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EDITORIALE

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A causa di questa maledetta pandemia da SARS-Cov-2, che pare non finire mai, non potevamo esimerci da dedicare di nuovo un intero numero della Rivista a un aggiornamento in merito al possibile ruolo della carenza di vitamina D e della sua supplementazione sul rischio di COVID-19. Peraltro continua sul tema un'esuberante produzione scientifica, di entità tale da rendere necessaria una sezione dedicata della selezione bibliografica anche in questo numero.
Notate come i prestigiosi Autori a cui è stato affidato il compito di un update sui rapporti tra vitamina D, immunità e infiammazione e in particolare sul rischio di ammalarsi di COVID-19, giungano, seppur con motivazioni e argomenti a supporto in gran parte diversi, alle stesse conclusioni, onestamente prudenti:

- "Considerate la mole e l'importanza delle evidenze che si sono sin qui accumulate, diversi studi controllati, randomizzati, in doppio cieco sono in corso… È, quindi, francamente possibile che in tempo ragionevolmente breve possa giungere la conferma del ruolo della vitamina D e del colecalciferolo in particolare, come possibile farmaco che possa coadiuvare nella lotta contro la pandemia generata dal SARS-Cov-2";
- "Esistono numerosi segnali secondo i quali la vitamina D potrebbe esercitare un'efficace azione protettiva attraverso la modulazione della risposta immunologica, l'attenuazione della tempesta citochinica e della risposta infiammatoria, la conservazione dell'integrità della barriera epiteliale polmonare e l'azione antitrombotica… Non è tuttavia ancora disponibile un'evidenza conclusiva circa gli effetti della supplementazione nel paziente COVID-19, in quanto i risultati dei diversi studi osservazionali e dei pochi trial clinici oggi disponibili non sono univoci, pur manifestando nel complesso la tendenza a un effetto favorevole. Le discrepanze tra i diversi studi sono spiegabili in base… Resta dunque chiara la necessità di attendere i risultati degli ulteriori trial tuttora in corso…".

Alla luce di ciò, secondo me, appare comprensibile e condivisibile la seguente affermazione ribadita nella recente circolare del Ministero della Salute relativa alla gestione domiciliare dei pazienti con infezione da SARS-CoV-2, aggiornata al 26 aprile 2021 [1]: "Si segnala che non esistono, a oggi, evidenze solide e incontrovertibili (ovvero derivanti da studi clinici controllati) di efficacia di supplementi vitaminici e integratori alimentari (ad esempio vitamine, inclusa vitamina D, lattoferrina, quercitina)…".
Trovo invece che potrà prossimamente essere rivista… o meglio supportata… la

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conclusione a seguire: "… il cui utilizzo per questa indicazione non è, quindi, raccomandato". Capisco la preoccupazione del nostro Ministero di non promuovere presunti interventi protettivi, che non garantendo in realtà con certezza una protezione dal SARS-Cov-2, possono magari falsamente indurre comportamenti imprudenti che ignorano le note misure precauzionali per ridurre il rischio di infezione.
Credo tuttavia che la conclusione possa essere mal interpretata come raccomandazione al non uso. Io penso che si possa non raccomandare al non uso solo ciò che può comportare rischi per la salute o che ha evidenze solide e incontrovertibili di inefficacia: non mi pare che a oggi ciò valga per la supplementazione vitaminica D in soggetti carenti, considerati:

- il ruolo fisiologico immunomodulante della vitamina D, riconosciuto anche dall'Agenzia Italiana del Farmaco nel background della nota 96;
- il presunto coinvolgimento fisiopatologico;
- i risultati di numerosi studi osservazionali che indicano una possibile associazione tra ipovitaminosi D e rischio di infettarsi di SARS-Cov-2 o di ammalarsi seriamente di COVID-19;
- il forte razionale e la largamente condivisa esigenza di specifici trial clinici sulla supplementazione con vitamina D, come recentemente concluso anche in una review dedicata della Cochrane [2].

Tutto ciò mi pare generi perlomeno il ragionevole dubbio che non si possa oggi escludere per la vitamina D un contributo nella prevenzione del rischio di contrarre l'infezione COVID-19 e/o delle sue manifestazioni cliniche più severe.
Vi faccio inoltre notare che tra le Fake news del Ministero della Salute, al pari di quella ad esempio secondo la quale "applicare la vaselina o altre creme intorno alle narici, intrappola il virus così non entra nel naso"…, ritroviamo ancora quella pubblicata il 9 aprile 2020 [3] che afferma che "la vitamina D protegge dall'infezione da nuovo coronavirus". Allora quella classificazione come bufala poteva essere giustificata poiché quell'affermazione poteva generare pericolose illusioni, considerato che non vi erano all'epoca sufficienti evidenze scientifiche che la vitamina D potesse giocare un ruolo nella protezione, ma oggi ne siamo ancora sicuri? Non sarebbe saggio oggi escluderla dalle bufale in attesa dei risultati imminenti degli studi clinici controllati, perché ci sono attualmente numerose evidenze scientifiche indirette che inducono a ritenere che la vitamina D possa effettivamente giocare un ruolo nella protezione dall'infezione da nuovo coronavirus o nella prevenzione almeno di alcune sue gravi manifestazioni?
È vero anche che c'è un altro tema di interesse e di attualità non ancora abbastanza esplorato: il possibile effetto dello stato vitaminico D nei confronti della risposta al vaccino e ai diversi vaccini per la prevenzione del COVID-19 e nei confronti dei relativi eventuali effetti collaterali indesiderati.
Dopo aver letto i due articoli e la selezione bibliografica specifica di questo numero Voi cosa ne pensate?
Buona Lettura e statemi bene.

