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Aggiornamento sul ruolo della vitamina D nella prevenzione dell'osteoporosi

Impatto della Nota 96 dell'Agenzia Italiana del Farmaco sull'uso della vitamina D in Italia

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EDITORIALE

VITAMIN D
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Sino al 2019 si è verificato in Italia un progressivo aumento del consumo di vitamina D (VitD), con conseguente incremento della spesa a carico del Servizio Sanitario Nazionale (SSN) [Rapporto OsMed (Osservatorio Nazionale sull'impiego dei Medicinali), Agenzia Italiana del Farmaco (AIFA)]. L'entità e la crescita nei consumi di VitD ha fatto ipotizzare una possibile inappropriatezza d'uso e con il dichiarato intento di ridurla, a fine ottobre 2019 l'AIFA ha pubblicato la Nota 96 che individua i criteri di rimborsabilità della supplementazione di VitD per la prevenzione e il trattamento degli stati carenziali nell'adulto [1]. Nei primi 20 mesi di applicazione della Nota si è registrata una diminuzione dei consumi e della relativa spesa per la VitD oggetto della Nota, rispetto ai periodi precedenti [2] (Fig. 1), ma non è noto se ciò sia da attribuire a un miglioramento nell'appropriatezza d'uso.
In questo numero pubblichiamo due contributi che sollevano dubbi e inducono preoccupazioni sul fatto che la Nota 96 abbia comportato, perlomeno per alcuni aspetti, un miglioramento dell'appropriatezza ma piuttosto un peggioramento.

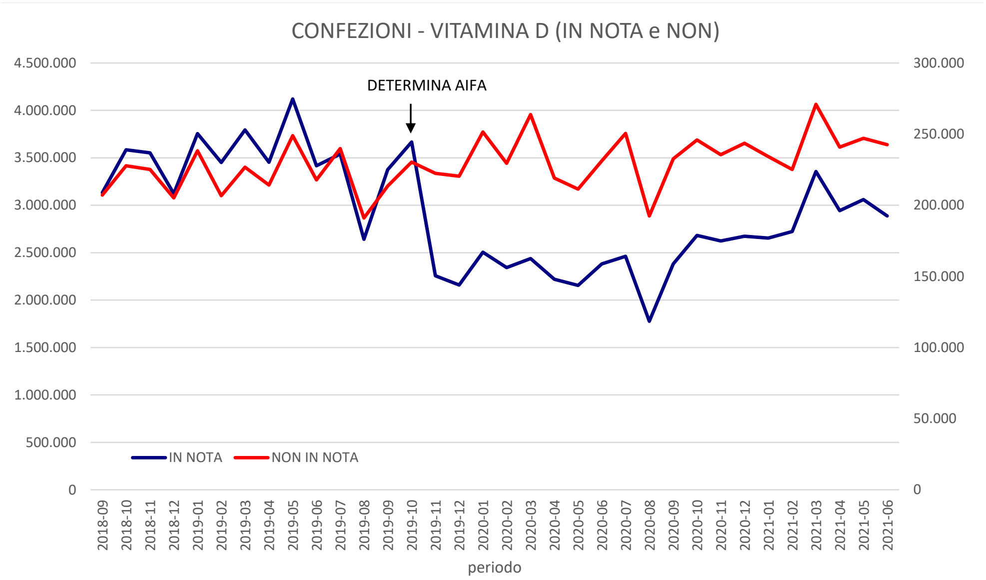

FIGURA 1.
(Fonte: https://www.aifa.gov.it/ documents/20142/1030827/NOTA_96_20mesi_22.10.2021.pdf) [2].

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Nel primo articolo si sintetizza, considerando la fisiologia, il ruolo della vitD nella prevenzione dell'osteoporosi e si aggiorna il tema alla luce di alcune recenti pubblicazioni, evidenziandone talora in maniera critica i limiti, che potrebbero spiegare alcune incongruenze o discordanze. Si esprime, inoltre, la preoccupazione che la contrazione dei consumi anche nelle fasce senili di età, a rischio di carenza di vitD e di osteoporosi, possa aver compromesso un'opportuna e spesso a queste età necessaria supplementazione. Vi ricordo che questo rischio era stato segnalato ad AIFA dal sottoscritto nella veste allora di Presidente della Società Italiana dell'Osteoporosi, del Metabolismo Minerale e delle Malattie dello Scheletro (SIOMMMS) subito dopo la pubblicazione della Nota 96 e comunicato come preoccupazione nell'aprile 2020 alla luce dei risultati preliminari di un report di monitoraggio di AIFA a 3 mesi dall'introduzione della Nota 96 [3]. In particolare, si faceva notare che i dati disponibili non consentivano alcuna valutazione sul fatto che la riduzione dei consumi e della relativa spesa per la vitD fosse da attribuire a un miglioramento dell'appropriatezza. Ci preoccupava in particolare la riduzione significativa dell'uso della vitamina D in età avanzata, notoriamente la più esposta al rischio di carenza, anche perché è noto e da tempo [4], ma ignorato dalla Nota 96, che sopra i 60 anni vi è una ridotta capacità della cute di produrre adeguate quantità di vitD nonostante l'esposizione solare, principale fonte per soddisfare il fabbisogno. La Nota 96 trascura questo aspetto e in particolare non prevede l'età avanzata come condizione di rischio per ipovitaminosi D e quindi non tutela adeguatamente gli anziani dal rischio di carenza di vitD.

