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EDITORIALE

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Cari Colleghi

in questo numero ospitiamo, come vedete, due contributi relativi al dibattito su possibili effetti extrascheletrici della supplementazione con vitamina D, in particolare sul diabete mellito tipo 2 (T2DM) e in ambito oncologico.
Noterete che entrambi gli Autori concludono correttamente che complessivamente i trial disponibili non hanno evidenziato risultati significativi su questi fronti, ma essendo stati condotti in popolazioni largamente non carenti, non sono in grado di escludere un effetto protettivo della supplementazione con vitamina D in soggetti carenti, specie se si considera che le sub-analisi relative a questi ultimi suggeriscono effettivamente un effetto positivo.
Notate, ad esempio, come in una post-hoc analisi dello trial clinico randomizzato (RCT) di Pittas et al. [1] nei pochi partecipanti che avevano livelli circolanti di 25-idrossi-vitamina D_3 <12 ng/ml (< 30 nmol/l) al basale, il rischio di sviluppare T2DM risultasse ridotto del 60% in quelli trattati con colecalciferolo rispetto quelli trattati con placebo (hazard ratio (HR) 0,38, 95% IC 0,18-0,80).
Oppure notate come nello studio condotto in pazienti affetti da tumore al polmone la supplementazione con vitamina D non abbia dato complessivamente i risultati sperati, ma selezionando i pazienti con *early-stage* adenocarcinoma con bassi livelli di vitamina D la supplementazione abbia in realtà ridotto la mortalità di più del 60% rispetto al placebo (HR = 0,37; 95% IC 0,15-0,95) [2].
Anche il tempo necessario per valutare l'outcome potrebbe essere determinante: notate, ad esempio, come la conclusione negativa del VITAL trial [3] cambierebbe se si escludessero, secondo me ragionevolmente considerando la biologica latenza, i primi 1-2 anni di follow-up: la supplementazione con vitamina D in tal caso dimostra di ridurre significativamente il rischio di morte per cancro del 25% (HR = 0,75; 95% IC 0,59-0,96).
Relativamente alla documentazione di un effetto significativo della supplementazione con vitamina D nei soli soggetti con bassi livelli sierici di 25-idrossi-vitamina D_3 al basale, vi ricordo che in letteratura vi sono numerosi altri esempi, sia scheletrici che extrascheletrici [4]: nella FIG.1 vedete qualche esempio di diversi effetti della supplementazione su alcuni rischi extrascheletrici a seconda dei livelli sierici basali, bassi o no, nei pazienti supplementati.
La cosa non ci sorprende [5] visto che la vitamina D agisce come un nutriente, cioè serve quando manca, ma non serve quando non manca …

In conclusione non credo si possa oggi affermare che stiamo sovrastimando i possibili benefici extrascheletrici della supplementazione con vitamina D o che si possano negare, perché il disegno e i risultati dei trial clinici sin qui condotti non ci consentono di escluderli.

Cosa ne pensate?
Buona Lettura

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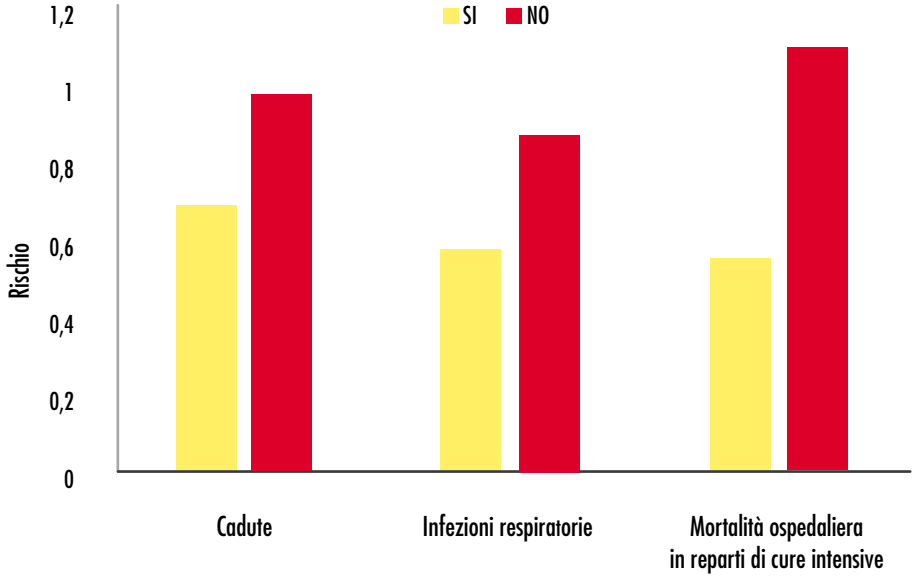

FIGURA 1.
Effetti della supplementazione con vitamina D su rischi (rischio relativo, odds ratio o hazard ratio) extrascheletrici a seconda dei livelli sierici basali di 25-idrossi-vitamina D_3, bassi (SI) o non bassi (NO) ($p < 0,05$ tra i gruppi).

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EFFETTO DELLA SUPPLEMENTAZIONE CON VITAMINA D_3 SUL RISCHIO DI INSORGENZA DI DIABETE TIPO 2: stiamo sovrastimando i suoi possibili benefici extra-scheletrici?