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La vitamina D nativa e la sua relazione con COVID-19

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INTRODUZIONE

Il primo caso di malattia severa da SARS-Cov-2 (*Severe Acute Respiratory Syndrome-CoronaVirus-2*), poi denominata COVID-19 (*CoronaVirus Disease-19*) è stato riportato nella città di Wuhan, Cina, nel gennaio 2020 [1]. Successivamente l'infezione virale e la malattia si sono diffuse rapidamente in molte aree geografiche del mondo e, nel marzo 2020, la malattia è stata riconosciuta come pandemia dall'Organizzazione Mondiale della Sanità (OMS) [2]. Alla data del 23 marzo 2021, nel mondo erano stati registrati poco meno di 125.000.000 di casi confermati dall'inizio della pandemia, con 2.727.837 decessi [3]. Come noto, in Italia e in larga parte del pianeta, l'infezione e la malattia sono state caratterizzate da ondate subentranti, anche in relazione alle misure di contenimento dei contagi adottate da vari Paesi (Fig. 1). I pazienti affetti da COVID-19 tipicamente presentano sintomi e segni di severa malattia respiratoria infettiva, aumento dei leucociti e dei parametri dell'infiammazione e frequente linfocitopenia [4]. Diviene solitamente evidente una polmonite interstiziale di gravità variabile. Una notevole parte dei soggetti con infezione da SARS-CoV-2 può, in realtà, rimanere asintomatica o sviluppare sintomi assai lievi. Al contrario, una parte non modesta di soggetti sviluppa una malattia così severa da necessitare di ospedalizzazione. Il 20% circa di questi soggetti dimostra condizioni respiratorie tali da richiedere il trasferimento in Unità di Terapia Intensiva (ICU) [5]. In questi soggetti, la mortalità può essere molto elevata, particolarmente in coloro che appartengono alle fasce di età più avanzate e presentano importanti comorbidità [6].

VITAMINA D E COVID-19: QUALE RELAZIONE?

A oggi, nessuna reale terapia è stata identificata per il trattamento dell'infezione da SARS-CoV-2 e, sebbene molti vaccini sembrino essere di promettente efficacia, la comunità scientifica guarda con grande attenzione a qualunque sostanza farmacologica in grado di rallentare la replicazione virale e/o migliorare il decorso della malattia [7]. L'attivazione del *pathway* di segnale del recettore della vitamina D (VDR) sembra generare effetti positivi nella sindrome da distress respiratorio acuto (ARDS) [8], inducendo una mitigazione della cosiddetta "tempesta citochinica", svolgendo così un importante ruolo immuno-modulatorio e antinfiammatorio [9]. Il possibile ruolo protettivo della supplementazione vitaminica D è supportato da numerosi studi osservazionali e da metanalisi di trial clinici concernenti la prevenzione delle infezioni virali respiratorie acute [10]. Uno stato vitaminico D insufficiente è stato proposto come fattore di rischio per le affezioni respiratorie acute, indotte da virus [11,12]. Uno stato vitaminico D compromesso è, peraltro, comune nel nostro come in molti altri Paesi [13]. Questo ha posto l'attenzione su una possibile relazione tra ipovitaminosi D, infezione da SARS-CoV-2 e COVID-19 [14,15]. Ilie et al. [16], analizzando i dati di 20 Paesi europei, hanno osservato una correlazione negativa ($r = -0,44$, $p = 0,05$) tra vitamina D sierica (56,8 ± 10,6 nmol/L) e il numero di casi di COVID-19 per milione di abitanti. Nello stesso studio, la mortalità da COVID-19 era maggiore nei soggetti con livelli bassi di vitamina D. Un andamento dose-risposta è stato evidenziato su una coorte > 190.000 pazienti nei quali l'infezione da SARS-CoV-2 era stata messa in relazione con i livelli sierici di vitamina D nei precedenti 12 mesi [17]. In questa coorte, veniva osservata una correlazione inversa tra livelli di vitamina D e positività per SARS-CoV-2. Inoltre, il tasso di positività al virus era decisamente più elevato nei 39.190 pazienti con vitamina D < 20 ng/mL (12,5%, IC 95%: 12,2-12,8%), rispetto ai 27.870 pazienti con valori sierici "adeguati" (30-34 ng/mL) (8,1%, IC 95%: 7,8-8,4%) e ai soggetti con livelli sierici > 55 ng/ml (5,9%, IC 95%: 5,5-6,4%). In un'analisi multivariata, coloro che avevano una vitamina D sierica < 20 ng/ml dimostravano un tasso di positività più elevato del 54% rispetto ai sog-

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L'Autore dichiara nessun conflitto di interessi.

