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 Editoriale

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nelle malattie
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di narrazione!

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Cari Colleghi

in questo numero troverete innanzitutto un update sul possibile ruolo della vitamina D in diverse malattie dermatologiche, poiché il suo deficit può concorrere alla patogenesi di alcune malattie cutanee, sia neoplastiche che immunomediate.

Da reumatologo sono in particolare interessato alla psoriasi, la cui incidenza e gravità si sono dimostrate associate in numerosi studi a carenza di vitamina D e il cui trattamento prevede da anni l'uso di analoghi topici della vitamina D.

L'associazione della psoriasi con manifestazioni artriche è frequente e ben nota: l'artrite psoriasica è classificata tra le spondiloartriti (SpA), che rappresentano un gruppo eterogeneo di malattie reumatologiche infiammatorie croniche accomunate da caratteristiche genetiche, radiologiche e cliniche, tra cui il possibile coinvolgimento delle entesi, dello scheletro assiale e delle articolazioni sacroiliache oltre che di quelle periferiche. Numerose evidenze dimostrano che specifiche citochine infiammatorie sono coinvolte nella patogenesi delle SpA (IL17, IL23, TNF- α , IL6). In particolare l'IL17 svolge un ruolo patogenetico sia per quanto riguarda l'impegno articolare che per quello a livello delle entesi e dell'osso. Recenti evidenze indicano inoltre che nella patogenesi delle SpA sono coinvolti anche fattori metabolici oltre che immunologici, tra cui in particolare quelli che modulano il metabolismo osseo, come DKK1, sclerostina e PTH, come da noi dimostrato¹⁻⁵. Su entrambe queste componenti patogenetiche, immunologiche e metaboliche, vi è il razionale scientifico per ritenere che la vitamina D, spesso descritta carente in pazienti affetti da SpA⁶⁻¹⁰, possa avere un ruolo importante. Infatti, oltre a svolgere un ruolo essenziale nella regolazione del metabolismo fosfo-calcico, tra cui il controllo del PTH, la vitamina D è anche riconosciuta per le sue azioni immunomodulatorie e antinfiammatorie¹¹. La vitamina D può infatti agire con meccanismo endocrino (la tipica azione di regolazione del metabolismo osseo), ma anche autocrino-paracrino, grazie alla presenza all'interno delle singole cellule dell'enzima 1- α -idrossilasi in grado di produrre il metabolita attivo 1,25(OH)₂ vitamina D. Sia il recettore per la vitamina D che l'1- α -idrossilasi sono espressi da diversi tipi di cellule immunitarie tra cui macrofagi, cellule T, cellule dendritiche, monociti e cellule B, e studi preclinici indicano che la vitamina D esercita effetti biologici sia sul sistema immunitario innato che su quello adattativo, tra cui quelli sulla produzione di citochine proinfiammatorie.

È noto che la carenza di vitamina D è associata a un aumento dei livelli sierici di mediatori pro-infiammatori, tra cui IL-6 e TNF- α , che sono correlati sia allo sviluppo che alla progressione di patologie reumatologiche infiammatorie come le SpA. Recentemente abbiamo inoltre osservato che in soggetti sani, ma carenti di vitamina D, la supplementazione con quest'ultima determina una riduzione significativa dei livelli di IL-6 e IL-17¹².

Il secondo articolo di questo numero è dedicato al dibattito in corso sulla scelta tra colecalciferolo e calcifediolo. Gli Autori concludono che sulla base delle conoscenze di fisiologia e delle attuali evidenze scientifiche il colecalciferolo dovrebbe essere considerato la terapia di prima scelta nella prevenzione e nel trattamento della carenza di vitamina D e che l'uso del calcife-

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	Differenze % rispetto ai 31 mesi APRILE 17 - OTTOBRE 19 (PRE NOTA 96)		31 MESI NOVEMBRE 19 - MAGGIO 22 (POST NOTA 96)	
	IN NOTA	ATC 5	Numero confezioni	Spesa lorda
Alfacalcidolo	NO	A11CC03	45,9%	54,5%
Calcitriolo	NO	A11CC04	-4,8%	-3,9%
Colecalciferolo	SI	A11CC05	-21,3%	-16,4%
Calcifediolo	SI	A11CC06	41,1%	49%
Colecalcif. + calcio	SI	A12AX	-27,1%	-28,9%
TOTALE ATC IN NOTA			-19,6%	-15,7%
TOTALE ATC NON IN NOTA			8,5%	18,2%

IN NOTA	
lorda mensile ATC media POST	21.341.970
lorda mensile ATC media ANTE	25.331.506
RISPARMIO MEDIO MENSILE	3.989.536
NON IN NOTA	
lorda mensile ATC media POST	2.027.640
lorda mensile ATC media ANTE	1.714.870
AGGRAVIO MEDIO MENSILE	312.770
Risparmio medio mensile osservato negli ultimi 19 mesi nelle ATC in nota: 2.807.326	

FIGURA 1.

NOTA 96 – Monitoraggio andamento dei consumi della nota relativa alla vitamina D. Ufficio Monitoraggio della Spesa Farmaceutica e Rapporti con le Regioni. Agenzia Italiana del Farmaco (AIFA). Ultimo dato analizzato: maggio 2022. Analisi su 31 mesi dopo l'introduzione della nota (https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_31mesi_08.11.2022.pdf).

diolo dovrebbe essere limitato a situazioni particolari, quali per esempio sindromi da malassorbimento, obesità di grado severo o insufficienza epatica.

Anche nelle "Particolari avvertenze" della Nota 96 dell'Agenzia Italiana del Farmaco (AIFA)¹³ si precisa che le principali prove di efficacia antifratturativa sono state conseguite utilizzando colecalciferolo, che risulta essere la molecola di riferimento per tale indicazione e che la documentazione clinica in questa area di impiego per gli analoghi idrossilati è molto limitata. Dovrebbe preoccupare pertanto che dal monitoraggio di AIFA dei consumi di vitamina D in seguito alla Nota 96¹⁴, a fronte di un risparmio di spesa per la riduzione nell'uso di colecalciferolo, emerge un aumento del consumo di calcifediolo e di alfacalcidolo, trascurabile dal punto di vista economico ma non da quello dell'appropriatezza (Fig. 1).

Cosa ne pensate?

Buona lettura

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Il ruolo della vitamina D nelle malattie dermatologiche

VITAMIN D

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INTRODUZIONE

La vitamina D è di grande interesse anche in ambito dermatologico. Tra questa e la cute esiste un duplice rapporto, infatti, da un lato è sintetizzata dai cheratinociti in risposta all'esposizione solare e dall'altro agisce attivamente sulla cute stessa. A tale processo bidirezionale è stato dato il nome di sistema fotoendocrino della vitamina D¹.

Da un punto di vista biochimico la cute sintetizza il pro-ormone vitamina D₃ (colecalfiferolo) attraverso l'interazione tra 7-deidrocolesterolo e la luce ultravioletta. Tale processo riesce a soddisfare fino all'80% del nostro fabbisogno giornaliero. Numerosi sono i fattori che influenzano la capacità della cute di sintetizzare la vitamina D e tra i più importanti ci sono latitudine, stagionalità, fototipo e modalità di esposizione solare². Una percentuale minoritaria del fabbisogno, pari al 20%, è assunta tramite l'alimentazione in forma di vitamina D₂ (ergocalciferolo), presente in frutta e verdura, e vitamina D₃, contenuta in quantità elevate soprattutto in salmone e aringa. La vitamina D₃, biologicamente inattiva, viene convertita a livello epatico in 25-idrossi-vitamina D₃ (calcifediolo), la forma maggiormente presente nel circolo sistemico. Il calcifediolo è nuovamente idrossilato a livello renale in 1,25-diidrossi-vitamina D₃ (calcitriolo) la quale, interagendo con specifici recettori nucleari, denominati *Vitamin D Receptor* (VDR), è il principale mediatore degli effetti biologici di questa molecola (Fig. 1)³.