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La carenza di vitamina D è stata associata alla presenza di molteplici patologie croniche non scheletriche (tra cui la malattia cardiovascolare, ipertensione, epatopatia steatosica non alcolica, alcune neoplasie e diabete), suggerendo la possibilità che tale vitamina possa svolgere numerosi effetti pleiotropici a livello extra-scheletrico, grazie alla distribuzione ubiquitaria del suo recettore [1-3].

Tra queste patologie croniche non scheletriche che sono potenzialmente associate a ridotti livelli circolanti di vitamina D, il diabete mellito tipo 2 (T2DM) ha rappresentato uno dei più importanti focus della ricerca scientifica nell'ultimo decennio [4].

Diversi studi epidemiologici hanno documentato che i pazienti con T2DM hanno livelli circolanti di vitamina D ridotti rispetto alla popolazione non diabetica (paragonabile per età, sesso e grado di obesità) e che bassi livelli di vitamina D si associano a una maggior prevalenza di complicanze croniche micro- e macro-vascolari del diabete [4-6]. In modelli sperimentali è stato inoltre dimostrato che ridotti livelli di vitamina D si associano ad aumentata resistenza insulinica e alterata secrezione insulinica da parte della beta cellula oltre che a elevati livelli di diversi fattori pro-coagulanti e markers infiammatori, e che la maggior parte di tali alterazioni migliorano dopo somministrazione di vitamina D_3 [2,4,7].

Sulla base di tali evidenze, vari studi prospettici di tipo osservazionale hanno successivamente documentato l'esistenza di una significativa associazione fra ridotti livelli circolanti di vitamina D e aumentato rischio di sviluppare T2DM (specie nei soggetti con ridotta tolleranza glucidica) [8], confermando così la plausibilità biologica di un coinvolgimento della vitamina D nello sviluppo del T2DM. Tuttavia, i risultati finora disponibili sono esclusivamente basati su dati che non permettono di definire un possibile ruolo causale della vitamina D nello sviluppo del diabete. In particolare, non è ancora chiaro se la supplementazione con vitamina D_3 sia in grado di ridurre il rischio di sviluppare il diabete.

A questa domanda ha cercato di dare una risposta il recente trial clinico randomizzato (RCT) che è stato pubblicato da Pittas e colleghi sul numero di agosto del *New England Journal of Medicine* [9]. In questo ampio RCT, denominato "D2d trial", gli Autori hanno arruolato un campione di oltre 2.400 soggetti adulti (45% femmine, 67% caucasici, età media 60 anni, BMI medio 32 kg/m^2) a elevato rischio di sviluppare diabete (cioè soggetti caratterizzati da avere almeno due delle seguenti alterazioni: glicemia a digiuno compresa fra 100 e 125 mg/dl, glicemia a 2 ore dopo OGTT compresa fra 140 e 199 mg/dl o emoglobina glicata compresa fra 5,7 e 6,4%) ma che non sono stati selezionati sulla base del loro stato vitaminico D al baseline; infatti, i loro valori medi circolanti di 25-idrossi-vitamina D erano di 28 ± 10 ng/ml; solo il 21,7% del campione aveva valori di 25-idrossi-vitamina D < 20 ng/ml al baseline. Tali soggetti

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sono stati successivamente assegnati, in maniera randomizzata e in doppio cieco, a un gruppo di trattamento attivo con vitamina D_3 ad alte dosi (colecalciferolo 4.000 UI al giorno; n = 1.211) oppure a un trattamento con placebo (n = 1.212) e sono stati seguiti per un follow-up (mediana) di 2,5 anni. L'outcome primario dello studio era la comparsa di nuovi casi di T2DM. Durante il trial, i livelli circolanti di vitamina D sono più che raddoppiati in quelli trattati con colecalciferolo (passando da valori medi al baseline di 27,7 ng/ml a 54,3 ng/ml al termine dello studio) mentre si sono mantenuti pressoché invariati nel gruppo trattato con placebo (passando da valori medi al baseline di 28,2 ng/ml a 28,8 ng/ml al termine dello studio). Gli Autori dello studio hanno osservato che il rischio di sviluppare T2DM durante il follow-up era sostanzialmente sovrapponibile nel gruppo in trattamento con colecalciferolo rispetto al gruppo trattato con placebo (9,4 e 10,7 eventi ogni 100 persone-anno; hazard ratio 0,88, 95% IC 0,75-1,04; p = 0,12) (Fig. 1). L'aderenza complessiva al trattamento dei partecipanti è stata molto elevata (~86%), mentre l'incidenza degli eventi avversi (incluso ipercalcemia, riduzione e-GFR e nefrolitiasi) è stata bassa e assolutamente comparabile fra i pazienti trattati con alte dosi giornaliere di colecalciferolo e quelli trattati con placebo. L'analisi statistica condotta su sottogruppi pre-specificati di soggetti non ha evidenziato la presenza di alcuna significativa eterogeneità fra i due gruppi di trattamento (Fig. 2). In particolare, i risultati dello studio erano invariati quando la popolazione veniva suddivisa per sesso, razza, latitudine geografica, presenza di obesità e anche livelli circolanti di 25-idrossi-vitamina D al baseline (< 20 ng/ml *vs* ≥ 20 ng/ml) [9]. Tuttavia, in una post-hoc analisi dei dati dei pochi partecipanti (n = 103, 4,3% del totale) che avevano livelli circolanti di 25-idrossi-vitamina D < 12 ng/ml (< 30 nmol/l) al baseline, il rischio di sviluppare T2DM era significativamente inferiore in quelli trattati con colecalciferolo rispetto quelli trattati con placebo (hazard ratio 0,38, 95% IC 0,18-0,80). Al contrario, nei partecipanti (n = 2.319, 95,7% del totale) che avevano livelli di 25-idrossi-vitamina D ≥ 12 ng/ml al baseline, il rischio di sviluppare T2DM era paragonabile nei due gruppi di trattamento (hazard ratio 0,92, 95% IC 0,78-1,08) [9].