Il secondo articolo analizza alcuni aspetti molto interessanti dell'impatto della Nota 96 sull'uso appropriato della vitD in Italia. In particolare, utilizzando i flussi amministrativi relativi alla prescrizione di farmaci e di esami di un'Azienda ULSS, si è cercato di verificare se la riduzione del consumo di vitD riscontrata dopo l'entrata in vigore della Nota 96 fosse accompagnata da una maggiore appropriatezza nell'uso. Ebbene in realtà dopo la pubblicazione della Nota 96, si è osservato una riduzione dell'opportuna e raccomandata associazione della vitD ai farmaci per il trattamento dell'osteoporosi, secondo me da attribuirsi alla poca chiarezza del testo della Nota 96 su questo aspetto e alla conseguente spesso errata interpretazione da parte dei medici. Da questo punto di vista pertanto il calo osservato del consumo di vitD non è coinciso con un miglioramento dell'appropriatezza prescrittiva ma anzi con un suo peggioramento. Inoltre, la suddetta analisi non ha evidenziato alcun miglioramento nell'altro indicatore valutato e cioè la quota di pazienti in trattamento con vitD senza ipovitaminosi accertata negli ultimi 12 mesi, anche se francamente andrebbero secondo me considerate le condizioni per i quali la stessa Nota non prevede il dosaggio sierico del 25(OH)D o quei pazienti per i quali la continuità terapeutica o il persistere di pregresse note condizioni di rischio di carenza di vitD rendono superfluo, sconveniente, inapplicabile o addirittura non etico pretendere il dosaggio per aver diritto alla supplementazione a carico del SSN.

A ulteriore supporto della necessità di valutare meglio l'effettivo impatto della Nota 96 sull'appropriatezza dell'uso della vitD trovate tra le conclusioni dell'ultimo citato report del monitoraggio di AIFA [2] anche le seguenti:

- "dai dati presentati, dopo 20 mesi la Nota sembra iniziare a perdere di efficacia, se confrontata coi primi mesi della sua applicazione…";
- "valutare campagna di sensibilizzazione alla corretta prescrizione da rivolgere ai medici di medicina generale".

Cosa ne pensate?

Buona lettura!

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Aggiornamento sul ruolo della vitamina D nella prevenzione dell'osteoporosi

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Negli ultimi anni i possibili molteplici effetti positivi (antineoplastici, cardioprotettivi, immunomodulanti ecc.) della vitamina D hanno suscitato crescente interesse e un incremento delle pubblicazioni scientifiche (e non) al riguardo, ma hanno anche sollevato perplessità sulla sua utilità nella prevenzione dell'osteoporosi, a seguito dei risultati discordanti presenti in letteratura, al di là dei ragionevoli dubbi sugli effetti extrascheletrici.

L'osteoporosi impatta pesantemente sul sistema sanitario: in Italia ne sono affette circa 3.5 milioni di donne e 1 milione di uomini, l'incidenza aumenta con l'età (il costante invecchiamento della popolazione comporta un incremento dei casi). A partire dai 50 anni cresce progressivamente l'incidenza delle fratture da fragilità, che diventa equiparabile a quella di ictus e carcinoma mammario [1]. I costi annui riconducibili a tali fratture (gestione in acuto e disabilità a lungo termine) aumentano con l'invecchiamento della popolazione. È necessaria un'adeguata strategia di prevenzione, utilizzando al meglio le risorse.

NOTA 96

La recente Nota AIFA 96 regolamenta la prescrizione a carico del Servizio Sanitario Nazionale (SSN) dei composti con indicazione "prevenzione e trattamento della carenza di vitamina D" nell'adulto nell'intento di far collimare la necessità di raggiungere sufficienti livelli di vitamina D con quella di contenere le spese di prescrizione dei prodotti a base di vitamina D.