La vitamina D svolge attività fondamentali sul tessuto osseo, regolando l'omeostasi fosfo-calcica e una carenza della stessa causa osteomalacia, osteoporosi e maggiore predisposizione a fratture ossee.

Gli effetti di questa vitamina non sono tuttavia limitati allo scheletro e si hanno crescenti evidenze sulle sue ubiquitarie proprietà antiproliferative e immunomodulanti. Una carenza di vitamina D è stata documentata in diverse patologie cardiovascolari, oncologiche, neurologiche, autoimmuni e infettive^{2,4}.

Di particolare interesse sono le molteplici funzioni che la vitamina D esplica a livello cutaneo. Agendo sui cheratinociti mediante un meccanismo autocrino e paracrino, ne controlla la differenziazione e la proliferazione e ne stimola la produzione di ceramidi, che sono dei lipidi essenziali per mantenere l'idratazione cutanea¹. La vitamina D svolge, inoltre, un ruolo importante nella difesa contro le infezioni cutanee inducendo la produzione di peptidi antimicrobici, quali catelicidina LL-37 e beta-defensina⁵. La vitamina D esercita una rilevante funzione immunomodulatoria, inibendo la presentazione antigenica da parte delle cellule di Langerhans e la proliferazione sia di linfociti B che T, inducendo complessivamente uno *shift* da una risposta di tipo Th1 a una risposta Th2. Inibisce la produzione di citochine proinfiammatorie, quali IL-1, -6, -8, -12, TNF-alfa e interferon-gamma, inducendo invece la produzione di citochine antinfiammatorie, quali IL-10, e la differenziazione di cellule T regolatorie¹.

Tra le principali patologie dermatologiche associate a deficit di vitamina D sono comprese sia le neoplasie della cute sia alcune tra le più frequenti patologie immunomediata, quali la dermatite atopica, la psoriasi e la vitiligine.

NEOPLASIE CUTANEE

La vitamina D è coinvolta nella differenziazione, maturazione e senescenza cellulare e ha un effetto inibitorio sulla neoangiogenesi e oncogenesi⁶. Tuttavia, l'associazione tra deficit di vitamina D e neoplasie cutanee è controversa perché i dati raccolti dagli studi sono contrastanti³. L'esposizione solare è allo stesso tempo uno dei principali fattori di rischio per questo tipo di neoplasia ma anche la principale fonte di colecalfiferolo. Per lo stesso motivo la fotoprotezione raccomandata dalle linee guida dermatologiche con lo scopo di prevenire fotoinvecchiamento e fotocarcinogenesi potrebbe, in linea teorica, determinare una minore produzione di vitamina D a livello cutaneo¹. Le evidenze attuali sembrano suggerire che tale fenomeno sia improbabile con

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Conflitto di interessi

Gli Autori dichiarano nessun conflitto di interessi.

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L'80% del fabbisogno di vitamina D è garantito dall'irradiazione solare UVB (290-315 nm)

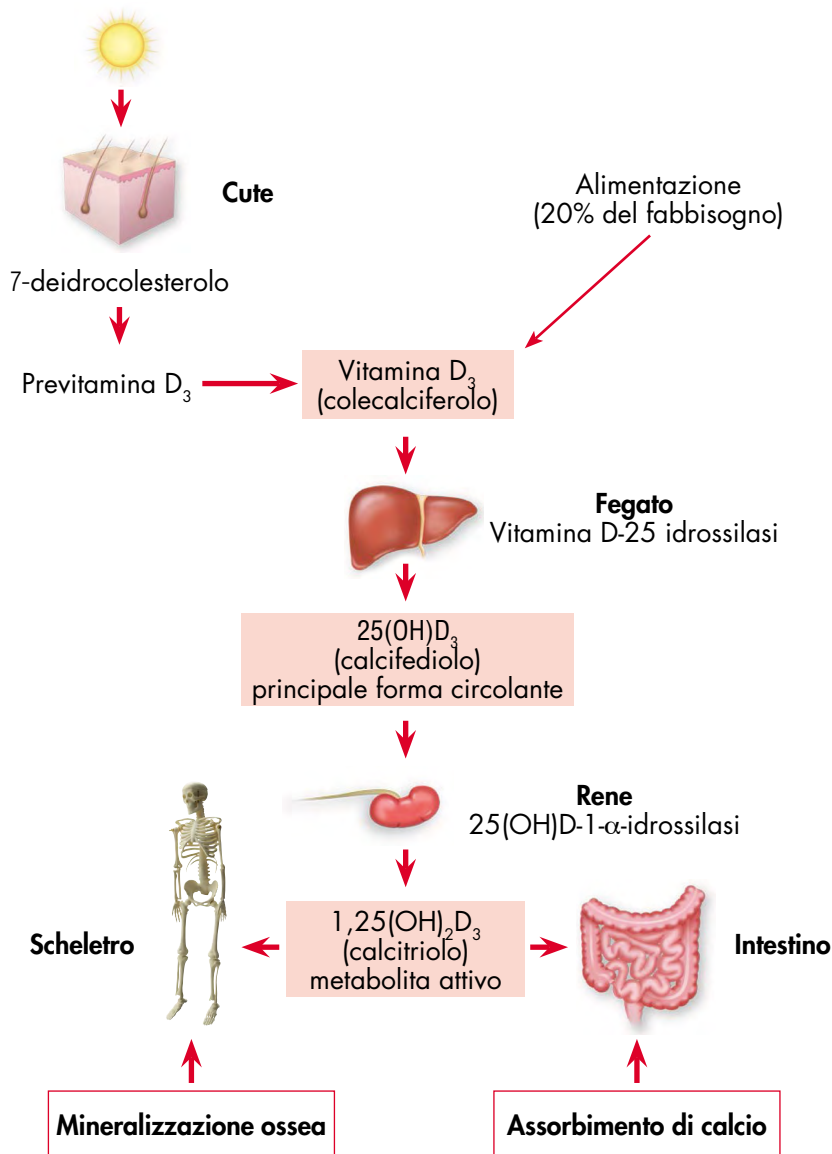


FIGURA 1. Sintesi e metabolismo della vitamina D³.

in comuni filtri solari. Non sono disponibili validi studi che abbiano definito il rapporto tra esposizione solare, fotoprotezione, livelli di vitamina D e rischio di neoplasie². La vitamina D potrebbe essere coinvolta nello sviluppo di *Non Melanoma Skin Cancer* (NMSC), tumori che hanno come cellula di origine il cheratinocita e si manifestano come noduli eritematosi, talora ulcerati, in genere nelle zone fotoesposte (volto, cuoio capelluto, dorso). Più specificatamente è stato osservato che la vitamina D ha la

proprietà di inibire la via di segnale Hedgehog, la quale ha un ruolo chiave nello sviluppo di carcinomi basocellulari (BCC)². I dati clinici presenti in letteratura sono tuttavia contrastanti, talora associando positivamente e talvolta negativamente livelli sierici di vitamina D e incidenza di NMSC, sia BCC che carcinomi squamocellulari. È stata persino osservata un'associazione positiva tra NMSC ed elevati livelli sierici di vitamina D, ma non tra NMSC e supplementazione orale⁷.