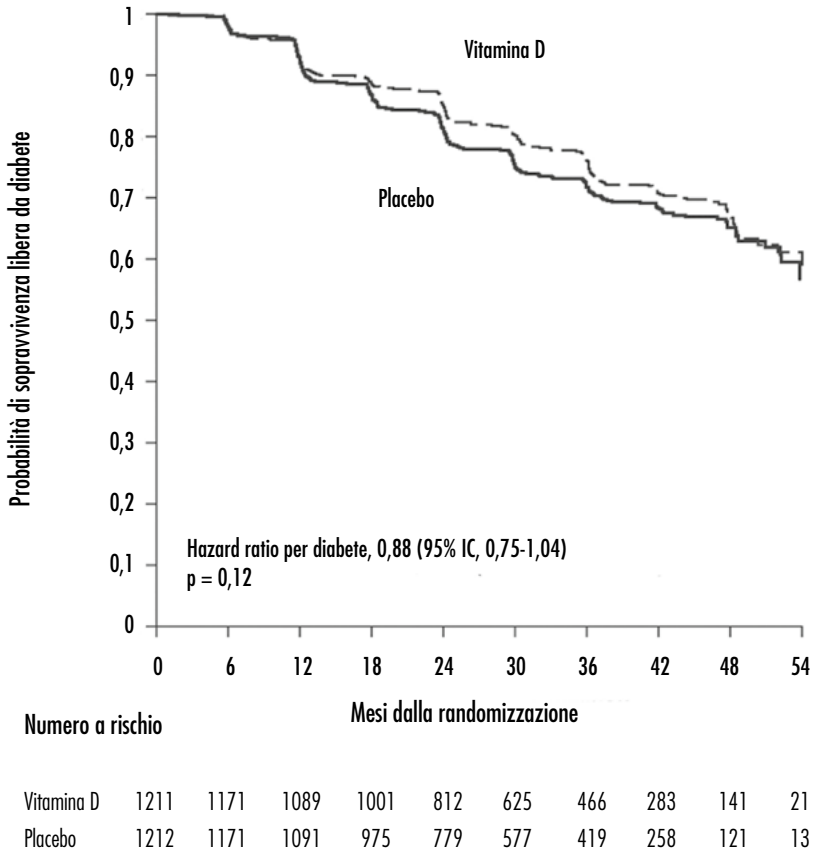

FIGURA 1.
Curve di Kaplan-Meier sull'effetto del trattamento con colecalciferolo ad alte dosi (4.000 UI/die) *vs* placebo sul rischio di sviluppare diabete tipo 2 in 2.423 soggetti adulti con prediabete. Dati pubblicati e tratti dal "D2d trial" [9].

I risultati di questo ampio RCT dimostrano che la supplementazione di vitamina D_3 a elevate dosi (4.000 UI/die di colecalciferolo per os) a soggetti con prediabete (cioè a elevato rischio di sviluppare diabete), che non sono stati selezionati per carenza di vitamina D al baseline, risulta ben tollerata (senza nessun rischio di tossicità da eccessivo introito di colecalciferolo) ma non si associa ad alcuna significativa riduzione di insorgenza di T2DM durante il follow-up di 2,5 anni [9].

Questi risultati confermano, in larga parte, quanto era già stato osservato in un precedente RCT con una dimensione campionaria più ridotta, che è stato pubblicato nel 2016 [9]. In tale studio norvegese, denominato "Tromso Vitamin D and T2DM trial", sono stati randomizzati 511 soggetti affetti da prediabete (61% maschi, età media 62 anni, BMI medio 30 kg/m^2 e valori medi di 25-idrossi-vitamina D di 24 ± 8 ng/ml) a un trattamento con placebo o con colecalciferolo 20.000 UI alla settimana (pari a circa 2.900 UI/die) per una durata di 5 anni [9]. Analogamente a quanto osservato nel "D2d trial", anche gli Autori di questo studio non hanno documentato alcun beneficio significativo della supplementazione con vitamina D_3 sull'insorgenza di T2DM nel corso del follow-up dello studio (hazard ratio 0,90; 95% IC 0,69-1,18) [9].

