-23]. In studi osservazionali prospettici, i livelli di 25(OH)D sono inversamente correlati con i fattori di rischio e con gli eventi cerebrovascolari [24-26]. Tuttavia, i risultati dei trial clinici fin qui disponibili, hanno generalmente fallito nel dimostrare un miglioramento significativo degli endpoint di prevenzione vascolare. Questa contraddizione di risultati, piuttosto che gettare ombre, crea le premesse per un ulteriore approfondimento sul ruolo della vitamina D nella prevenzione delle patologie cerebrovascolari. L'analisi dei dati di outcome dei trial non consente, infatti, di escludere definitivamente il possibile effetto benefico della vitamina D nella prevenzione delle malattie cerebrovascolari. È possibile identificare un triplice ordine di fattori responsabili dei risultati negativi: popolazione di studio che non presentava un alto rischio cerebrovascolare, con livelli non carenziali di vitamina D, con presenza di cofattori non adeguatamente valutati.

Si pone, pertanto, la necessità di identificare la popolazione a rischio vascolare che potrebbe effettivamente beneficiare di una integrazione con la vitamina D. È possibile ipotizzare che i livelli protettivi di vitamina D per le patologie vascolari siano più bassi rispetto a quelli di altre patologie, per esempio le neoplasie. Molto probabilmente i pazienti inclusi in trial clinici aventi come endpoint principali l'incidenza di neoplasie ed eventi vascolari, presentavano già un livello basale di vitamina D protettivo per questi ultimi. In quest'ottica occorrerebbe focalizzare l'attenzione sul sottogruppo di popolazione ad alto rischio cerebrovascolare che presenta una carenza severa di vitamina D (≤ 10 ng/mL).

Il deficit di vitamina D, piuttosto che come singolo fattore di rischio, dovrebbe essere considerato nell'ottica di un'alterazione nutrizionale complessa che determina una disfunzione, a livello endoteliale, dell'omeostasi della circolazione e della coagulazione ematica e del metabolismo glucidico e lipidico, con il conseguente possibile aumento del rischio per eventi vascolari maggiori.

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