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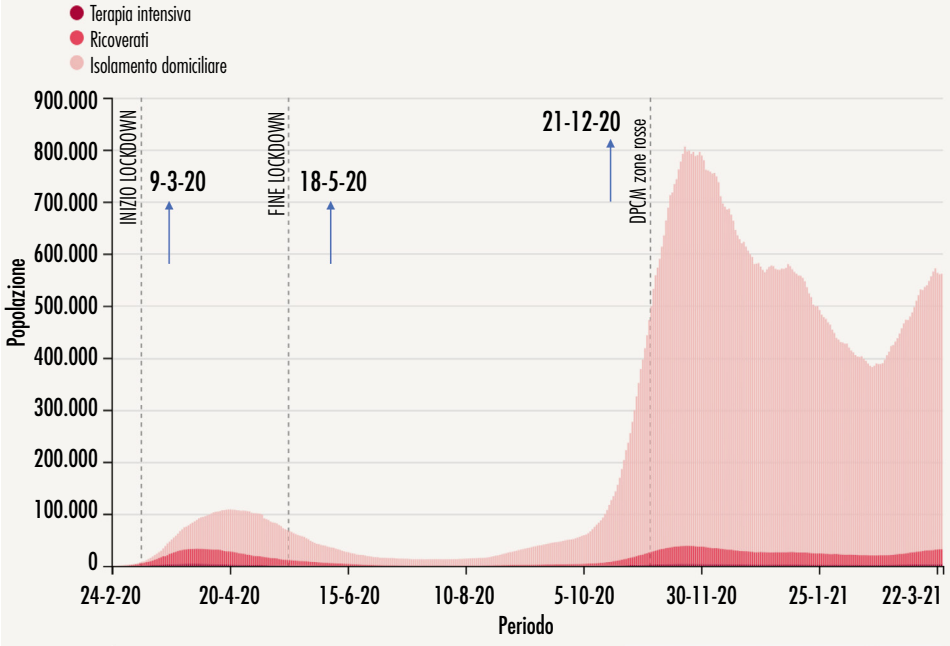
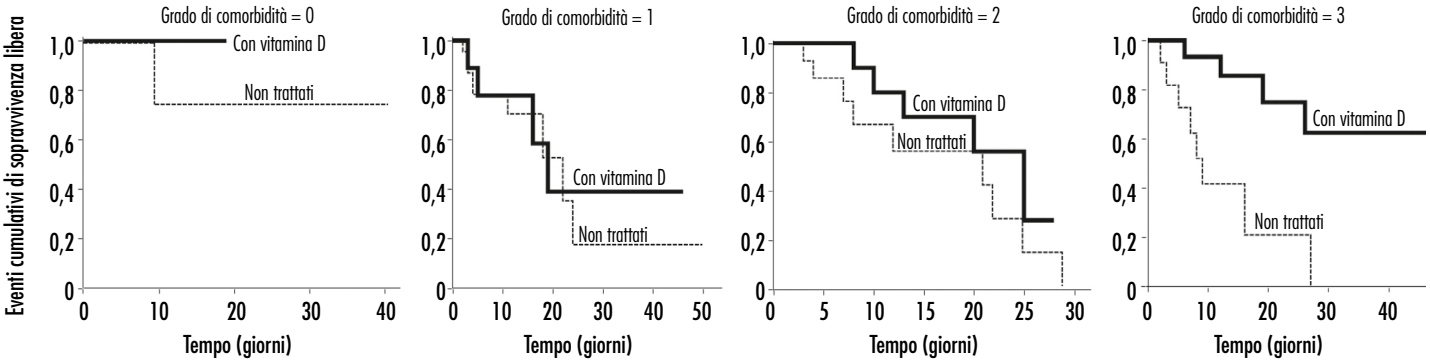


FIGURA 1.
Andamento della pandemia da SARS-CoV-2 in Italia (da https://lab24.ilsole24ore.com/coronavirus, mod).

getti con valori normali. Il rischio di contrarre il SARS-CoV-2 diminuiva progressivamente fino al raggiungimento di valori di 55 ng/ml. Molti altri studi hanno ulteriormente confermato la relazione tra ipovitaminosi D, infezione da SARS-CoV-2 e mortalità da COVID-19. Negli ultimi mesi, due studi Italiani hanno contribuito a rafforzare l'ipotesi di una relazione tra ipovitaminosi D e COVID-19. Uno studio retrospettivo su 137 pazienti, età media 65 anni, ricoverati per COVID-19, dimostrava una prevalenza di ipovitaminosi D del 100%. I soggetti che andavano incontro al decesso tuttavia, avevano valori sierici di vitamina D significativamente inferiori rispetto a coloro che sopravvivevano alla malattia (12 ng/mL *vs* 8 ng/mL, $p < 0,01$). In un'analisi di regressione logistica multivariata, i livelli di vitamina D correlavano inversamente con la mortalità intra-ospedaliera (OR = 0,91; IC 95%: 0,85-0,98; $p < 0,01$) [18]. In uno studio retrospettivo, condotto presso l'Università di Verona, su una coorte di 61 pazienti, età media 69 anni, ricoverati perché affetti da COVID-19, il 72,1% risultava vitamina D-deficiente (< 20 ng/mL) e il 57,4% aveva 25(OH)D sierica <15 ng/mL. I pazienti con insufficienza respiratoria (PaO2 < 60 mmHg) dimostravano valori di vitamina D più bassi rispetto ai soggetti con normale ossiemia (13,3 ng/mL *vs* 20,4 ng/mL, rispettivamente, $p = 0,03$). L'ipovitaminosi D si associava a un rischio 3 volte maggiore di ipossiemia e a un aumento della PCR e del grado di dispnea [19].

IL TRATTAMENTO CON VITAMINA D NEL COVID-19

Un aspetto realmente differente è se possa esserci un legame tra somministrazione di vitamina D e andamento clinico del COVID-19. In altri termini, se il colecalciferolo possa comportare effetti positivi sull'evoluzione del COVID-19.
Lo studio certamente più recente [20] non ha fornito risultati incoraggianti. Tuttavia, la coorte, pur ampia di soggetti considerati (240), aveva una età media piuttosto giovane (circa 56 anni) e la terapia con vitamina D (colecalciferolo), 200.000 UI, veniva somministrata oltre 10 giorni dopo l'inizio dei sintomi. La durata del ricovero costituiva l'outcome principale e non era diversa tra i soggetti in trattamento attivo e soggetti in placebo. La stessa era tuttavia di soli 7 giorni, indicando che i soggetti selezionati non dovevano presentare uno sviluppo di malattia particolarmente severo. Tra gli outcome secondari, non differivano tra i gruppi neppure mortalità o necessità di trasferimento in ICU. Tuttavia, ancora una volta, la mortalità di questi pazienti era nel complesso contenuta (intorno al 6%), così come la necessità di trasferimento in ICU, circa il 18% dei pazienti. Questi risultati erano del tutto analoghi anche in quella parte di soggetti inclusi nello studio che dimostravano valori sierici di vitamina D al basale < 20 ng/mL, che tuttavia erano la minoranza. Uno studio randomizzato controllato in doppio cieco [21] ha invece fornito risultati molto più incoraggianti. Soggetti con infezione da SARS-CoV-2 e con deficienza vitaminica D (< 20 ng/mL, valore medio circa 9 ng/mL), ricevevano oltre 400.000 UI in circa 7 giorni. I pazienti trattati con vitamina D nativa, rispetto a quelli con placebo, mostravano una più precoce negativizzazione dal virus e un calo significativo del fibrinogeno, uno dei potenziali marker di severità di malattia.
Uno studio inglese retrospettivo, condotto su pazienti ospedalizzati, anziani (età media 74 anni), ha poi dimostrato come una dose elevata di colecalciferolo (> 200.000 UI), era in grado di diminuire la mortalità in pazienti ricoverati per COVID-19 [22].
Annweiler et al. [23], in uno studio prospettico su soggetti molto anziani (88 ± 5 anni) e molto fragili, hanno suddiviso i 77 pazienti del lavoro in tre gruppi: Gruppo 1: pazienti COVID-19 ricoverati in Ospedale, ma che avevano ricevuto nell'anno precedente colecalciferolo a dosi comprese tra 50.000 UI al mese o fino a 100.0000 UI ogni 2-3 mesi; Gruppo 2: pazienti non in supplementazione stabile con vitamina D nativa, ma che dopo l'ingresso in ospedale a causa del COVID-19 avevano ricevuto 80.000 UI di colecalciferolo; Gruppo 3: pazienti con le medesime caratteristiche cliniche, ma che non avevano mai ricevuto vitamina D, né l'assumevano durante la degenza. L'outcome primario era costituito dalla mortalità durante la degenza e quello secondario dall'*Ordinal Scale for Clinical Improvement Score for COVID-19 in Acute Phase* (OSCI). Considerata la morbidità e la fragilità dei pazienti, una lunga serie di covariate venivano adoperate per confondimenti sull'esito delle analisi. Nel Gruppo 1, il 93% dei pazienti sopravviveva a 14 giorni, rispetto all'81% nel Gruppo 2 e al 68% nel Gruppo 3 ($p < 0,05$). Considerando il Gruppo 3 (non trattato) come riferimento, l'HR per mortalità a 14 giorni, ampiamente corretto per possibili fattori confondenti, era pari a 0,07 ($p < 0,05$) per il Gruppo 1 (trattati nell'anno prece-