Sulla base dei risultati di questi due RCT, si evince quindi che la supplementazione ad alte dosi di vitamina D_3 (con dosi giornaliere variabili da 2.900 a 4.000 UI di colecalciferolo) a individui adulti a elevato rischio di diabete, che non sono stati selezionati sulla base dei loro livelli circolanti di 25-idrossi-vitamina D, non sembra esercitare un importante effetto protettivo sul rischio di sviluppare T2DM, avendo evidenziato entrambi i trial clinici che tale supplementazione si associava solo a

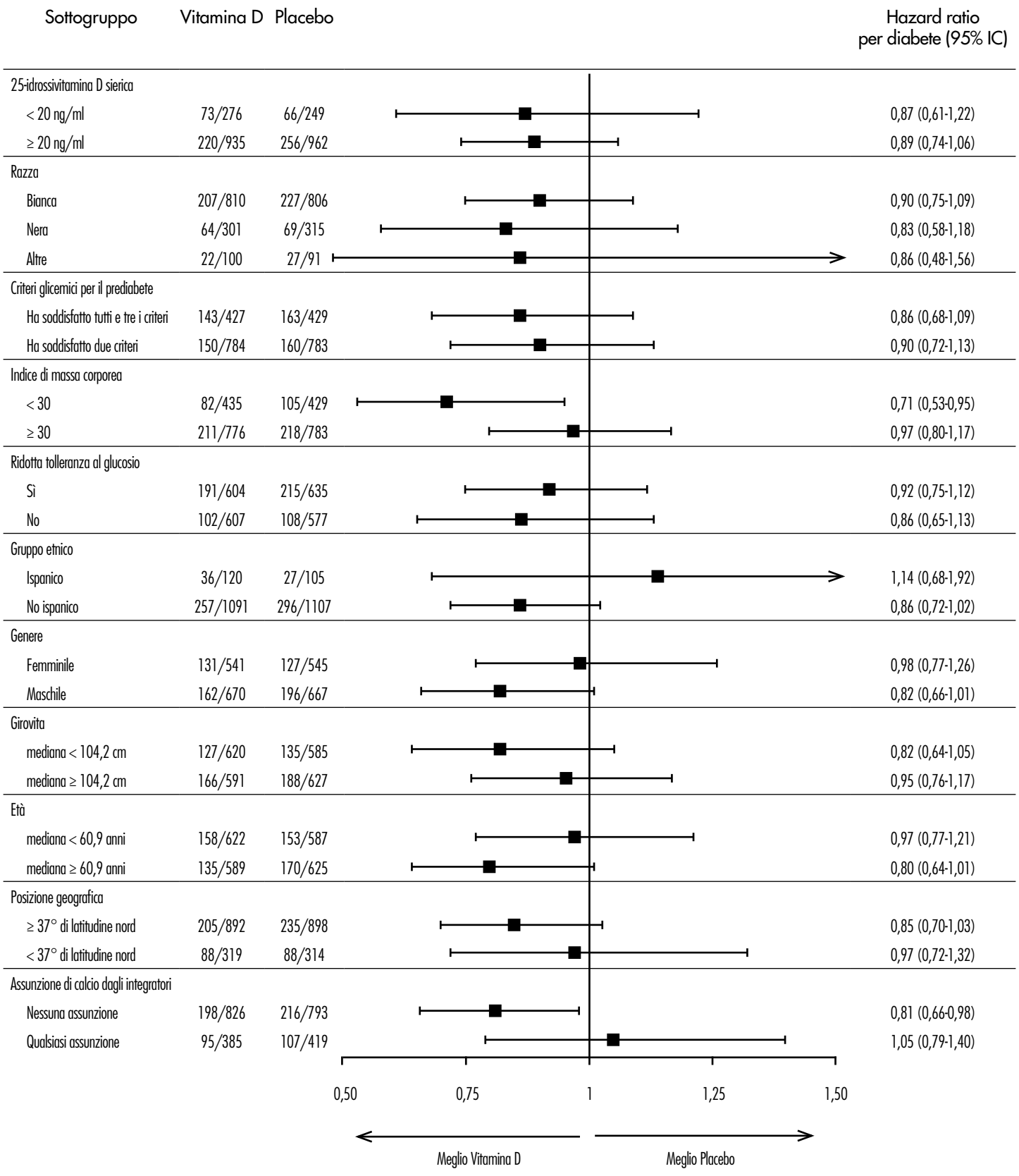

FIGURA 2.
Effetto del trattamento con colecalciferolo ad alte dosi (4.000 UI/die) *vs* placebo sul rischio di sviluppare diabete tipo 2 in vari sottogruppi pre-specificati di soggetti con prediabete. Dati pubblicati e tratti dal "D2d trial" [9].