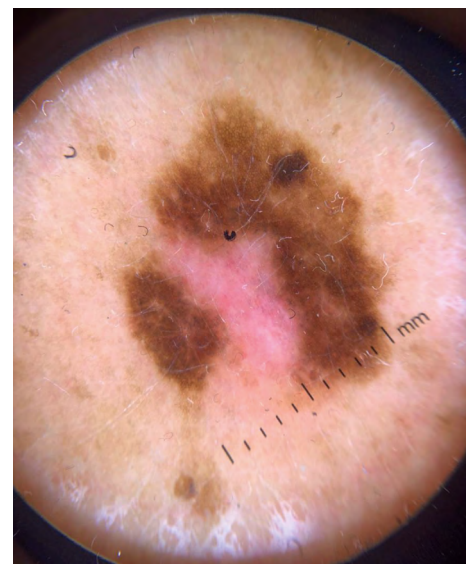


FIGURA 2. Melanoma maligno della cute. Immagine in epiluminescenza (ingrandimento ottico 10X).

Il melanoma cutaneo (Fig. 2) è un tumore che deriva dalla trasformazione neoplastica dei melanociti che fanno parte, insieme ai cheratinociti, dell'epidermide e hanno il compito di produrre melanina, un pigmento che protegge dagli effetti dannosi dei raggi ultravioletti solari. Per quanto riguarda il melanoma studi in vitro hanno dimostrato che la vitamina D e i suoi metaboliti sono in grado di inibire la proliferazione di cellule di melanoma sia in modelli animali che umani⁶. Tale effetto sembra in parte dipendere dall'espressione di VDR all'interno delle cellule neoplastiche e dalla presenza di specifici polimorfismi di singolo nucleotide a livello del gene codificante⁶. I risultati, sebbene talvolta contrastanti, sembrano suggerire un'associazione clinica tra bassi livelli sierici di vitamina D e insorgenza, progressione e outcome del melanoma^{8,9}. In particolare, l'ipovitaminosi sembra rivestire un ruolo significativo per i melanomi insorti in sedi non fotoesposte, i quali spesso presentano una prognosi peggiore. Tale risultato potrebbe dipendere non solo da un ritardo diagnostico ma anche da un effetto protettivo mediato dalla vitamina D a livello delle aree fotoesposte¹⁰. Non sono ancora disponibili dati conclusivi su possibili effetti di prevenzione delle neoplasie cutanee mediante supplementazione orale di vitamina D^{1,2}.

DERMATITE ATOPICA

La dermatite atopica (DA) è la più frequente malattia infiammatoria cutanea. È caratterizzata da un'eziologia multifattoriale comprendente fattori di predisposizione genetica, alterazione della funzione di barriera cutanea, tra cui un difetto della filaggrina, e risposta immunitaria Th2. La vitamina D possiede capacità sia immunomodulatoria che di stimolazione della produzione di filaggrina. La DA è stata associata a ipovitaminosi D sia nell'adulto che nel bambino⁵. Questo dato è coerente con il dato epidemiologico che entrambe queste condizioni presentano un'incidenza maggiore all'aumentare della latitudine e di conseguenza con una ridotta esposizione solare. È stato inoltre osservato che bambini affetti da DA presentano un miglioramento clinico in seguito a migrazione verso latitudini inferiori¹¹. La scarsa esposizione alla luce solare durante i mesi invernali potrebbe in parte spiegare le esacerbazioni di malattia che avvengono comunemente nei mesi freddi, mentre in genere la DA tende a migliorare in estate. Inoltre, la DA presenta un aumentato rischio di infezioni da *Staphylococcus aureus* correlato a minori livelli cutanei di peptide LL-37, la cui sintesi è indotta dalla vitamina D². Nella DA la supplementazione orale ha mostrato un miglioramento degli indici di gravità della malattia e anche una diminuzione della colonizzazione cutanea da parte di *Staphylococcus aureus*⁵.

PSORIASI

La psoriasi è una patologia cutanea infiammatoria cronica che trova i suoi caratteri anatomopatologici distintivi in un'eccessiva proliferazione cheratinocitaria, una differenziazione anomala degli stessi e la compresenza di un importante infiltrato infiammatorio (Fig. 3). Tutti processi in cui la vitamina D riveste un ruolo biologicamente importante¹². Numerosi studi hanno identificato un'associazione tra bassi livelli sierici di calcifediolo e psoriasi con una correlazione inversa statisticamente significativa tra l'entità del deficit e la gravità della psoriasi^{12,13}. Altri studi hanno riscontrato una diminuzione del rischio di sviluppare psoriasi con l'aumentare dei livelli sierici di vitamina D¹⁴. Il suo effetto terapeutico in questa patologia è noto da decenni e infatti farmaci analoghi topici della vitamina D, quali calcipotriolo e calcitriolo, sono comunemente utilizzati nel trattamento locale della psoriasi spesso in combinazione con



FIGURA 3.

Placca eritemato-squamosa a margini netti di forma rotondeggiante localizzata al gomito, in una paziente con psoriasi.

un corticosteroide. Tali farmaci hanno la proprietà non solo di inibire la proliferazione e aumentare la differenziazione dei cheratinociti ma anche quella di modulare la risposta immunitaria, agendo direttamente sull'eziopatogenesi della placca psoriasica su più livelli¹. L'evidenza che una supplementazione orale di vitamina D possa essere di beneficio per il paziente psoriasico è ancora dibattuta¹².

VITILIGINE

La vitiligine è una patologia acquisita di natura autoimmunitaria che ha come bersaglio i melanociti epidermici. Si manifesta con delle macule acromiche, prive di pigmento melanico (Fig. 4). La vitamina D₃ aumenta l'attività della tirosinasi e la melanogenesi tramite il recettore nucleare dell'ormone – il recettore della vitamina D nei melanociti. La tirosinasi catalizza la trasformazione ossidativa della tiroxina in diidrossifenilalanina, da cui poi si formano le melanine. È stato anche riportato che la forma attiva della vitamina D diminuisce l'attività apoptotica nei melanociti indotta dai raggi ultravioletti di tipo B. Come molte altre patologie autoimmuni, anche la vitiligine è associata a bassi livelli di vita-



FIGURA 4.

Macule acromiche a margini netti della coscia dx da riferire a vitiligine.

mina D, sebbene non sia ancora chiaro il meccanismo alla base^{1,15}. Non è stata dimostrata una correlazione diretta tra la carenza della vitamina D e la gravità e/o estensione della vitiligine sulla superficie corporea. È stato invece osservato che la supplementazione di vitamina D in pazienti carenti con vitiligine ha portato a una diminuzione delle dimensioni delle lesioni dopo 6 mesi di trattamento rispetto al controllo, ovvero pazienti che hanno ricevuto solo terapia topica cortisonica. Ci sono dei dati preliminari che suggeriscono che l'applicazione topica degli analoghi della vitamina D possa esercitare un effetto terapeutico nei pazienti con vitiligine. Infatti, è stato osservato che l'uso aggiuntivo di calcipotriolo o tacalcitolo topico rispetto a NB-UVB può esercitare un effetto terapeutico sinergico nella vitiligine¹⁶. Altre possibili associazioni tra patologie cutanee e vitamina D sono in fase di studio per quanto riguarda ad esempio il lupus eritematoso sistemico, la sclerosi sistemica, l'alopecia areata, la micosi fungoide, l'eruzione polimorfa solare e l'ittiosi¹.