Dall'aggiornamento al giugno 2021 (a 20 mesi dalla sua introduzione) del monitoraggio AIFA sull'andamento dei consumi della Nota [2] si evince, relativamente ai farmaci in Nota, un contenimento della spesa sostenuta dal SSN del 25% rispetto ai periodi precedenti, con poco significativi incrementi dei consumi e della spesa degli analoghi della vitamina D non in Nota. Sono valutazioni generali e preliminari, considerando l'eterogenea situazione "pre-Nota" nelle varie Regioni e l'altrettanto eterogenea risposta "post-Nota", sono necessari approfondimenti specifici e a lungo termine. In tutte le fasce di età (tranne la 0-10 anni) c'è stata una riduzione dei consumi (anche tra i giovani adulti, verosimilmente eccessivi). Tuttavia, la maggiore riduzione riguarda la classe di età 40-60 anni, specie nel sesso femminile, ma anche la fascia 60-80 anni (Tab. I), ambedue a rischio sia di ipovitaminosi D che di osteoporosi, per cui è particolarmente importante la corretta supplementazione insieme a eventuali terapie antifratturative, per la cui efficacia clinica la correzione dell'ipovitaminosi D è propedeutica, come specificano la Nota stessa e la letteratura [3].

VITAMINA D E OMEOSTASI OSSEA

La vitamina D è un composto liposolubile che agisce come un ormone steroideo. La fonte principale (una minoritaria deriva dalla dieta) è rappresentata dalla conversione della provitamina D (7-deidrocolesterolo) negli strati profondi dell'epidermide, per esposizione ai raggi UVB, in vitamina D_3 (colecalciferolo), precursore inattivo. Il colecalciferolo subisce due idrossilazioni enzimatiche: la prima epatica in 25(OH)D o calcidiolo, composto con la maggiore emivita e utilizzato per il dosaggio dei livelli sierici di vitamina D; la seconda, renale, dà luogo alla forma biologicamente attiva, 1,25$(OH)_2$D o calcitriolo (Fig. 1), che lega il recettore per la vitamina D (VDR) tramite cui induce gli effetti biologici, primo fra tutti quello sul metabolismo fosfocalcico [stimolo all'assorbimento di calcio e fosfato nel tenue, inibizione di sintesi e secrezione di paratormone (PTH), attivazione sistema RANKL/RANK e conseguente osteoclastogenesi per induzione dell'espressione di RANKL sugli osteoblasti], regolando così i livelli sierici di calcio e fosforo e la mineralizzazione ossea (Fig. 2) [4]. Ne deriva che livelli al di sotto della norma

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Conflitto di interessi
Gli Autori dichiarano nessun conflitto di interessi.

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TABELLA I.
Monitoraggio AIFA dell'andamento dei consumi della Nota 96 relativa alla vitamina D. Analisi preliminare su 20 mesi dopo l'introduzione della Nota (novembre 2019 - giugno 2021). Dati per classi di età - ATC in Nota 96. In rosso i valori al di sotto della media nazionale [2]. NB: per una quota dello 0,5% di confezioni, non si dispone delle informazioni di genere ed età (https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_20mesi_22.10.2021.pdf).

	Confezioni femmine	Delta confezioni % periodo precedente	Lorda femmine	Delta confezioni % periodo precedente	Confezioni maschi	Delta spesa % periodo precedente	Lorda maschi	Delta spesa % periodo precedente
Totale Italia	42.295.282	-27,1	337.593.955	-24,7	8.230.373	-19,3	64.113.376	-17,5
Classi di età								
0-10	400.521	1,7	2.070.124	1,4	431.335	1,6	2.220.819	1,4
10-20	269.051	-11,6	1.891.416	-14,3	198.484	-9,5	1.353.184	-11,9
20-30	427.089	-23,9	3.459.222	-23,0	186.544	-19,6	1.515.270	-18,1
30-40	787.504	-26,5	6.334.166	-25,7	232.703	-22,8	1.875.888	-20,9
40-50	2.298.338	-34,1	18.748.999	-32,7	470.127	-26,0	3.749.088	-24,2
50-60	6.839.559	-35,1	55.733.820	-33,2	981.648	-21,1	7.812.630	-19,3
60-70	10.043.108	-30,2	81.406.064	-27,5	1.572.989	-21,7	12.588.757	-19,7
70–80	11.762.214	-26,2	94.008.595	-23,1	2.251.209	-21,8	17.946.285	-19,3
> 80	9.467.898	-16,7	73.941.548	-13,3	1.905.334	-15,4	15.051.454	-12,5

di tale nutriente possono alterare l'equilibrio descritto: con valori di 25(OH)D < 30 ng/ml si riduce l'assorbimento intestinale di calcio (che aumenta in modo lineare con i livelli di 25(OH)D fino a un *plateau* raggiunto a 32 ng/ml) [5] e aumenta la secrezione di PTH, stimolante il riassorbimento tubulare di calcio, l'idrossilazione renale del calcidiolo a calcitriolo, l'espressione di RANKL sugli osteoblasti e in ultima analisi lo sbilanciamento dell'omeostasi ossea verso la dissoluzione della matrice ossea mineralizzata [4].