una riduzione media del 10-12% del rischio relativo di sviluppare T2DM in un periodo di follow-up compreso fra 2 e 5 anni [9,10].
Questo dato, ovviamente, non esclude che futuri trial clinici randomizzati con una dimensione campionaria maggiore non possano essere in grado di rilevare una significatività statistica del trattamento con colecalciferolo sul rischio a lungo termine di sviluppare T2DM (dato che nessuno dei due trial clinici aveva una dimensione campionaria sufficiente per rilevare una riduzione significativa del rischio di diabete del 10-12%). Un altro aspetto ancora più rilevante da sottolineare è che la maggioranza dei soggetti inclusi nei due RCT aveva livelli ottimali di vitamina D circolante [9,10]. Infatti, nel "D2d trial" 42,2% dei partecipanti avevano valori di 25-idrossi-vitamina D ≥ 30 ng/ml, 36,1% avevano valori compresi fra 20-29 ng/ml e solo il 21,7% dei partecipanti avevano valori di 25-idrossi-vitamina D < 20 ng/ml [9]. È possibile, quindi, ipotizzare che l'elevata percentuale di soggetti con valori adeguati di vitamina D, che sono stati inclusi in questi due RCT, possa aver ridotto la capacità di documentare un beneficio della supplementazione con colecalciferolo sul rischio di insorgenza di T2DM tra i due gruppi di trattamento.
Peraltro, come riportato in precedenza, è utile anche rimarcare che proprio una post-hoc analisi dei dati del "D2d trial", che è stata condotta nei partecipanti (n = 103, 4,3% del totale) che avevano livelli circolanti di 25-idrossi-vitamina D estremamente bassi al baseline (< 12 ng/ml), ha suggerito che il rischio di sviluppare T2DM era ridotto di oltre il 60% nei soggetti trattati con colecalciferolo rispetto a quelli trattati con placebo (hazard ratio 0,38, 95% IC 0,18-0,80) [9].
Ciò sottolinea in maniera sempre più evidente la necessità che nella futura pianificazione di RCT che valuteranno i possibili benefici della supplementazione orale con vitamina D_3 sul rischio di insorgenza di T2DM (e molto probabilmente anche di altri importanti outcome scheletrici ed extra-scheletrici – come peraltro già evidenziato in recenti trial e meta-analisi) [11-13] venga tenuto in considerazione anche lo stato vitaminico D dei partecipanti arruolati in tali RCT, dato che è ragionevole ritenere che il beneficio della supplementazione con vitamina D_3 ad alte dosi sul rischio a lungo-termine di sviluppare T2DM possa essere maggiore nei pazienti con carenza di vitamina D rispetto a quelli che hanno valori di vitamina D circolante nella norma [14].

Conflitto di interessi

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

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LA VITAMINA D IN ONCOLOGIA

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INTRODUZIONE

Studi in vitro e in vivo hanno dimostrato che il metabolita della vitamina D fisiologicamente attivo (1,25(OH)D o calcitriolo), il quale esercita la sua azione tramite il recettore della vitamina D (VDR), ha effetti antiproliferativi in vari tipi di cellule, si è scoperto che regola l'espressione dei geni correlati con la tumorigenesi, ed è un mediatore nell'inibizione della crescita cellulare, dell'adesione, della migrazione cellulare, delle metastasi e dell'angiogenesi. Inoltre, numerosi studi epidemiologici hanno mostrato un'associazione inversa con l'*incidence* di alcuni tumori e l'incremento di 25-idrossicolecalciferolo (25(OH)D). Tuttavia, gli studi osservazionali sono inficiati dal rischio di causalità inversa, mentre gli studi interventistici non hanno confermato tali associazioni. Discrepanze con le sperimentazioni cliniche randomizzate (RCT) suggeriscono che un basso 25(OH)D potrebbe essere semplicemente un indicatore di un peggioramento della salute. I processi infiammatori coinvolti nell'evento patologico e il decorso clinico ridurrebbero il 25(OH)D, il che spiegherebbe perché un basso livello di vitamina D (misurato attraverso il 25OHD) viene rilevato in un vasto gruppo di disturbi.

Risultati più convincenti sono stati ottenuti relativamente alla mortalità: infatti, la dimostrazione proviene non solo da studi basati sull'osservazione ma anche da sperimentazioni cliniche. Una meta-analisi di studi osservazionali ha mostrato una relazione non lineare del rischio complessivo di mortalità e il 25(OH)D in circolo, con concentrazioni ottimali intorno a 30-35 ng/ml. Una meta-analisi di sperimentazioni cliniche randomizzate in soggetti sani ha mostrato che dosi ordinarie di integratori di vitamina D sono associate a una significativa diminuzione della mortalità complessiva per l'integrazione di vitamina D_3, mentre non è stata rilevata nessuna associazione con la vitamina D_2.

Studi recenti suggeriscono di indagare il legame tra vitamina D, sopravvivenza al cancro e mortalità, individuando in questo tema una delle aree di ricerca più promettenti.

STUDI BASATI SULL'OSSERVAZIONE

Una meta-analisi internazionale di studi di coorte [1] ha dimostrato che le persone con un elevato 25(OH)D di base avevano un rischio di morte per cancro significativamente minore. Le stime di rischio sono state: rischio relativo riassuntivo (SRR) = 0,91 (intervallo di confidenza al 95% (IC 95%): 0,85-0,98) e 0,69 (IC 95%: 0,61-0,78) per le coorti di prevenzione primaria (partecipanti non selezionati sulla base di patologia cronica preesistente) e per le coorti di prevenzione secondaria (condizioni di base preesistenti), rispettivamente, tenendo conto anche degli altri fattori di rischio potenziali. Le analisi di sottogruppo hanno indicato che le associazioni inverse di 25(OH)D con la mortalità specifica per cancro erano notevolmente più forti nelle popolazioni con un ridotto uso di integratori di vitamina D (< 10%).