CONCLUSIONI

La vitamina D svolge un ruolo fondamentale nella salute della pelle e il suo deficit può concorrere nella patogenesi di alcune malattie cutanee, sia neoplastiche che immuno-mediate ¹⁴.

L'esposizione al sole sicuramente può incrementare i livelli di vitamina D ma al contempo costituisce un fattore di rischio e pertanto la fotoprotezione rimane un elemento fondamentale nel prevenire i tumori cutanei ². L'esposizione solare rappresenta uno strumento utile se utilizzato correttamente, tramite il ricorso a filtri solari ed evitando il conseguente eritema, il quale è un noto marker di danno al DNA ².

La carenza di vitamina D è associata a una sopravvivenza complessiva significativamente peggiore dei pazienti affetti da melanoma. La sopravvivenza a 5 anni è del 90% se i livelli sierici di vitamina D superano la soglia di 10 ng/ml, ma scende all'84% se i livelli scendono sotto la soglia.

Particolarmente interessanti sono anche gli studi con gli eczemi, come la DA, perché essi sono molto frequenti nella popolazione adulta e pediatrica. Livelli elevati di vitamina D nel sangue del cordone ombelicale sono stati associati a una ridotta prevalenza di eczema a/vicino all'età di un anno ¹⁶.

La supplementazione orale di vitamina D è indicata per la correzione e la prevenzione della ipovitaminosi D nella popolazione generale e nei pazienti con malattie della pelle. Non ci sono ancora dati consolidati che confermino il suo ruolo nel trattamento di patologie dermatologiche in assenza di una carenza documentata ¹².

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Colecalciferolo o calcifediolo? Una questione di narrazione!

VITAMIN D

UpDates

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Riassunto

Nell'ultimo decennio, le strategie di prevenzione e trattamento della carenza di vitamina D hanno fatto significativi passi avanti grazie ai trial clinici e agli studi di farmaco-cinetica, che hanno anche permesso di definire le proprietà farmacologiche del colecalciferolo e del calcifediolo.

Sebbene il colecalciferolo e il calcifediolo siano spesso considerati e impiegati in modo paritetico nella pratica clinica, esistono numerose e significative differenze, tra loro, sia sul piano farmacologico sia sul piano clinico, di cui è necessario tenere conto nella scelta della strategia più appropriata per il trattamento/prevenzione della carenza di vitamina D, e per la prevenzione delle fratture da fragilità.

In particolare, recentemente, è stato proposto l'uso del calcifediolo quale farmaco di prima scelta, alternativo al colecalciferolo, nel trattamento della carenza di vitamina D, in virtù della sua maggiore potenza e rapidità nel normalizzare la concentrazione della 25-idrossi-vitamina D sierica. Tuttavia, l'approfondita valutazione delle evidenze disponibili, e in particolare degli studi clinici randomizzati e controllati, conferma il primato del colecalciferolo nella prevenzione e nel trattamento della carenza di vitamina D e nella prevenzione primaria e secondaria delle fratture da fragilità nei soggetti osteoporotici in associazione con un farmaco anti-riassorbitivo o osteo-anabolico. Sulla base delle attuali evidenze, pertanto, l'uso del calcifediolo dovrebbe essere limitato a situazioni particolari, quali per esempio sindromi da malassorbimento, obesità di grado severo o insufficienza epatica.

INTRODUZIONE

Gli studi epidemiologici descrivono un'elevata prevalenza di ipovitaminosi D nella popolazione generale adulta e anziana non appropriatamente integrata con supplementi di vitamina D, particolarmente in sottopopolazioni a rischio, quali soggetti fragili o affetti da malattie croniche, pazienti affetti da sindrome da malassorbimento e soggetti istituzionalizzati¹⁻³.

La vitamina D, e in particolare la sua carenza, gioca un ruolo significativo nella patogenesi delle fratture da fragilità, delle cadute e di numerose condizioni cliniche "extra-scheletriche" acute e croniche (ad es. malattie infettive e COVID-19, malattie reumatologiche, neoplasie, diabete e malattie cardiovascolari)¹⁻⁷. In questo contesto clinico-epidemiologico, come atteso, si è aperto un crescente dibattito

internazionale sulle strategie terapeutiche più appropriate per la prevenzione e il trattamento della carenza di vitamina D.⁷⁻¹² In particolare, recentemente, il dibattito si è concentrato su un quesito preciso, ovvero se sia più appropriato usare il calcifediolo al posto del colecalciferolo, tradizionalmente impiegato, nel trattamento dell'ipovitaminosi D⁹⁻¹². Numerosi studi randomizzati e controllati (RCTs), e studi di farmaco-cinetica hanno tentato di rispondere a questa domanda, permettendo di ampliare le conoscenze sugli effetti farmacologici e clinici di queste due molecole. Sebbene i risultati degli studi più recenti abbiano permesso di generare evidenze significative e di impatto clinico, i numerosi limiti dei lavori pubblicati, quali ad esempio la scelta di outcome surrogati e l'estrema eterogeneità dei dosaggi impiegati, hanno determinato

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Conflitto di interessi

Gli Autori dichiarano nessun conflitto di interessi.

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una significativa confusione sull'argomento, determinando una narrazione non sempre appropriata.

Obiettivo della nostra revisione narrativa è quello di riassumere alcune delle caratteristiche farmacologiche e non del colecalciferolo e calcifediolo, riconducendo la narrazione sul piano clinico per definirne il ruolo nella pratica clinica quotidiana.

PRODUZIONE E METABOLISMO DELLA VITAMINA D

Un'approfondita conoscenza della fisiologia e del metabolismo della vitamina D rappresenta il fondamento essenziale e la "condicio sine qua non" per dirimere il quesito di questa revisione, ovvero se sia più appropriato utilizzare il colecalciferolo o il calcifediolo nella pratica clinica.

Con il termine vitamina D normalmente si fa liberamente riferimento sia alla vitamina D₃ (colecalciferolo) di produzione animale e umana, sia alla vitamina D₂ (ergocalciferolo) di produzione vegetale^{1,10-12}.

La fonte principale di vitamina D per l'organismo dovrebbe essere quella endogena, derivante dalla conversione del 7-deidrocolesterolo a seguito dell'esposizione della cute a raggi ultravioletti di specifica lunghezza d'onda. Questo meccanismo dovrebbe produrre la quota preponderante (circa 80%) di vitamina D (vitamina D₃), per il fabbisogno dell'organismo, mentre quantità minori (circa 20%) di vitamina D₃ e vitamina D₂ possono essere assunte attraverso la dieta¹.

La produzione cutanea di colecalciferolo è fortemente influenzata dalle stagioni, dalla latitudine, dalle caratteristiche della cute esposta al sole, dall'uso di creme solari e dall'età.¹ Una quota minore di vitamina D₃ può essere assunta attraverso l'alimentazione e in particolare attraverso i grassi animali, mentre è assolutamente trascurabile la quota di vitamina D₂ presente nei grassi vegetali¹. In alcuni paesi, la libera fortificazione degli alimenti con colecalciferolo ha permesso di incrementare la quota di vitamina D assunta con la dieta, sebbene questa strategia non sempre sia in grado di ottimizzarne l'assunzione¹.