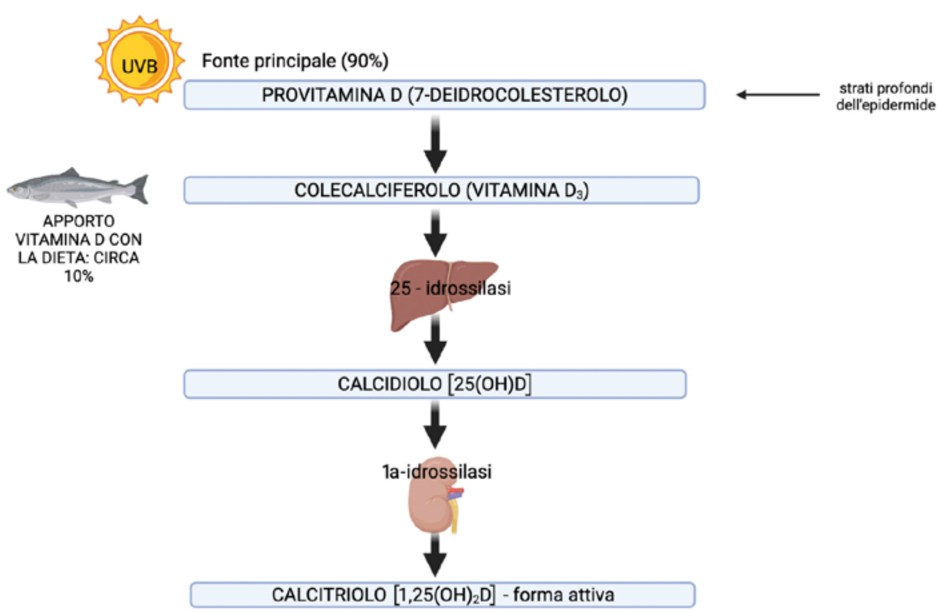
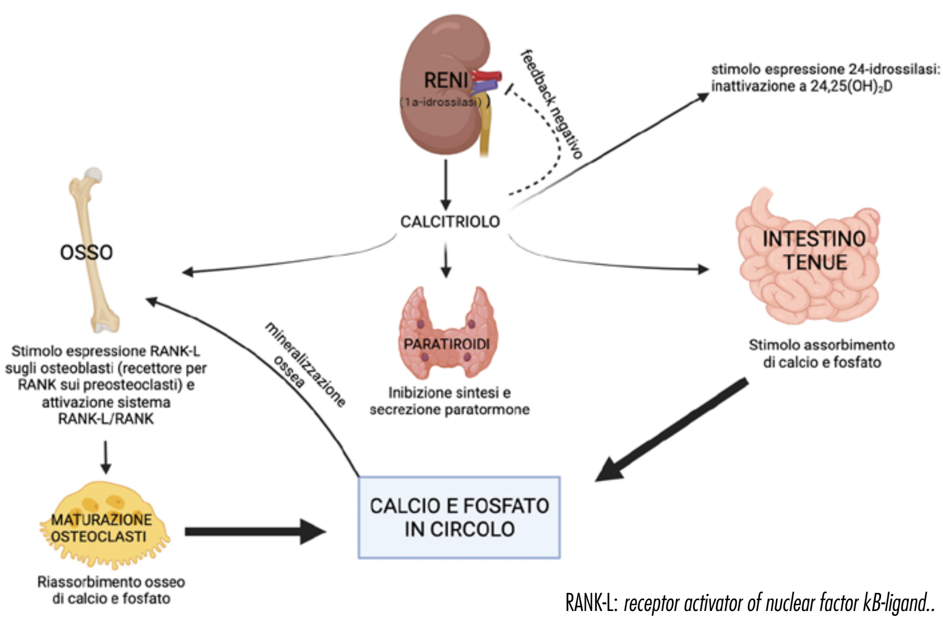


FIGURA 1.
Metabolismo vitamina D. La fonte principale (90%) è rappresentata dalla conversione della provitamina D negli strati profondi dell'epidermide, per esposizione ai raggi UVB solari, in colecalciferolo, il quale andrà incontro a due idrossilazioni consecutive (prima epatica, poi renale) che daranno luogo al metabolita attivo, il calcitriolo.