In una meta-analisi di dati individuali appartenenti a 8 studi di coorte è stato osservato un aumento della mortalità per i soggetti con concentrazioni di 25(OH)D < 40 nmol/L. La prevalenza delle concentrazioni di 25(OH)D < 40 nmol/L è stata valutata intorno al 20%. Non è stata dimostrata una chiara relazione tra 25(OH)D e la mortalità per cancro [2], tuttavia in una precedente analisi aggregata è stata osservata una significativa associazione con la mortalità per cancro tra i soggetti con un'anamnesi di cancro (tasso di rischio = 1,70 (IC 95%: 1,00-2,88)) [3].

Un'analisi aggregata mendeliana della Biobanca del Regno Unito ha valutato se le concentrazioni di 25(OH)D predeterminate geneticamente siano associate alla mortalità per cancro riassumendo i dati di 438.870 soggetti e di 6.998 decessi specifici per cancro. I risultati hanno mostrato che basse concentrazioni plasmatiche di 25(OH)D non erano associate alla mortalità per cancro [4].

Risultati più promettenti, che suggerivano un'associazione inversa del 25(OH)D con

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TABELLA I.
Recenti meta-analisi su 25(OH)D e sopravvivenza/mortalità per cancro.

	Sedi tumorali	Primo autore, anno di pubblicazione	N. studi	N. soggetti	Endpoint	Valutazione di rischio in sintesi (IC 95%)	Contrasti
Meta-analisi	Pancreas	Zhang, 2017	8	2166	Mortalità	0,81 (0,68-0,96)	Alta rispetto a bassa
	Seno	Hu, 2018	6	5984	Sopravvivenza complessiva	0,67 (0,56-0,79)	Massima rispetto a minima
	Polmone	Huang, 2017	8	2166	Sopravvivenza complessiva	0,80 (0,59-1,08)	Alta rispetto a bassa
		Feng, 2017	4	17919	Mortalità	0,76 (0,61-0,94)	Alta rispetto a bassa
			5		Sopravvivenza complessiva	1,01 (0,88-1,16)	Alta rispetto a bassa
	Prostata	Song, 2018	7	7808	Sopravvivenza complessiva	0,91 (0,87-0,97)	20 nmol/L aumento
	Colon retto	Maalmi, 2018	11	7718	Sopravvivenza complessiva	0,67 (0,57-0,78)	Massima rispetto a minima
	Ematologico	Wang, 2015	7	2643	Sopravvivenza complessiva	0,54 (0,45-0,65)	Normale rispetto a bassa
	Qualsiasi	Chowdhury, 2014	17	120735	Mortalità	0,80 (0,70-0,91)	Alta rispetto a bassa
Analisi aggregata	Qualsiasi	Ong, 2018*		6998	Mortalità	0,97 (0,84-1,11)	
		Gaksch, 2017	8	26916	Mortalità	0,79 (0,60-1,04)	> 100 rispetto a 75-99 nmol/L
		Schöttker, 2014	8	26018	Mortalità	0,60 (0,35-1,00)	Quintili superiori rispetto a inferiori

* Randomizzazione mendeliana.

la mortalità per cancro, sono stati riscontrati con meta-analisi che indagavano in particolare alcune specifiche sedi tumorali: pancreas, seno, polmone, prostata, colon retto ed ematologico (Tab. I). Alcuni studi di coorte singoli hanno anche rilevato un rischio di mortalità per cancro significativamente minore per i pazienti con bassi livelli di 25OHD affetti da un tumore del tratto aerodigestivo superiore e per i tumori gastrici (Tab. II).

Dato che l'esposizione al sole è un fattore di rischio riconosciuto per il melanoma, il consiglio comunemente dato ai pazienti di melanoma dopo la diagnosi è di ridurre la loro esposizione al sole, ma ciò potrebbe ulteriormente aggravare la loro insufficienza di vitamina D. Inoltre, in una coorte potenziale di 1.171 pazienti di melanoma la variazione di 25(OH)D rispetto allo standard di base è risultata associata al rischio di recidiva: un aumento del rischio è stato rilevato con una riduzione o un aumento nel 25(OH)D [5]. I pazienti che non avevano cambiato le loro abitudini e avevano trascorso vacanze al sole dopo la diagnosi di melanoma corrispondono probabilmente alla categoria di riferimento con nessun cambiamento nel 25(OH)D, dello studio di Saiag et al. [5]. In una coorte di 691 pazienti di melanoma abbiamo rilevato che il rischio di ricomparsa del melanoma era significativamente minore nei pazienti che trascorrevano vacanze al sole dopo la diagnosi di melanoma [6], avendo cura di non esporsi nelle ore calde. Inoltre, si è rilevato che vacanze al sole prima della diagnosi di melanoma erano significativamente associate a un minore spessore di Breslow, il principale fattore prognostico del melanoma. Più settimane di vacanze al sole erano anche significativamente e inversamente correlate con lo spessore, in modo dipendente dalla durata dell'esposizione [6]. Una vasta coorte di 1.042 pazienti di melanoma, dopo un tempo medio di follow-up pari a 7 anni, ha mostrato che la vitamina D bassa era significativamente associata ai peggiori fattori prognostici del melanoma (elevato spessore del tumore, tumore ulcerato e melanoma in stadio avanzato). Le stime di rischio provenienti dai modelli multiva-