La vitamina D è fortemente liposolubile e questa liposolubilità ne influenza significativamente le caratteristiche farmacologiche. Il suo assorbimento a livello gastrointestinale richiede la presenza di acidi biliari e avviene attraverso il sistema linfatico¹⁻¹². Una volta entrata nel circolo ematico, la vitamina D

viene immagazzinata nel tessuto adiposo, che ne rilascia piccole quantità. Questo è anche uno dei motivi per cui i soggetti obesi siano a maggiore rischio di deficienza, a seguito della "diluizione" in una massa adiposa maggiore^{1,11-14}. L'elevata liposolubilità della vitamina D, infine, ne determina anche una prolungata emivita funzionale, stimata essere di circa 2 mesi¹². La vitamina D rimane poco tempo nel circolo ematico e le sue concentrazioni ematiche sono pertanto molto ridotte (1-2 ng/ml)¹.

Per diventare metabolicamente attiva la vitamina D deve essere sottoposta a due processi enzimatici di idrossilazione, che avvengono prevalentemente a livello epatico e renale^{1,12}. Nel corso del transito epatico, la vitamina D viene convertita in 25-idrossi-vitamina D [25(OH)D] a opera dell'enzima 25-idrossilasi. Il processo di trasformazione della vitamina D in 25(OH)D può avvenire anche in presenza di una riduzione significativa del tessuto epatico funzionante, sebbene sia evidente una più elevata prevalenza di ipovitaminosi D nei pazienti affetti da epatite cronica HCV-correlata¹.

La 25(OH)D, anche detta calcifediolo, ha un'elevata affinità per la proteina legante la vitamina D (*Vitamin D Binding Protein*, VDBP), rappresenta il principale metabolita ematico della vitamina D e, in assoluto, le sue concentrazioni rappresentano l'indice più attendibile dello stato vitaminico D di un soggetto¹. Il dosaggio della 25(OH)D sierica è un preciso indicatore dei nostri depositi di vitamina D. Pertanto, la definizione dello stato vitaminico D di un soggetto (carenza, insufficienza e sufficienza) si basa al momento esclusivamente sull'interpretazione dei livelli sierici di 25(OH)D (Tab. I).

La 25(OH)D (o calcifediolo) è un metaboli-

ta parzialmente idrofilo e si deposita solo a livello epatico e muscolare.¹ L'emivita della 25(OH)D è più breve di quella della vitamina D, tale da soddisfare il fabbisogno per non più di 12-18 giorni^{1,8}. La 25(OH)D ha una bassa affinità per il recettore specifico della vitamina D (*Vitamin D Receptor*, VDR) e pertanto necessita di essere trasformata in calcitriolo o 1,25-diidrossi-vitamina D [1,25(OH)₂D], per diventare metabolicamente attiva^{1,8}. È stato stimato che il calcifediolo, ovvero la 25(OH)D, possiede un'affinità per il VDR circa 50 volte inferiore rispetto al calcitriolo o 1,25(OH)₂D¹⁵. Nonostante la minore affinità per il VDR, studi sperimentali recenti hanno dimostrato come il calcifediolo possa produrre attraverso il legame con i recettori nucleari e/o di membrana, effetti cellulari genomici (stimolazione della trascrizione di geni) e non-genomici (formazione di secondi messaggeri cellulari, fosforilazione di alcune proteine)¹⁵.

La conversione in 1,25(OH)₂D per opera della 1- α -idrossilasi, avviene prevalentemente a livello renale, ma può essere attuata anche in altri tessuti¹. La quota più rilevante di 1,25(OH)₂D, e quella più attinente al controllo del metabolismo minerale, è prodotta nei tubuli prossimali renali. La produzione della 1,25(OH)₂D per opera della 1- α -idrossilasi richiede la presenza di ormone paratiroideo (PTH) ed è modulata dai livelli sierici del calcio, del fosforo e del FGF23.^{1,12} La 1,25(OH)₂D non viene depositato a livello tissutale e ha emivita brevissima^{1,8}.

L'insufficienza renale riduce progressivamente la produzione di 1,25(OH)₂D¹. Tuttavia, un deterioramento significativo dell'attività della 1- α -idrossilasi, tale da

TABELLA I.

Interpretazione dei livelli sierici di 25(OH)D (da Adami et al., 2011 e Rossini et al., 2016, mod.)^{1,2}.

Definizione	Unità di misura della 25(OH)D	
	nmol/L	ng/ml
Deficienza severa	< 25	< 10
Deficienza	25-50	10-20
Insufficienza	50-75	20-30
Range ottimale	75-125	30-50
Eccesso	> 250	> 100
Intossicazione	> 375	> 150

non essere più in grado di assicurare livelli ormonali normali, è rilevabile solo in presenza di una notevole compromissione della funzione renale (in genere stadio 4-5/5D)^{1,16}. Si deve tuttavia sottolineare come, anche in condizioni di severa compromissione dell'attività della 1- α -idrossilasi renale, i livelli di 25(OH)D debbano essere mantenuti nel range di normalità per garantire un adeguato substrato alle 1- α -idrossilasi extra-renali^{1,16}.

La 1,25(OH)₂D (metabolita attivo) legandosi a uno specifico recettore (VDR, presente sia nel nucleo sia nella membrana cellulare), produce l'effetto finale della vitamina D a livello cellulare¹. Tale effetto si esplica sia attraverso la stimolazione della trascrizione di geni (meccanismo genomico), sia attraverso la formazione di secondi messaggeri cellulari o la fosforilazione di alcune proteine (meccanismo non genomico)¹. I recettori per la vitamina D sono ubiquitari nell'organismo.

COLECALCIFEROLO, CALCIFEDILOLO E L'ANNOSA QUESTIONE DELLA NORMALIZZAZIONE DELLA CONCENTRAZIONE DELLA 25(OH)D

Oltre alle due forme naturali di vitamina D, la vitamina D₃ (colecalfiferolo) e la vitamina D₂ (ergocalciferolo, in disuso), numerosi farmaci/metaboliti con attività vitaminica D si sono resi disponibili nella pratica clinica quotidiana^{1,2,8}. Alcuni di essi sono stati sintetizzati e impiegati prevalentemente in ambiti specifici, quali il trattamento dei disordini sistemici del metabolismo minerale nella malattia renale cronica o l'ipoparatiroidismo, e pertanto non hanno rilevanza rispetto al quesito oggetto della nostra revisione. Il colecalfiferolo e il calcifediolo invece, come già illustrato, rappresentano le due molecole di gran lunga più investigate e utilizzate per la correzione dell'ipovitaminosi D e per la prevenzione delle fratture da fragilità nella popolazione non-nefropatica.

Colecalciferolo

Il colecalfiferolo (D₃) è il naturale composto della vitamina D, di origine animale/umana. Come già descritto, il colecalfiferolo è un pro-ormone, precursore delle due forme idrossilate [25(OH)D e 1,25(OH)₂D] della vitamina D e pertanto ha bisogno di

essere sottoposto a due processi naturali di idrossilazione per trasformarsi nella sua forma attiva metabolicamente^{1,8}.