Non c'è accordo sui livelli sierici minimi di 25(OH)D sufficienti a prevenire l'osteoporosi: in base a quanto detto, sono ottimali livelli > 30 ng/ml, come affermato dall'*International Osteoporosis Foundation* (IOF) e dall'*Endocrine Society* e *National Osteoporosis Foundation* (NOF), ma la *World Health Organization* (WHO), l'*European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis* (ESCEO) e la *National Osteoporosis Society* (NOS) ritengono sufficienti livelli di 25(OH)D ≥ 20 ng/ml, soglia recepita dalla Nota 96. Raccomandazioni e linee guida che si basano sulle evidenze della letteratura, ne rispecchiano le controversie e sono anch'esse criticabili nella metodica: una recente review sistematica [7] ha valutato il metodo di sviluppo di 47 "Bone Health Guidelines" pubblicate tra il 2009 e il 2019 (nelle quali si enunciano le raccomandazioni circa i livelli sierici di 25(OH)D ai fini della prevenzione di osteoporosi e fratture, variabili da 10 a 30~100 ng/ml) sulla base di 25 criteri adottati da WHO per il corretto sviluppo di linee guida, e in media ogni linea guida soddisfaceva solo 10 criteri metodologici su 25.



RANK-L: *receptor activator of nuclear factor kB-ligand*..

FIGURA 2.
Effetti del calcitriolo [1,25(OH)$_2$D] sul metabolismo fosfocalcico.

Ulteriore fattore confondente è la mancata standardizzazione delle metodiche di misurazione dei livelli sierici di 25(OH)D, in particolare negli studi precedenti al 2009 (anno di attuazione delle prime procedure di misurazione certificate, a partire dall'US *National Institute of Standards and Technology*, NIST), considerati in diverse metanalisi, inevitabilmente condizionate nei risultati. Sono state dimostrate significative variazioni nei risultati di dosaggi di 25(OH)D con metodiche non standardizzate, dopo standardizzazioni effettuate retrospettivamente [8].

VITAMINA D E PREVENZIONE OSTEOPOROSI

Se da un lato molteplici evidenze suggeriscono la correzione dell'ipovitaminosi D per ridurre il rischio di osteoporosi, fratture da fragilità e cadute specie negli anziani (ove l'ipovitaminosi D è più frequente per ridotta esposizione al sole, ridotta capacità di sintesi da parte della cute, minore introito con la dieta), a maggior ragione in caso di terapia medica per osteoporosi [3], i risultati di alcuni RCT (*randomized controlled trial*) e relative metanalisi non rilevano i suddetti benefici, consigliandone l'uso solo in rare condizioni di rachitismo e osteomalacia [9]. Diverse criticità rendono queste ultime conclusioni non generalizzabili, a partire dal reclutamento del campione, caratterizzato 7 volte su 10 da individui con livelli sierici normali di 25(OH)D al baseline [10]: essendo la vitamina D un nutriente, i soggetti che gioveranno della supplementazione saranno i più carenti del nutriente stesso, paradossalmente "poco considerati" nei trial; a maggior ragione se questi soggetti sono in salute e a basso rischio di osteoporosi e cadute, è verosimile che non vedranno migliorare un rischio di per sé già contenuto. In più, in alcuni casi, le sottoanalisi riferite a gruppi con carenza di vitamina D e a rischio osteoporosi hanno mostrato, invece, effetti positivi dopo supplementazione, e una metanalisi basata su RCT caratterizzati da popolazione con età > 65 anni e con somministrazione di adeguati dosaggi di vitamina D con frequenza ravvicinata (almeno 800 IU/die, come suggerito dalle più recenti raccomandazioni per la popolazione anziana [11] e non in boli che potrebbero essere controproducenti o poco efficaci [12]), in combinazione con calcio, ha mostrato una significativa riduzione del 15% delle fratture totali (*relative risk*, RR = 0,85; 95% *confidence interval*, IC 0,73-0,98) e del 30% di quelle di femore (RR = 0,70; 95% IC 0,56-0,87) rispetto a placebo [13]. Inoltre, il mancato dosaggio di 25(OH)D all'endpoint in diversi studi, considerando la variabilità di posologia e frequenze di somministrazione utilizzate nei vari trial, lascia il dubbio che parte dei pazienti carenti non abbia comunque raggiunto un livello sufficiente di vitamina D a fine studio, riducendo l'attendibilità dei risultati. In aggiunta, diversi RCT hanno durata non superiore a 12 mesi, non garantendo un adeguato periodo di osservazione per valutare effetti a lungo termine quali fratture o variazioni significative della BMD [3]. E non dimentichiamo la già discussa problematica delle metodiche non standardizzate di misurazione dei livelli di 25(OH)D [8].