Grado di comorbidità	Analisi dell'effetto di modificazione* (OR, IC 95% e valore p)	Analisi dell'effetto di modificazione aggiustato** (OR, IC 95% e valore p)
0	1,81 (0,45-7,27)	1,76 (0,44-7,06)
1	0,82 (0,35-1,93)	0,78 (0,32-1,90)
2	0,37 (0,19-0,72)	0,35 (0,17-0,73)
≥ 3	0,17 (0,06-0,46)	0,16 (0,05-0,46)
P come effetto di modificazione del grado di comorbidità	**0,02**	**0,02**

* Aggiustato per l'effetto principale del trattamento con vitamina D e il grado di comorbidità. ** Aggiustato per l'effetto principale del trattamento con vitamina D, grado di comorbidità e punteggio di propensione 2. OR: odds ratio; IC: intervallo di confidenza. Valore p < 0,05 in grassetto.

FIGURA 2.
Curve di Kaplan-Meier che evidenziano l'effetto di modificazione da parte del grado di comorbidità sull'efficacia del colecalciferolo sull'endpoint combinato "decesso/trasferimento in ICU" (da Giannini et al., 2021, mod.) [24].

dente il ricovero con colecalciferolo) e 0,37 (p ns) per il Gruppo 2, trattati solo durante il ricovero. Il Gruppo 1 si associava, inoltre, a un migliore OSCI rispetto al Gruppo 3 (p < 0,05). Gli autori concludevano per un effetto positivo della terapia con colecalciferolo, in grado di indurre un COVID-19 meno severo e di aumentare la sopravvivenza in anziani fragili.
Risultati del tutto simili sono, poi, venuti, da un nostro studio retrospettivo su 91 pazienti ricoverati per COVID-19, di età avanzata (74 anni), con rilevanti comorbidità e livelli basali di vitamina D assai ridotti (36 mmol/L, range interquartile 16-60) [24]. In 36 soggetti (39,6%) veniva somministrato colecalciferolo alla dose di 400.000 UI per os, suddiviso in due giorni consecutivi al momento del ricovero. I rimanenti 55 soggetti (60,4%) non erano stati trattati con vitamina D. Lo studio aveva l'obiettivo di valutare se la proporzione di pazienti che andavano incontro al trasferimento in ICU e/o al decesso potesse essere condizionata dall'assunzione di vitamina D. Durante un periodo di follow-up di 14 giorni circa, 27 (29,7%) pazienti venivano trasferiti in ICU e 22 (24,2%) andavano incontro al decesso. Nel complesso, 43 pazienti (47,3%) andavano incontro a "Decesso o trasferimento in ICU". L'analisi statistica rivelava che il "peso" delle comorbidità (rappresentate dalla storia di malattie cardiovascolari, broncopneumopatia cronica ostruttiva, insufficienza renale cronica, malattia neoplastica non in remissione, diabete mellito, malattie ematologiche e malattie endocrine) modificava in modo ampiamente significativo l'effetto protettivo della vitamina D sull'obiettivo dello studio, in modo tale che maggiore era il numero delle comorbidità presenti, più evidente era il beneficio indotto dalla vitamina D. In particolare, il rischio di andare incontro a "decesso/trasferimento in ICU" era ridotto di circa l'80% rispetto ai soggetti che non l'avevano assunta (OR = 0,18, IC 95%: 0,04-0,83, p < 0,05, dopo correzione per multipli fattori confondenti). L'analisi di Kaplan-Meier confermava appieno questo risultato (Fig. 2).
In conclusione, in pazienti anziani, molto comorbidi e affetti da COVID-19, il colecalciferolo riduceva in modo sensibile la mortalità e la severità della malattia.

CONCLUSIONI

Considerata la mole e l'importanza delle evidenze che si sono fin qui accumulate, diversi studi controllati, randomizzati, in doppio cieco (RCT) sono in corso per confermare l'importanza dell'uso della vitamina D in pazienti con COVID-19. Allo stato attuale, almeno 3 grossi RCT [25-27] sono in fase di avanzato svolgimento e almeno due di questi [25,26] si propongono con outcome molto robusti. È, quindi, francamente possibile che in tempo ragionevolmente breve possa giungere la conferma del ruolo della vitamina D e del colecalciferolo in particolare, come possibile farmaco che possa coadiuvare nella lotta contro la pandemia generata dal SARS-CoV-2, che ormai da molto tempo affligge la quasi totalità degli abitanti del nostro Pianeta, con conseguenze, ancora oggi, troppo spesso fatali.