Il colecalfiferolo è fortemente lipofilo. In relazione a questa sua caratteristica l'assorbimento gastrointestinale è influenzato alla presenza di acidi biliari, avviene attraverso il sistema linfatico e può essere significativamente compromesso in presenza di malassorbimento.¹² Sempre in virtù della sua lipofilia, il colecalfiferolo è normalmente immagazzinato nel tessuto adiposo, dove crea dei depositi da cui è rilasciato lentamente.¹ Proprio per questo motivo ha un'emivita ematica piuttosto breve (T_{1/2} stimato di 19-25 ore), ma presenta un'emivita funzionale decisamente più lunga (parecchie settimane)⁸. L'elevata emivita funzionale del colecalfiferolo rappresenta uno dei principali punti di forza nell'uso clinico, rendendolo un prodotto estremamente flessibile e adattabile nella pratica, permettendone regimi di somministrazione intermittente^{1,2}. Pertanto, se da un lato l'elevata lipofilia rappresenta un vantaggio in relazione all'emivita funzionale, dall'altro può costituire uno svantaggio, come già descritto, nei soggetti obesi (elevata diluizione) e nei pazienti affetti da malassorbimento (ridotto assorbimento intestinale).

Il colecalfiferolo è disponibile in formulazioni per uso orale e intramuscolare. A eccezione di condizioni cliniche particolari (sindromi da malassorbimento), la via di somministrazione orale è preferibile, poiché superiore in termini di efficacia nell'incrementare la concentrazione di 25(OH)D sierica rispetto alla formulazione intramuscolare^{17,18}.

Negli RCTs disegnati per identificare la posologia e il regime terapeutico più appropriato per la normalizzazione e il mantenimento di una concentrazione ottimale di 25(OH)D (30-50 ng/ml), il colecalfiferolo è stato impiegato con dosaggi e regimi di somministrazione piuttosto variabili, che spaziano da dosi di 400-4.000 UI al giorno a dosi di 25.000-50.000 UI al mese, utilizzando anche dosi "bolo" terapeutiche fino a 600.000 UI (sconsigliate). In generale, gli RCTs hanno dimostrato una grande eterogeneità di risposta, in termini di incremento della concentrazione della 25(OH)D, alla supplementazione con dosi standard di colecalfiferolo. Questa significativa eterogeneità, che rende meno prevedibile la

dose-risposta al trattamento, sembrerebbe essere legata a numerosi fattori (alcuni dei quali non completamente chiariti), quali il valore basale di 25(OH)D, l'indice di massa corporea e fattori in grado di condizionare l'assorbimento intestinale e il metabolismo^{12-14,19-20}.

Tenendo conto dei fattori interferenti illustrati, e considerando i risultati dei principali RCTs, si può comunque affermare che se impiegato a dosaggi e regimi terapeutici appropriati, il colecalfiferolo è in grado di normalizzare efficacemente e mantenere nel range ottimale/desiderabile la concentrazione della 25(OH)D (30-50 ng/ml). L'approccio più appropriato e largamente sostenuto dalle Linee guida italiane, prevede, in caso di severa ipovitaminosi D (< 10 ng/ml), la somministrazione di una dose terapeutica di 3.000-10.000 UI al giorno per 1-2 mesi, seguita da una dose di mantenimento di circa 2.000 UI al giorno^{1,2,21}. Nei soggetti con ipovitaminosi D meno severa e nei pazienti candidati a terapia remineralizzante (anti-riassorbitiva o osteoanabolica), le più recenti Linee guida italiane suggeriscono dosi giornaliere (o equivalenti cumulativi) comprese tra 800 UI e 2.000 UI al giorno (con singola dose massima non eccedente le 100.000 UI)²¹.

La principale perplessità sollevata rispetto all'uso del colecalfiferolo e ai regimi terapeutici illustrati, sarebbe la "relativa lentezza" del colecalfiferolo nel normalizzare la concentrazione della 25(OH)D in termini assoluti e rispetto al calcifediolo¹¹⁻¹⁴. Questo aspetto, come vedremo, rappresenta uno dei principali cavalli di battaglia dei sostenitori dell'uso del calcifediolo nella pratica clinica. In questo contesto, riteniamo pertanto importante enfatizzare i risultati di un recente studio RCT, pubblicato da Fassio et al., che ha messo in discussione il sopracitato postulato²². Lo studio di farmacocinetica di Fassio et al.²², investigando l'effetto di tre differenti regimi terapeutici di colecalfiferolo (10.000 UI al giorno per 8 settimane seguito da 1.000 UI al giorno per 4 settimane; 50.000 UI a settimana per 12 settimane; 100.000 UI ogni 2 settimane per 12 settimane), ha dimostrato come la supplementazione con colecalfiferolo 10.000 UI al giorno per 8 settimane, seguita da 1.000 UI al giorno per 4 settimane, in soggetti sani ipovitaminosici (valore basale 25(OH)D medio 14 ng/ml), fosse in grado in sole due settimane di determinare il raggiungimento del target di concentrazione

ne della 25(OH)D > 20 ng/ml in tutti i soggetti. Risultati simili sono stati descritti anche per gli altri due regimi terapeutici. Inoltre, dopo 4 settimane di trattamento, la quasi totalità dei soggetti avevano raggiunto un valore di 25(OH)D > 30 ng/ml. Tale regime terapeutico si era dimostrato sicuro, non essendo stati registrati casi in cui la concentrazione della 25(OH)D sierica superava il limite di sicurezza di 100 ng/ml (Tab. I).

In conclusione, sulla base delle evidenze descritte, il colecalciferolo deve essere considerato la terapia di prima scelta nel trattamento e nella prevenzione della ipovitaminosi D.

Calcifediolo

Il calcifediolo [25(OH)D] è il metabolita epatico della vitamina D e grossolanamente si può dire che si differenzia dal colecalciferolo per la presenza di un gruppo idrossilico in posizione C-25¹². Nella via metabolica della vitamina D, pertanto, il calcifediolo è un passo avanti rispetto al colecalciferolo verso la forma biologicamente attiva (il calcitriolo)¹².

La 25-idrossilazione conferisce al calcifediolo alcune proprietà che stanno alla base della diversa farmacocinetica e farmacodinamica e rappresentano il presupposto che ha portato a proporlo come alternativa al colecalciferolo. Essendo più idrofilo, il calcifediolo viene assorbito direttamente nel sistema portale, e non attraverso il sistema linfatico, e non subisce la "diluizione" nel tessuto adiposo. Inoltre, sebbene con minore affinità rispetto al calcitriolo, è in grado di legarsi al VDR e, potenzialmente, di produrre effetti cellulari genomici (stimolazione della trascrizione di geni) e non-genomici (formazione di secondi messaggeri cellulari, fosforilazione di alcune proteine)¹⁵.