CONCLUSIONI

Sulla scorta di quanto considerato, è necessario ai fini della prevenzione dell'osteoporosi e delle sue complicanze mantenere livelli di 25(OH)D al di sopra di 20 ng/ml (auspicabile un range 30-40 ng/ml, in grado di conferire i massimi benefici, ciò è particolarmente importante per gli anziani e soggetti a rischio), insieme all'adeguata somministrazione di calcio, se deficitario [14]. Giovano della supplementazione soprattutto i soggetti carenti o insufficienti in vitamina D e i soggetti a rischio di carenza: un soggetto con adeguati livelli di vitamina D ha già i benefici di questa condizione fisiologica. Va previsto un dosaggio di mantenimento dei livelli raggiunti per anziani, soggetti a rischio deficit o in terapia per osteoporosi.
Sono necessari RCT con metodiche standardizzate di misurazione di 25(OH)D, che coinvolgano soggetti con carenza di vitamina D e a rischio osteoporosi, con valutazione dell'effettivo raggiungimento post supplementazione di livelli sierici normali.
Infine, in base al monitoraggio della Nota 96, sorge il dubbio che la contrazione dei consumi nelle fasce di età a rischio comporti una supplementazione insufficiente. Va tenuto conto che i costi relativi alla supplementazione sono ampiamente ripagati dal risparmio di quelli legati alle complicanze dell'osteoporosi [15], per cui la prevenzione resta l'arma vincente anche dal punto di vista dei costi.

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Impatto della Nota 96 dell'Agenzia Italiana del Farmaco sull'uso della vitamina D in Italia

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La vitamina D (VitD) svolge un ruolo fondamentale nel mantenere i livelli sierici di calcio all'interno del range fisiologico necessario per la salute muscolo-scheletrica e per il metabolismo osseo.[1]

La VitD garantisce una corretta mineralizzazione dell'osso e un suo deficit rappresenta un fattore di rischio per la fragilità scheletrica negli anziani e per le fratture osteoporotiche [2,3]. Inoltre, studi scientifici hanno mostrato come l'integrazione di VitD prevenga la perdita ossea sistemica a seguito di una frattura e riduca il rischio di fratture multiple [4,5].

Le linee guida nazionali e internazionali sulla gestione dell'osteoporosi raccomandano un adeguato apporto di calcio e VitD in aggiunta alle terapie anti-osteoporotiche [6,7].

La Nota AIFA 79, nel definire la rimborsabilità dei farmaci per la prevenzione primaria e secondaria del rischio di fratture osteoporotiche, riporta che, prima di avviare la terapia con tali farmaci, è raccomandato un adeguato apporto di calcio e VitD, ricorrendo, ove dieta ed esposizione solari siano inadeguati, a supplementi con sali di calcio e vitamina D_3 (e non ai suoi metaboliti idrossilati) [8].

Negli ultimi anni si è verificato in Italia un progressivo aumento del consumo di VitD, con conseguente incremento della spesa a carico del Servizio Sanitario Nazionale (SSN) [9,10].

La crescita nei consumi di VitD ha fatto ipotizzare una possibile inappropriatezza d'uso e conseguentemente, a fine ottobre 2019, l'AIFA ha pubblicato la Nota 96 che individua i criteri di rimborsabilità della supplementazione di VitD per la prevenzione e il trattamento degli stati carenziali nell'adulto [11].

Nei primi 15 mesi di applicazione della Nota si è registrata una diminuzione di quasi il 30% dei consumi e della spesa di VitD rispetto ai periodi precedenti,[12] ma non è ancora chiarito se vi sia stato anche un miglioramento nell'appropriatezza d'uso.

Di recente, CliCon S.r.l. Società Benefit in collaborazione con l'Azienda ULSS 8 Berica ha condotto un'analisi per verificare se la riduzione del consumo di VitD riscontrata dopo l'entrata in vigore della Nota 96 fosse accompagnata da una maggior appropriatezza nell'uso di tali supplementazioni. I risultati sono stati presentati all'ultima edizione del Congresso Europeo ISPOR 2021.[13] L'analisi è stata elaborata utilizzando i flussi amministrativi dell'Azienda Sanitaria Locale. Sono stati inclusi tutti i pazienti adulti con almeno una prescrizione dei farmaci in Nota 96 (colecalciferolo, colecalciferolo/sali di calcio, calcifediolo) o in Nota 79 (bifosfonati, teriparatide, ranelato di stronzio, raloxifene, denosumab, bazedoxifene) nei 12 mesi precedenti (dall'1/10/2018 al 30/09/2019) e successivi (dall'1/10/2019 al 30/09/2020) l'entrata in vigore della Nota 96. Il miglioramento dell'appropriatezza prescrittiva, misurato come riduzione dello scostamento tra pratica clinica e raccomandazioni terapeutiche, è stato valutato attraverso gli indicatori riportati di seguito:

- indicatore 1: quota di pazienti in trattamento con farmaci per l'osteoporosi che associano VitD (VitD in Nota 79, uso appropriato);
- indicatore 2: quota di pazienti in trattamento con VitD senza ipovitaminosi accertata negli ultimi 12 mesi (VitD fuori Nota 96, uso non appropriato).