TABELLA II.
Studi di coorte su 25OHD e sopravvivenza/mortalità per cancro in base alle sedi tumorali

Sede tumorale	Primo autore, PY	Paese	N. di soggetti	Valutazione di rischio (IC 95%)	Contrasti*
Melanoma	Fang, 2016			0,71 (0,55-0,93)	> 20 rispetto a < 20
Tratto aerodigestivo superiore	Gugatschka, 2011	Austria	88	0,89 (0,83-0,97)	> 10 rispetto a < 10
Gastrico	Ren, 2012 (NHANES)	Cina	197	0,59 (0,37-0,91)	> 50 rispetto a < 50
Testa e collo	Meyer, 2011	Canada	522	0,85 (0,57-1,28)	> 78 rispetto a < 48

PY: anno di pubblicazione; * ng/mL.

TABELLA III.
Sperimentazione clinica randomizzata (CRT) sulla vitamina D e sulla sopravvivenza/mortalità per cancro

Struttura dello studio	Sede tumorale	Primo autore, PY	Bracci	N. sperimentazioni	Endpoint	N. di decessi	HR (IC 95%)
RTC	Seno	Chlebowski, 2008	Vitamina D + calcio Placebo	1	Mortalità	46	0,99 (0,55-1,76)
Meta-analisi di RCT	Prostata	Shahvazi, 2019	Vitamina D rispetto a controllo	3	Sopravvivenza	477	1,05 (0,81-1,36)
RTC	Qualsiasi	Trivedi, 2003	Vitamina D Placebo	1	Mortalità	63	0,86 (0,61-1,20)
RTC	Qualsiasi	Wactawski-Wende, 2006; Brunner, 2011	Vitamina D + calcio Placebo	1	Mortalità	744	0,90 (0,77-1,05)
RTC	Qualsiasi	Avenell, 2011 (UFFICIALE)	Vitamina D Calcio Vitamina D + calcio Placebo	1	Mortalità	329	0,85 (0,68-1,06)
Meta-analisi di RCT	Qualsiasi	Keum, 2019	Vitamina D rispetto a controllo	5	Mortalità	1591	0,87 (0,79-0,96)

PY: anno di pubblicazione.

riabili hanno confermato un rischio significativamente ridotto di recidiva, un aumento della sopravvivenza complessiva e di quella relativa al melanoma per valori crescenti di 25(OH)D [7], tenendo conto dei marcatori di infiammazione.

SPERIMENTAZIONI CLINICHE RANDOMIZZATE

Alcuni RCT hanno indagato l'effetto dell'integrazione di vitamina D sulla mortalità per cancro e sulla sopravvivenza nei pazienti oncologici (Tab. III).

La collaborazione Cochran nel 2014 ha esaminato 18 sperimentazioni cliniche e ha dimostrato che la vitamina D_3 (colecalciferolo), somministrata da sola (senza calcio), è associata a una diminuzione della mortalità per cancro e della mortalità per qualsiasi causa, anche se sono state delineate delle limitazioni dovute alla bassa potenza statistica e al rischio di bassa aderenza al trattamento [8].

Una sperimentazione a livello nazionale, randomizzata, controllata tramite placebo (VITAL), con vitamina D_3 a un dosaggio di 2.000 IU/die, condotta su 25.871 partecipanti, non ha mostrato nel complesso nessun risultato su tutti i principali endpoint, come l'incidenza tumorale. Tuttavia, quando i primi 1-2 anni di follow-up sono stati esclusi per prendere in considerazione l'effetto latenza, è stata stimata una significativa diminuzione del rischio di morte per cancro nel braccio con vitamina D; rapporto di rischio (HR) = 0,75 (IC 95%: 0,59-0,96) [9].

Una sperimentazione randomizzata in doppio cieco su 155 pazienti con cancro al polmone, che hanno ricevuto integrazioni di vitamina D (1,200 IU/die) per 1 anno dopo l'intervento chirurgico o un placebo, non ha rilevato risultati nel complesso. Tuttavia, selezionando pazienti con adenocarcinoma in fase iniziale con basso 25(OH)D, l'integrazione di vitamina D si è dimostrata significativamente associata a ridotto rischio del 63% (HR = 0,37; IC 95%: 0,15-0,95) [10].

Una sperimentazione clinica randomizzata su 417 pazienti con cancro del tratto digestivo ha valutato l'effetto della vitamina D (2.000 IU/g), rispetto al placebo, sulla sopravvivenza senza recidiva (sperimentazione AMATERASU). Nel complesso non è stato rilevato nessun effetto, tuttavia nei pazienti con livelli sierici basali di 25(OH)D medi (tra 20 e 40 ng/mL), si è osservato che l'integrazione è associata ad una significativa diminuzione del rischio di recidiva (HR = 0,46; IC 95%, 0,24-0,86). Nessuna associazione è stata rilevata per i pazienti con 25OHD al di sotto di 20 ng/mL. La dose di vitamina D potrebbe essere stata insufficiente per aumentare i livelli di vitamina D in quel sottogruppo [11].