Pertanto, il calcifediolo presenterebbe alcuni vantaggi in termini farmacologici e clinici, fortemente enfatizzati, che posso essere schematizzati in cinque punti: 1) maggiore rapidità e potenza (rispetto al colecalciferolo) nell'incrementare la concentrazione della 25(OH)D sierica; 2) curva dose-risposta più lineare e prevedibile rispetto al colecalciferolo, indipendente dalla concentrazione basale della 25(OH)D e da altri fattori; 3) efficacia anche in presenza di compromissione della funzione epatica, non necessitando dell'idrossilazione epatica; 4) efficacia maggiore (rispetto al colecalciferolo) nei soggetti obesi, non essendo sequestrato

dal tessuto adiposo; 5) efficacia maggiore nei soggetti affetti da sindrome da malassorbimento, in relazione al diverso meccanismo di assorbimento intestinale (rispetto al colecalciferolo)¹². Complessivamente, questi aspetti, riassumibili in una maggiore potenza e rapidità del calcifediolo, sono stati avvalorati dai risultati di numerosi RCTs volti a confrontare l'efficacia di colecalciferolo e calcifediolo nel normalizzare la concentrazione della 25(OH)D sierica in soggetti affetti da ipovitaminosi D.^{9-14,23-25}

Nel complesso gli studi avrebbero dimostrato che a dosi "definite comparabili", il calcifediolo sarebbe in grado di produrre un più rapido e maggiore incremento della concentrazione della 25(OH)D rispetto al colecalciferolo. In termini di potenza, il calcifediolo presenterebbe una potenza relativa rispetto al colecalciferolo maggiore di circa 2-8 volte. L'estrema variabilità della stima della potenza relativa sarebbe da imputare alle dosi impiegate, al valore basale della concentrazione della 25(OH)D sierica (in grado di influenzare la risposta del colecalciferolo), e alla non lineare curva dose-risposta del colecalciferolo (maggiore incremento della 25(OH)D per valori basali di 25(OH)D molto bassi e viceversa)^{11,12}. Pertanto, osservando le curve di crescita della concentrazione della 25(OH)D in corso di terapia con colecalciferolo e calcifediolo appare evidente la maggiore rapidità e potenza del calcifediolo. Tali rilievi sono stati confermati anche in studi condotti in soggetti anziani o in sovrappeso/obesi e in pazienti affetti da sindrome da malassorbimento^{13-14,26}.

Sulla base di questi risultati, recenti Linee guida italiane, hanno incluso il calcifediolo nelle strategie terapeutiche per il management dell'ipovitaminosi D²¹. In particolare, nei soggetti affetti da osteomalacia o con concentrazione sierica della 25(OH)D < 10 ng/ml, è stato suggerito l'uso del calcifediolo (in alternativa al colecalciferolo) alla dose di 20-40 mcg al giorno per 20-30 giorni, prima di passare alla dose di mantenimento²¹. Tale raccomandazione è stata proposta limitatamente a specifiche condizioni, in cui, in particolare, si ritenga necessaria una rapida normalizzazione della concentrazione della 25(OH)D sierica. Dai tempi di Esopo, passando da "I Racconti di Canterbury", fino a "Il mercante di Venezia", è noto il proverbio *Non è tutto oro quel che luccica*, espressione che assume particolare rilevanza in questo contesto.

L'interpretazione degli studi comparativi tra colecalciferolo e calcifediolo merita infatti di essere integrata con alcune considerazioni volte a correggerne la narrazione, come anche enfatizzato dalle Linee guida italiane e da alcune revisioni della letteratura^{10,11,21}.

La limitata emivita del calcifediolo (12-18 giorni contro le numerose settimane del colecalciferolo) e il fatto che non sia in grado di determinare una replezione dei depositi di vitamina D (depositandosi solo a livello epatico e muscolare), possono rappresentare un problema in caso di ridotta aderenza o persistenza al trattamento^{1,8}. Sebbene siano pochi gli studi pubblicati sugli effetti negativi di una ridotta aderenza/persistenza al trattamento, uno studio recentissimo condotto in pazienti inizialmente ipovitaminosi supplementati con calcifediolo, ha dimostrato come dopo la sospensione del trattamento con calcifediolo sia già evidente, nelle prime settimane, una progressiva e significativa riduzione della concentrazione sierica della 25(OH)D, che tra gli 8-12 mesi si ristabiliva nel range della deficienza²³.

In relazione all'idrossilazione, il calcifediolo è un passo avanti rispetto al colecalciferolo verso la forma biologicamente attiva e pertanto è parzialmente affrancato dai meccanismi fisiologici di controllo del metabolismo della vitamina D^{10,21}. Sebbene le segnalazioni di intossicazione (ipercalcemia) siano relativamente poche, e perlopiù correlate a dosaggi inappropriate elevati per errori di assunzione, l'utilizzo del calcifediolo è strettamente vincolato a dosi definite e può in alcune circostanze richiedere un monitoraggio anche frequente dei valori sierici di 25(OH)D e calcio, allo scopo di identificare precocemente una condizione di intossicazione e ipercalcemia^{10,21,27}. Sulla base dei dati della letteratura questo rischio è assente con il colecalciferolo, così come non è ritenuto necessario alcun monitoraggio sierologico nel corso del trattamento con la vitamina D₃^{10,21}.

Sul piano farmacodinamico pochi studi hanno investigato l'effetto del colecalciferolo e del calcifediolo sui metaboliti della vitamina D, sui regolatori dell'omeostasi del calcio e del fosforo, sui marcatori di rimodellamento osseo e sugli inibitori del sistema Wnt²⁸. Senza inoltrarsi in dettaglio sull'argomento, è opportuno segnalare come rispetto agli effetti su paratormone (decremento) o marcatori di rimodellamento osseo, i risultati degli studi di confronto non siano univoci nello stabilire una superiorità del cal-

cifediolo sul colecalciferolo (Fig. 1) ^{23,24,26}. In questo contesto, tuttavia, la criticità più rilevante rispetto all'uso del calcifediolo riguarda l'assenza di evidenze in termini di efficacia antifratturativa. ^{10,11,21}

COLECALCIFEROLO E CALCIFEDIOLO NELLA PREVENZIONE DELLE FRATTURE

Nell'introduzione alla nostra revisione abbiamo accennato all'importanza della narrazione per dirimere il quesito circa la superiorità del colecalciferolo rispetto al calcifediolo o viceversa. Revisionando la letteratura, infatti, appare estremamente evidente come gli studi RCTs si siano concentrati unicamente su un outcome, sicuramente importante, quale la normalizzazione della concentrazione sierica della 25(OH)D, omettendo sistematicamente di investigare uno degli endpoint più rilevanti del trattamento con la vitamina D, ovvero la riduzione dell'incidenza di fratture da fragilità, per non citare l'effetto sulle cadute e i potenziali effetti extra-scheletrici.

Non è infatti necessaria una ricerca bibliografica approfondita per sostenere l'efficacia anti-fratturativa del colecalciferolo in popolazioni a rischio, carenti di vitamina D, quando impiegato in dosi appropriate (e in associazione alla supplementazione di calcio) ^{10,11,29}.

A fronte di ipertrofiche evidenze in sostegno dell'efficacia anti-fratturativa della supplementazione con colecalciferolo, decisamente limitato è il contributo degli studi RCTs condotti con il calcifediolo. Una recente meta-analisi della Cochrane, che ha revisionato i RCTs di intervento terapeutico (riduzione del rischio di frattura) condotti con la vitamina D e i suoi metaboliti, ha identificato solo due studi con il calcifediolo, ritenuti eleggibili sulla base della qualità del disegno sperimentale ²⁹. Va rilevato come in entrambi gli studi il rischio di "bias" non fosse valutabile. Sulla base dei risultati di questi due studi si può affermare che non vi siano, al momento, sufficienti evidenze scientifiche per supportare l'efficacia anti-fratturativa del calcifediolo ^{29,30}. Nel più

recente RCT pubblicato da Peacock et al., ad esempio, l'incidenza di nuove fratture vertebrali e non-vertebrali risultava simile nei soggetti trattati per 4 anni con calcio (750 mg al giorno), calcifediolo (15 ug al giorno) o placebo ³⁰.