Nei 12 mesi pre- e post- Nota 96, dal calcolo dell'indicatore 1, che misura l'aderenza ai criteri di rimborsabilità della Nota 79, è risultata una riduzione nella quota dei pazienti che associano la VitD ai farmaci per l'osteoporosi, che passano dal 70,2 al 60,4% del totale dei trattati con farmaci per l'osteoporosi, come mostrato in Figura 1.

Al contrario, non sono state riscontrate differenze apprezzabili nel calcolo dell'indicatore 2, che misura lo scostamento dai criteri

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Conflitto di interessi
Gli Autori dichiarano nessun conflitto di interessi.

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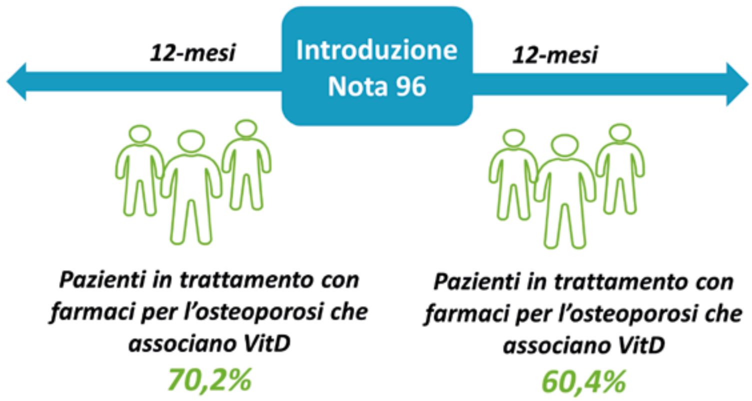

FIGURA 1.
Quota di pazienti in trattamento con farmaci per l'osteoporosi che associano VitD nei 12 mesi precedenti e successivi l'introduzione della Nota 96.

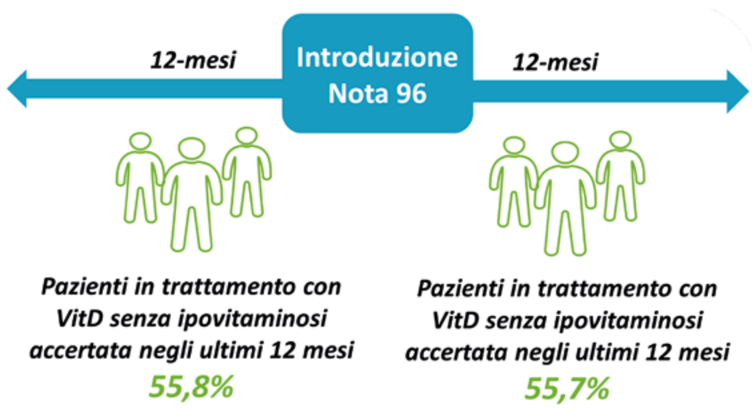

FIGURA 2.
Quota di pazienti nei 12 mesi precedenti e successivi l'introduzione della Nota 96 in trattamento con VitD senza ipovitaminosi accertata negli ultimi 12 mesi [esclusi i pazienti in Nota 79 per cui non è prevista la determinazione dei livelli di 25(OH)D].

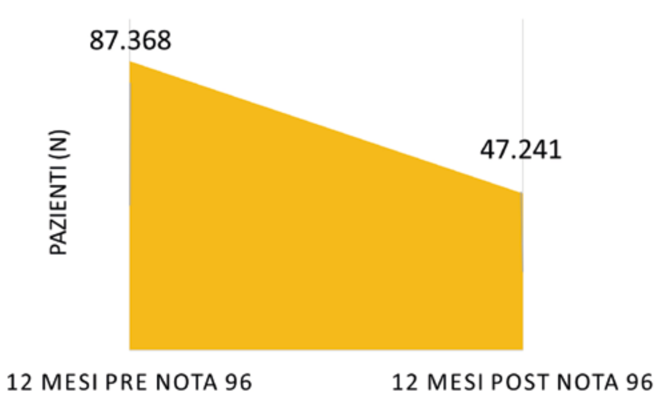

FIGURA 3.
Numero complessivo di pazienti trattati con VitD nei 12 mesi precedenti e successivi l'introduzione della Nota 96.