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Vitamina D, immunità e infiammazione: l'esperienza della pandemia da SARS-CoV-2

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INTRODUZIONE

Il sistema biologico della vitamina D comprende metaboliti attivi, enzimi e recettori che danno luogo a effetti genomici e non genomici a livello sistemico. Oltre che impattare sulla salute e sulle proprietà del sistema muscolo-scheletrico, questo sistema si è dimostrato in grado di influenzare numerose funzioni fisiologiche a livello metabolico e cardiovascolare [1]. Già da tempo sono stati anche riconosciuti importanti effetti della vitamina D e dei suoi metaboliti sul sistema immunitario e sulle reazioni infiammatorie da questo dipendenti [2]. La recente esplosione della pandemia da COVID-19 ha visto impegnati numerosi centri di ricerca nel tentativo di evidenziare il possibile ruolo della vitamina D relativamente alla suscettibilità all'infezione, all'espressione clinica della malattia e al suo decorso clinico. Questa breve rassegna si propone di sintetizzare lo stato delle conoscenze riguardo il ruolo della vitamina D in relazione a immunità e infiammazione, con particolare attenzione a quanto abbiamo fin qui imparato in relazione al suo impatto sull'infezione da SARS-CoV-2, mentre, per mancanza di spazio, non ne sarà invece preso in considerazione l'impatto sulle patologie di tipo autoimmunitario.

VITAMINA D E RISPOSTA IMMUNITARIA ASPECIFICA (IMMUNITÀ NATURALE)

In corso di infezione, tutti gli elementi cellulari dell'immunità innata, in primis macrofagi e monociti, esprimono in misura rilevante il fattore CYP27B1, che converte la 25(OH)D in $1,25(OH)_2D$: quest'ultimo incrementa l'attività antimicrobica di macrofagi e monociti in modo autocrino attraverso il segnale VDR-RXR, che a sua volta stimola la produzione dell'agente antimicrobico catelicidina LL-37. Quest'ultima agisce contro i batteri e i miceti invasori, destabilizzandone la membrana plasmatica ed esercita un'attività antivirale diretta verso numerosi virus respiratori, distruggendone il rivestimento proteico e alterando la vitalità delle cellule bersaglio (Fig. 1). La produzione macrofagica di catelicidina LL-37 è tale che questa, lasciando l'ambiente cellulare, può anche influenzare la funzione dei linfociti circostanti [2]. L'$1,25(OH)_2D$ modula inoltre la differenziazione e la funzione delle cellule APC (*Antigen Presenting Cells*), in primis cellule dendritiche e macrofagi, rendendole più immature e immuno-tolleranti, la qual cosa si traduce in una riduzione della presentazione dell'antigene nonché della produzione dell'interleuchina infiammatoria IL-12 e viceversa un aumento della produzione di IL-10. L'$1,25(OH)_2D$ sopprime inoltre l'espressione dei recettori TLR (*Toll-Like Receptors*) sui monociti e inibisce la produzione di altre citochine infiammatorie, quali IL-2, IL-6 e IL-17. Studi sperimentali hanno inoltre suggerito che la differenziazione dei linfociti NK (*Natural Killer*) possa essere modulata dalla stessa $1,25(OH)_2D$ [3,4].

VITAMINA D E RISPOSTA IMMUNITARIA SPECIFICA (IMMUNITÀ ACQUISITA)

I linfociti T, una volta attivati, sono anch'essi in grado di esprimere il CYP27B1, e quindi la conversione di 25(OH)D a $1,25(OH)_2D$, nonché il recettore della vitamina D (VDR). D'altra parte, l'$1,25(OH)_2D$ prodotto da monociti e macrofagi è protagonista di un netto viraggio del sistema verso una condizione di maggiore tolleranza immunitaria, attraverso un'azione sulla proliferazione e la differenziazione degli stessi linfociti T, nel senso di una ridotta formazione di cellule T_H1 e T_H17 e un incremento di cellule T_H2. Ciò si associa a una ridotta espressione di citochine pro-infiammatorie e, viceversa, a un incremento nella produzione di citochine ad azione antagonista [2,5]. Altri meccanismi di modulazione della flogosi sono l'inibizione dell'espressione di COX-2 e la promozione della differenziazione delle cellule T regolatorie (*Treg*), sia direttamente che indi-

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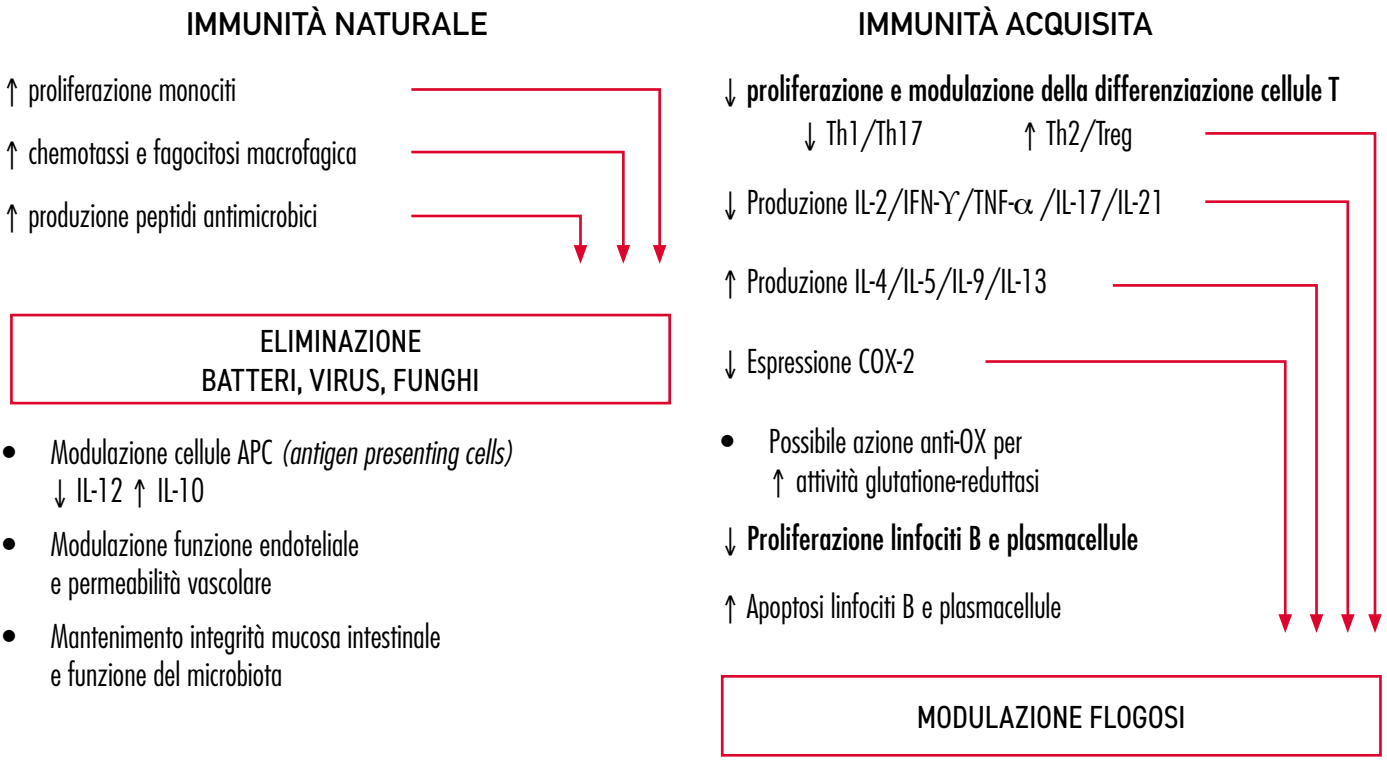