Per assecondare la corretta narrazione che fa riferimento alla riduzione del rischio di frattura, deve essere evidenziato anche quello che forse è l'aspetto più rilevante di questa storia, ovvero il fatto che in tutti i pivotal RCTs registrativi dei farmaci per la prevenzione delle fratture i pazienti sono stati supplementati con colecalciferolo (e calcio) a dosaggi variabili. Pertanto, l'efficacia anti-fratturativa dei bisfosfonati, del teriparatide, del denosumab e del romosozumab è stata dimostrata in presenza di supplementazione con colecalciferolo e calcio ^{10,11,21}. Si può concludere, pertanto, che robuste evidenze che inequivocabilmente dimostrino un effetto del calcifediolo sulla riduzione delle fratture sono mancanti.

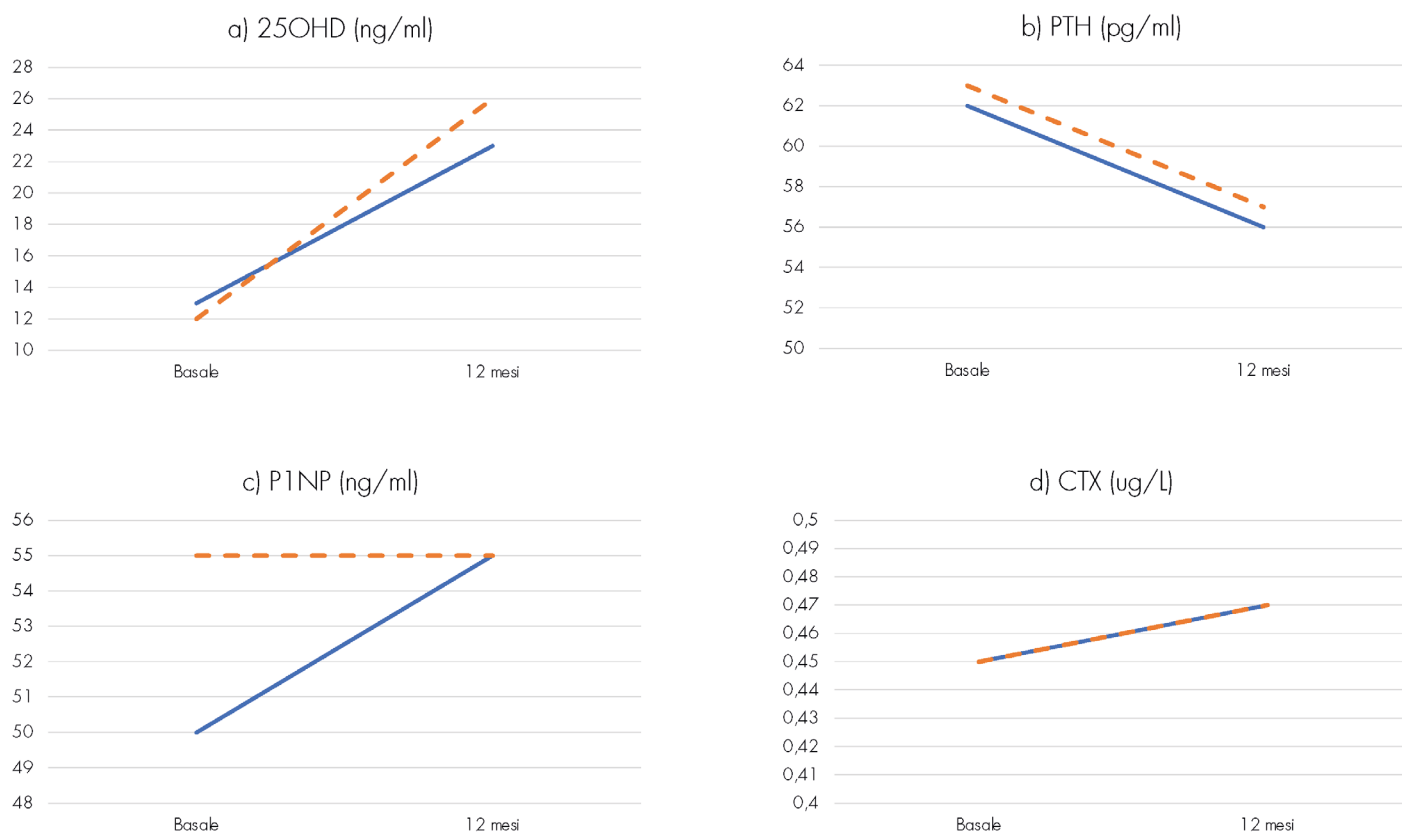


FIGURA 1.

Valore medio basale e a 12 mesi della concentrazione di 25(OH)D (a), PTH (b), P1NP (c) e CTX (d) in pazienti trattati con colecalciferolo (linea continua blu) o calcifediolo (linea tratteggiata arancione) (da Pérez-Castrillón et al., 2023, mod.) ²³.

CONCLUSIONI

In conclusione, nella pratica clinica quotidiana il colecalciferolo deve essere considerato la terapia di prima scelta nella prevenzione e nel trattamento della carenza di vitamina D, e nella prevenzione primaria e secondaria delle fratture da fragilità nei soggetti osteoporotici in associazione con un farmaco anti-risorbitivo o osteo-anabolico. Il calcifediolo potrebbe offrire alcuni vantaggi nei termini di una sua eventuale maggiore rapidità e potenza nell'incrementare e normalizzare la concentrazione sierica della 25(OH)D, sebbene questa affermazione necessiti di ulteriori approfondimenti alla luce del recente lavoro pubblicato da Fassio et al.²². Al riguardo è opportuno anche sottolineare come non sia stato chiarito in che termini, questa differente farmacocinetica, possa determinare maggiori benefici sul piano clinico (ad es. riduzione del rischio di frattura), in considerazione della mancanza di dati clinici dai RCTs.

Appare quindi inappropriato, come anche riportato nelle linee guida italiane, considerare il calcifediolo, un farmaco di prima scelta e alternativo al colecalciferolo nella prevenzione/trattamento della ipovitaminosi D e/o nella prevenzione delle fratture da fragilità nei pazienti osteoporotici in associazione con un anti-risorbitivo o un osteo-anabolico^{1,2,21}. Come recentemente suggerito, il calcifediolo, può essere preso in considerazione quale terapia di scelta in situazioni cliniche particolari quali l'obesità, l'epatopatia cronica avanzata e la sindrome da malassorbimento^{1,2,21}.

Studi clinici randomizzati e controllati saranno necessari per definire l'efficacia del calcifediolo nei diversi setting clinici, in termini di benefici scheletrici ed extra-scheletrici.

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PEDIATRIA

- [No authors listed] Correction to "High-Dose Vitamin D Intervention in Infants-Effects on Vitamin D Status, Calcium Homeostasis, and Bone Strength". *J Clin Endocrinol Metab.* 2023 Jun 12:dgad323. <https://doi.org/10.1210/clinem/dgad323>. Online ahead of print. PMID: 37303283

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