di rimborsabilità della Nota 96: la quota dei pazienti in trattamento con VitD senza ipovitaminosi accertata negli ultimi 12 mesi, esclusi i pazienti in Nota 79 per cui non è prevista la determinazione dei livelli di 25(OH)D, è rimasta invariata (55,8% *vs* 55,7%), evidenziando come, al netto dei pazienti osteoporotici, oltre la metà dei trattati con VitD non abbiano le indicazioni per la rimborsabilità dei farmaci (Fig. 2).
Si è invece notevolmente ridotto il numero complessivo di trattati con VitD che, come si può notare dalla Figura 3, passa da 87.368 a 47.041 soggetti, con conseguente riduzione della spesa (-1,1 milioni €: -44,8%).
Nel complesso, i risultati dell'analisi hanno confermato una riduzione nell'utilizzo di VitD a carico del SSN, determinata da un minor numero di pazienti che ricevono tali supplementi in regime di rimborsabilità. Tuttavia, tale decremento non è coinciso con un miglioramento dell'appropriatezza prescrittiva che, anzi, si è ridotta, soprattutto per quanto riguarda l'utilizzo in associazione con i farmaci per l'osteoporosi. Se infatti la quota di pazienti in trattamento con VitD senza determinazione della 25(OH)D è rimasta ugualmente alta nei 2 periodi, si è ridotta di 10 punti in percentuale la quota dei pazienti che associano la VitD ai farmaci per l'osteoporosi, suggerendo la necessità di implementare azioni di monitoraggio della pratica clinica al fine di individuare azioni tempestive volte all'ottimizzazione dell'appropriatezza prescrittiva.
È ampiamente noto in letteratura come una non adeguata integrazione di VitD in associazione ai trattamenti antiosteoporotici possa ridurre l'effetto di tali terapie e portare ad un aumento di esiti negativi [14,15]. Alcuni studi pubblicati hanno osservato in contesti Italiani un maggiore aumento della densità ossea e una sensibile diminuzione del rischio di frattura nelle donne in post-menopausa trattate con farmaci per l'osteoporosi in combinazione con integratori di VitD rispetto alle pazienti che assumevano solo terapie antiosteoporotiche[14]. Inoltre, un precedente studio osservazionale retrospettivo condotto in una coorte di pazienti osteoporotici con una precedente frattura da fragilità basato su database amministrativi di un campione di ASL, ha mostrato un tasso di incidenza di ri-frattura inferiore tra i pazienti con supplementazione di calcio/VitD rispetto a chi o riceveva solo farmaci per l'osteoporosi o non presentava alcun trattamento per la patologia [16]. Inoltre, i pazienti con supplemento di calcio/VitD in aggiunta al farmaco per l'osteoporosi presentavano un rischio ridotto del 64% di sviluppare una frattura successiva e un rischio di morte due volte inferiore rispetto al gruppo che riceveva solo il farmaco per l'osteoporosi [16]. Coerentemente con gli esiti clinici, anche i costi assistenziali dei

pazienti osteoporotici in supplementazione di calcio/VitD sono risultati inferiori.[17]

D'altro canto, l'apporto supplementare di VitD in situazioni diverse dalla prevenzione delle fratture osteoporotiche è uno dei temi più dibattuti in campo medico, fonte di controversie e di convinzioni tra loro anche fortemente antitetiche.

Diversi studi osservazionali hanno riportato in varie situazioni patologiche (cardiopatie, neoplasie, malattie degenerative, metaboliche respiratorie ecc.) peggiori condizioni di salute in popolazioni con bassi livelli di vitamina D [18].

I risultati di trial clinici randomizzati di elevata numerosità non hanno tuttavia confermato tali ipotesi e hanno delineato, soprattutto in oncologia e cardiologia, aree di documentata inefficacia della supplementazione con VitD. Il valore di 25(OH)D pari a 20 ng/ml (50 nmol/l) è ritenuto 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.

In definitiva, come riassunto nelle 2 Note AIFA, la letteratura sottolinea l'importanza di garantire un'adeguata integrazione di VitD nella prevenzione delle fratture da fragilità osteoporotica, per diminuire l'incidenza di tali eventi e per limitare il pesante carico economico associato, e di supplementare con VitD in presenza di valori di 25(OH)D > 20 ng/ml nei pazienti osteoporotici.

Su queste basi, l'analisi condotta evidenzia chiaramente la necessità di ottimizzare l'appropriatezza d'uso della VitD sia sui pazienti osteoporotici in Nota 79, sui quali la VitD dovrebbe essere maggiormente prescritta, sia nei presunti stati carenziali, in cui oltre il 50% dei pazienti riceve la supplementazione senza aver avuto un dosaggio della 25(OH)D, come invece previsto dalla Nota 96.

L'implementazione e il monitoraggio periodico di indicatori di appropriatezza, progettati per identificare impieghi dove non c'è indicazione all'uso (vitD fuori Nota 96) e aree in cui esiste raccomandazione ma non c'è prescrizione (vitD in Nota 79), offre l'opportunità di organizzare e sviluppare all'interno delle singole realtà locali processi di governo clinico e di monitoraggio interno, per il miglioramento dell'assistenza al paziente, in forma di audit clinico. Il coinvolgimento dei medici di medicina generale consentirebbe infine di individuare i pazienti fuori target sui quali effettuare l'audit, concorrendo a ridurre l'inappropriatezza prescrittiva, con conseguente miglioramento dello stato di salute del paziente e minimizzazione del consumo di risorse sanitarie.

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