FIGURA 1.
Vitamina D e sistema immunitario. La figura sintetizza lo stato attuale delle conoscenze circa gli effetti principali della vitamina D sul sistema immunitario.

rettamente, attraverso l'interazione con le cellule APC [6]. L'1,25(OH)$_2$D eserciterebbe inoltre un'azione anti-ossidativa nei confronti dei monociti, incrementando l'attività della glutatione-reduttasi, con conseguente riduzione della formazione di radicali liberi dell'ossigeno [7] (Fig. 1).
È stato dimostrato che l'1,25(OH)$_2$D modula l'attività, oltre che dei linfociti T, anche dei linfociti B. In presenza di un'attivazione del sistema, l'1,25(OH)$_2$D riduce la formazione delle plasmacellule e induce apoptosi sia dei linfociti B attivati, che delle plasmacellule stesse. Inoltre, inibisce l'attivazione dei linfociti B mediata dalle citochine, agendo sui linfociti *T Helper*, e promuove direttamente la produzione di citochine antinfiammatorie IL-10 e CCR10 da parte dei linfociti B. Infine, sopprime la differenziazione dei linfociti B maturi in plasmacellule e cellule della memoria immunologica (*Memory B Cells*). Si ritiene che queste azioni possano ridurre la probabilità di risposte di tipo autoimmunitario spesso presenti nelle condizioni di risposta infiammatoria accentuata da un agente esterno [8].

VITAMINA D E INFEZIONI: LE EVIDENZE CLINICHE

In molti Paesi in via di sviluppo è ancora frequente una forma latente di tubercolosi caratterizzata dalla formazione di un granuloma che circoscrive il micobatterio nel tentativo di controllarne la proliferazione: allorché quest'azione di contenimento fallisce, il paziente diventa sintomatico e viene formulata la diagnosi di TBC attiva [9]. In questa condizione la vitamina D sembra giocare un ruolo importante nel combattere l'infezione grazie all'attivazione di macrofagi e monociti e alla produzione di catelicidina. Una metanalisi di 7 studi osservazionali ha mostrato che, in presenza di un deficit di vitamina D, la probabilità di contrarre la TBC è significativamente più alta [10]. Numerosi studi osservazionali hanno anche riportato l'associazione tra bassi livelli di vitamina D circolante e il rischio di sepsi, così come di aumentata morbidità, mortalità e permanenza in terapia intensiva da parte di pazienti settici: questa relazione potrebbe essere spiegata dall'effetto di modulazione da parte dell'1,25(OH)$_2$D sull'eccessiva espressione di citochine infiammatorie nel paziente critico e anche dalle azioni di tipo non-genomico sull'endotelio vasale orientate a contenere l'aumento della permeabilità vascolare, fattore importante nella patogenesi dello shock settico [2]. D'altra parte è anche possibile un meccanismo di *reverse-causality*, per il quale i bassi livelli di vitamina D circolante nella sepsi potrebbero essere invece spiegati dalla traslocazione extravascolare di *vitamin D binding protein* e da un incremento dell'attività della 25(OH)D-24 idrossilasi in relazione all'infiammazione sistemica. Purtroppo i trial clinici controllati condotti in corso di sepsi hanno fornito risultati eterogenei, pur se la maggioranza degli studi hanno riscontrato effetti positivi in termini di permanenza in terapia intensiva e di mortalità intra-ospedaliera [11].
Molti studi depongono a favore di un'associazione indipendente tra bassi livelli di vitamina D e incidenza o gravità delle infezioni del tratto respiratorio in bambini e adulti. I virus respiratori penetrano l'epitelio delle vie aeree e causano danno cellulare e tissutale, stimolando la risposta immunitaria con esito di infiammazione delle vie

respiratorie e, nei casi più severi, anche di sindrome da distress respiratorio acuto. L'1,25(OH)$_2$D esercita un'attività antivirale, favorendo la produzione di agenti antimicrobici, quali la catelicidina, modulando l'espressione dei recettori toll-like dei linfociti, così come la funzione delle cellule NK, e controllando l'eccessiva espressione di citochine pro-infiammatorie. Una recente metanalisi di 25 trial controllati e randomizzati ha dimostrato che la supplementazione di vitamina D_2 e D_3 protegge significativamente verso lo sviluppo di infezioni acute del tratto respiratorio in confronto con il placebo [12].