Lo studio SUNSHINE, una sperimentazione clinica randomizzata di fase 2 su 139 pazienti avanzati/metastatici con tumore del colon retto, ha valutato l'efficacia di un alto dosaggio di vitamina D_3 rispetto al dosaggio standard (+ chemioterapia standard): 8.000 IU/g per 14 giorni, in seguito 4.000 IU/die rispetto a 400 IU/g durante tutti i cicli. L'analisi multivariabile ha evidenziato un rischio di recidiva significativamente ridotto: HR = 0,64 (IC 95%: 0-0,90). L'effetto di un elevato dosaggio di vitamina D_3 sulla sopravvivenza senza progressione è apparso maggiore tra i pazienti con un IMC (indice di massa corporea) più basso, più sedi metastatiche e tumori KRAS di tipo normale (p = 0,04, p = 0,02 e p = 0,04 rispettivamente per l'interazione). Inoltre, la vitamina D era associata a una minore frequenza di episodi diarroici di grado 3 o superiore [12].

Nel 2019 una meta-analisi ha riassunto 5

sperimentazioni cliniche e ha incluso 1.591 decessi per cancro. I livelli di 25OHD raggiunti erano tra 54 e 135 nmol/l nel gruppo di intervento; la stima riassuntiva di rischio indicava una significativa riduzione del rischio di morte per cancro: SRR = 0,87 (IC 95%: 0,79-0,96), senza eterogeneità tra studi. Stranamente, l'effetto era in larga parte attribuibile a interventi con dosaggio giornaliero (in contrapposizione a un infrequente dosaggio in bolo). Non è stata osservata nessuna eterogeneità statisticamente significativa riguardo ai livelli raggiunti di 25(OH)D in circolo [13].

DISCUSSIONE

I risultati degli studi osservazionali costituiscono prove indicative della relazione tra vitamina D e sopravvivenza/mortalità al cancro, ma sono insufficienti per stabilire una causalità. I principali risultati delle RCT non hanno dimostrato, nel complesso, alcun effetto sulla mortalità/sopravvivenza al cancro, tuttavia le analisi di sottogruppo sono indicative e robuste a sufficienza per considerare che i RCT potrebbero non aver affrontato correttamente la questione. Sono state mosse diverse critiche relativamente alla validità delle conclusioni. Innanzitutto, i RCT includevano partecipanti allo studio senza riguardo al loro livello di 25(OH)D e potrebbero quindi aver mancato di individuare significativi effetti trattamentali in soggetti con carenza di vitamina D. Le dosi usate nella maggior parte delle sperimentazioni erano dosi ordinarie di integratori di vitamina D per quanto riguarda la prevenzione delle fratture, e non conosciamo la dose esatta che potrebbe essere efficace per la mortalità/sopravvivenza al cancro.

Un caso particolare è quello dei pazienti di melanoma. Dato che l'esposizione ai raggi ultravioletti è un fattore di rischio riconosciuto per il melanoma, un consiglio comune dopo la diagnosi di melanoma è di interrompere l'esposizione al sole. Pertanto, nel Regno Unito le linee guida per il melanoma raccomandano di controllare i livelli di vitamina D in tutti i pazienti di melanoma al momento della diagnosi e di proporre un'integrazione se necessario. Tuttavia, vi sono alcune perplessità riguardo al fatto che l'integrazione di vitamina D per via orale potrebbe non essere efficace quanto un'esposizione al sole limitata e controllata; in questo campo sono necessari ulteriori studi.

I soggetti obesi sono solitamente carenti di vitamina D a causa dell'"intrappolamento" del composto precursore della vitamina D, il colecalciferolo, nel tessuto adiposo. Oltre a ciò, l'obesità è associata in modo inverso all'attività fisica, la quale è associata in modo positivo al 25(OH)D nelle persone con IMC normale o in sovrappeso, ma non nelle persone con IMC obeso. L'associazione tra attività fisica e stato della vitamina D è stata spesso attribuita all'attività fisica come surrogato dell'esposizione al sole; tuttavia, nei pochi studi in cui entrambe le stime tenevano conto dell'esposizione al sole, la relazione attività fisica-vitamina D persisteva [14]. Si è anche ipotizzato che la capacità immunomodulante della vitamina D potrebbe fornire indicazioni per un'innovativa applicazione nei pazienti oncologici che ricevono un'immunoterapia, per rinforzare la risposta anti-tumorale e per prevenire e/o limitare l'insorgenza di eventi avversi sul piano immunitario [15].

Le risultanze delle RTC non consentono risposte definitive, ma fanno sorgere l'ipotesi che la terapia di combinazione sia necessaria per la sopravvivenza/mortalità dei pazienti oncologici. Nuovi RCT dovrebbero essere organizzati tenendo conto di questi aspetti, poiché abbiamo bisogno di maggiori informazioni sulle dosi di integrazione di vitamina D relativamente a ciascuna sede tumorale e a ciascuno stadio, e abbiamo bisogno di valutare i benefici nei pazienti con uno stato di bassa vitamina D alla diagnosi. Nuovi studi dovrebbero prendere in considerazione anche l'IMC e avere un buon follow-up di tutti i partecipanti, al fine di ridurre la bassa aderenza al trattamento o la perdita di informazioni al follow-up e inoltre di valutare l'effetto della vitamina D sulla tossicità della terapia oncologica.

Conflitto di interessi

L'Autore dichiara di non avere alcun conflitto di interessi

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