VITAMINA D E INFEZIONE DA SARS-CoV-2

Un'intensa reazione infiammatoria è l'elemento chiave dell'impegno polmonare nella patologia virale delle vie respiratorie. Sebbene la produzione di citochine pro-infiammatorie sia un fattore importante nella risposta all'infezione, una risposta infiammatoria intensa e prolungata è causa di danno tissutale e, nei casi più gravi, può condurre alla sindrome da stress respiratorio acuto e contribuire a un esito fatale. Questa sequenza di eventi è stata ben documentata per l'infezione da SARS-CoV-2 e ha condotto all'uso di farmaci idonei a placare la tempesta citochinica e a ridurre il livello di flogosi nei casi più gravi [13]. L'impatto accertato della vitamina D sulla risposta immunitaria in varie malattie dell'apparato respiratorio, quali la tubercolosi, l'influenza e altre patologie virali, è a supporto di un suo ruolo significativo anche nella risposta immune all'infezione da SARS-CoV-2, nella quale una risposta infiammatoria eccessiva è considerata un fattore responsabile di grave e, a volte irreversibile, danno polmonare, ma anche cardiaco, renale ed epatico nel decorso della malattia [14]. A ciò si aggiunge il fatto che il SARS-CoV-2 si lega al recettore dell'ACE2 (enzima di conversione dell'angiotensina) presente sulla superficie delle cellule epiteliali della mucosa respiratoria, delle cellule alveolari del polmone, delle cellule dell'endotelio vasale e dei macrofagi [15]. L'infezione da coronavirus deprime l'espressione del recettore ACE2, induce così un accumulo di angiotensina II a livello multiorgano, incrementando la tempesta citochinica [16]. Viceversa, la vitamina D promuove l'espressione del gene del recettore ACE2, oltre a ridurre l'espressione del gene della renina, modulando quindi complessivamente l'attività del sistema renina-angiotensina in senso inibitorio [17]. Infine, un ulteriore importante elemento patogenetico è dato dall'attivazione della cascata emocoagulativa con aumento dei valori circolanti di D-dimero e di fibrinogeno e fenomeni tromboembolici diffusi [18]. Meccanismo centrale degli eventi trombotici è la generazione di trombina mediata dalla liberazione massiva di *Tissue*

TABELLA I. Rassegna degli studi clinici su vitamina D e infezione da SARS-CoV-2.

Autore	Tipo di studio	Risultati essenziali
Ilie et al. Aging Clin Exp Res 2020	Ecologico	In un confronto tra Paesi europei: a) correlazione inversa tra livello medio di vitamina D circolante e numero di casi di COVID-19 per milione di abitanti ($r = -0,44$; $p = 0,050$); b) correlazione inversa tra livello medio di vitamina D circolante e numero di morti per COVID-19 ($r = -0,43$; $p = 0,050$)
Butler-Laporte et al. PLoS Med 2021	Randomizzazione mendeliana	In uno studio di randomizzazione mendeliana basato su oltre 14.000 casi di COVID-19 e circa 1.300.000 partecipanti senza la malattia, la predisposizione genetica a livelli più alti *vs* livelli più bassi di 25(OH)D non è risultata associata al rischio di malattia (OR = 0,95; IC 95%: 0,84, 1,08), di ospedalizzazione (OR = 1,09; IC 95%: 0,89, 1,33; p = 0,41) e di malattia grave (OR = 0,97; IC 95%: 0,77, 1,22; p = 0,77)
Petrelli et al. J Steroid Biochem Mol Biol 2020	Rassegna sistematica e metanalisi di studi osservazionali	Include 43 studi di tipo trasversale, caso-controllo e di coorte (retrospettivi o prospettici), con oltre 600.000 pazienti complessivi: suggerisce che la deficienza di vitamina D sia associata a una maggiore gravità della malattia da COVID-19 (OR = 2,6; IC 95%: 1,84-3,67; $p < 0,01$) e a una più elevata mortalità (OR = 1,22; IC 95%: 1,04-1,43; $p < 0,01$) rispetto a livelli normali. Qualità degli studi mediamente bassa, elevata eterogeneità e livello di bias elevato relativamente a criteri di selezione dei pazienti, valori soglia utilizzati e fattori di confondimento
Bassetne et al. Metab Clin Exp 2021	Rassegna sistematica e metanalisi di studi osservazionali	Rispetto all'altra rassegna sistematica ha preso in considerazione soltanto 31 studi in quanto pubblicati su riviste soggette a peer-review e ha rilevato a sua volta la tendenza a una più elevata mortalità e a un maggior rischio di ricovero in terapia intensiva e di necessità di ventilazione assistita per i pazienti con valori di 25(OH)D < 20 ng/mL rispetto a quelli con valori più alti: tuttavia questa tendenza non raggiungeva la significatività statistica, anche a causa del minor numero di studi disponibili per ciascun tipo di outcome e, peraltro, la qualità degli studi era generalmente bassa e il livello di eterogeneità cospicuo con elevato rischio di bias
Entrenas Castillo et al. J Steroid Biochem Mol Biol 2020	Trial clinico	Tra 76 pazienti ospedalizzati per COVID-19 (di cui solo 50 aveva ricevuto un trattamento che comprendeva calcifediolo), solo per 1 paziente trattato con calcifediolo è stato necessario il ricorso alla terapia intensiva contro la metà dei pazienti non trattati ($p < 0,001$)
Rastogi et al. J Postgrad Med 2020	Trial clinico	In un trial su pazienti COVID-19 con valori di 25(OH)D < 20 ng/mL, randomizzati a trattamento con colecalciferolo (n = 16) o placebo (n = 24), dopo 2 settimane il 62,5% dei trattati risultava negativo a SARS-CoV-2 *vs* 20,8% dei controlli. Nel primo gruppo si è avuta riduzione del fibrinogeno ma non di CRP, procalcitonina, ferritina e D-dimero sierici
Murai et al. JAMA 2021	Trial clinico	In un trial su 240 pazienti COVID-19, randomizzati per metà a una singola dose orale di 200.000 UI di vitamina D_3 e per l'altra metà a placebo, non sono state rilevate differenze nella durata del ricovero, ricorso alla terapia intensiva o alla ventilazione assistita e mortalità

Factor (TF) secondaria al danno vascolare infiammatorio. A tale riguardo, i metaboliti della vitamina D hanno mostrato la capacità di regolare la cascata emocoagulativa, riducendo l'espressione e l'attività del TF e, viceversa, aumentando l'espressione della trombomodulina (TM) [19].

All'evidenza degli studi di patologia clinica si aggiungono, purtroppo in direzione non univoca, i risultati della ricerca clinica ed epidemiologica. Uno studio ecologico condotto in 20 Paesi europei ha riportato una correlazione inversa tra il livello medio di vitamina D circolante in ciascun Paese e la rispettiva incidenza di COVID-19, così come tra livello medio di vitamina D e numero di morti da COVID-19 [20].
Sono state pubblicate due rassegne sistematiche e relative meta-analisi di studi osservazionali sulla relazione tra vitamina D e infezione da SARS-CoV-2: entrambe hanno incluso osservazioni trasversali (*cross-sectional*), confronti caso-controllo, studi di coorte retrospettivi o prospettici. La meta-analisi di Petrelli et al. ha incluso 43 studi con oltre 600.000 pazienti complessivi e ha suggerito che la deficienza di vitamina D sia associata a una maggiore gravità della malattia da COVID-19 (OR = 2,6; IC 95%: 1,84-3,67; p < 0,01) e a una più elevata mortalità (OR = 1,22; IC 95%: 1,04-1,43; p < 0,01) rispetto a livelli normali [21]. La seconda, di Bassatne et al., ha preso in considerazione soltanto 31 studi in quanto pubblicati su riviste soggette a peer-review e ha rilevato a sua volta la tendenza a una più elevata mortalità e a un maggior rischio di ricovero in terapia intensiva e di necessità di ventilazione assistita per i pazienti con valori di 25(OH)D < 20 ng/mL rispetto a quelli con valori più alti: tuttavia questa tendenza non raggiungeva la significatività statistica, anche a causa del minor numero di studi disponibili per ciascun tipo di outcome e, peraltro, la qualità degli studi era generalmente bassa e il livello di eterogeneità riscontrato nell'analisi molto elevato [22].
Sempre nell'ambito degli studi osservazionali, si è aggiunto recentemente uno studio di randomizzazione mendeliana che, contrapponendo soggetti con predisposizione genetica a valori plasmatici più bassi o più alti di 25(OH)D, non ha riscontrato differenze relativamente a suscettibilità a contrarre l'infezione da SARS-CoV-2, necessità di ricovero ospedaliero e severità della malattia [23]. Un limite importante di questo lavoro è però che esso non includeva soggetti con valori di 25(OH)D < 20 ng/mL.
Sono tre al momento i trial clinici completati e disponibili. Il primo, su 76 pazienti ospedalizzati per COVID-19, di cui 50 in trattamento con calcifediolo e 26 utilizzati come controlli, solo per 1 paziente trattato su 50 si è reso necessario il ricovero in terapia intensiva a confronto del 50% dei pazienti non trattati [24]. In un secondo piccolo trial in India di pazienti COVID-19 con valori di 25(OH)D < 20 ng/mL, randomizzati a trattamento con colecalciferolo (n = 16) o placebo (n = 24), dopo due settimane circa, due terzi dei partecipanti trattati risultavano negativi a SARS-CoV-2 *vs* circa un quinto dei controlli. Inoltre, nel gruppo in trattamento si sono ridotti i livelli plasmatici di fibrinogeno (ma non quelli di CRP, procalcitonina, ferritina e D-dimero) [25]. In un trial con 240 pazienti COVID-19 randomizzati per metà a una singola dose orale di 200.000 UI di vitamina D_3 e per l'altra metà a placebo, non sono state rilevate differenze nei diversi outcome clinici analizzati [26]. Tutti e tre i trial finora pubblicati presentano un rischio di bias significativo legato soprattutto ai metodi di selezione dei pazienti e alle modalità di randomizzazione.
In conclusione, l'evidenza fornita dagli studi sperimentali circa il ruolo fisiologico della vitamina D nella regolazione delle funzioni del sistema immunitario è ampia e robusta. Sembra inoltre accertato a livello clinico-epidemiologico il beneficio derivante dal mantenimento di adeguati livelli di vitamina D nella prevenzione delle infezioni acute delle vie respiratorie. Per quanto riguarda il paziente con infezione da SARS-CoV-2, esistono numerosi segnali secondo i quali la vitamina D potrebbe esercitare un'efficace azione protettiva attraverso la modulazione della risposta immunologica, l'attenuazione della tempesta citochinica e della risposta infiammatoria, la conservazione dell'integrità della barriera epiteliale polmonare e l'azione antitrombotica a sua volta correlata all'azione antinfiammatoria e di modulazione del sistema renina-angiotensina. Non è tuttavia ancora disponibile un'evidenza conclusiva circa gli effetti della supplementazione nel paziente COVID-19, in quanto i risultati dei diversi studi osservazionali e dei pochi trial clinici oggi disponibili non sono univoci, pur manifestando nel complesso la tendenza a un effetto favorevole. Le discrepanze tra i diversi studi sono spiegabili in base al contributo di numerosi fattori: le piccole dimensioni di molti degli studi condotti, l'eterogeneità nella selezione dei pazienti e nello stadio di malattia, le diversità nel cut-off utilizzato per definire la carenza di vitamina D ovvero nelle dosi e nelle modalità di somministrazione della vitamina, la possibilità che il livello di 25(OH)D circolante non rifletta la reale biodisponibilità della vitamina e dei suoi metaboliti nell'organismo e, ancora, la possibilità di un'ampia variabilità inter-individuale nella risposta alla supplementazione per effetto di fattori genetici e/o acquisiti (ad es. la presenza di obesità).
Resta dunque chiara la necessità di attendere i risultati degli ulteriori trial tuttora in corso [22], alcuni dei quali di notevoli dimensioni.

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