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EDITORIAL

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Dear Readers,

In this issue, we feature an update by Prof. Peroni on the role of vitamin D in pediatric patients as well as one by Prof. Triggiani on the effects of vitamin D in the prevention of cerebrovascular diseases.
Just think: only two years have passed since their previous contributions, and already we need updates!
In a balanced and objective manner, both authors admit that even though vitamin D has recognized biological effects, which go far beyond benefits to the skeletal system, studies that propose to assess the impact on the prevention or improvement of pathologies that are attributed to vitamin D deficiency are often contradictory, at least at present. Indeed, the results of clinical trials that are currently available have generally failed to show significant improvement in endpoints for the extra-skeletal system, for benefits in pediatric patients and for cerebrovascular diseases.
Nonetheless, both authors agree that this contradiction – between preclinical observations and associated observational studies, on the one hand, and the results of conducted trials, on the other – rather than casting doubt creates the premises for further research on the role of vitamin D in the prevention of extra-skeletal outcomes. They conclude that it is necessary to acquire new data to better assess optimal doses, the duration of supplementation, and optimal serum levels to attain positive biological and clinical results. In fact, current analysis of outcome data from the trials does not allow us to exclude the possible beneficial effect of vitamin D in extra-skeletal contexts. It is indeed possible to identify a fourfold order of factors responsible for negative results, as summarized in a recent publication of the Verona school [1]: a study population which did not show high risk for the evaluated event, the presence of co-factors that were not adequately assessed, a period of observation insufficiently long to evaluate the outcome, and pre-supplementation vitamin D levels that were not deficient, an essential requirement if we believe that vitamin D acts as a nutrient, in other words that it is useful only when it is missing.

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In addition, as was recently hypothesized by French colleagues, another intriguing explanation is also possible, namely the "autacoid paradigm". The term "autacoid" derives from the Greek *autos* (self) and *akos* (remedy). This system posits that molecules are produced and act locally, "upon request" at the intercellular or tissue level by means of autocrine or paracrine signaling.

As you know, at the level of circulation the endocrine system effectively aims to guarantee constant levels of $1,25(OH)_2D$ by means of refined regulation, in spite of the great variability of 25(OH)D levels due to the degree of exposure to sun or intake through food or supplementation, with the exception of conditions of great deficiency or extreme vitamin D overload. Nonetheless, an important form of vitamin D metabolism – by both the extra-hepatic 25-hydroxylase and the extra-renal 1α-hydroxylase enzymes – has been recently discovered, such as that at the skin and the adipose tissue levels and of the immune and nervous systems. In these various tissues, expression of these enzymatic activities and of vitamin D receptors indeed represent the "autacoid system". Contrary to the endocrine system, the autacoid system is inducible, as for example following inflammatory stimuli; it requires that local increase of $1,25(OH)_2D$ is transitory and self-limiting, thanks to the induction of deactivating 24-hydroxylase. The immunomodulatory functions of $1,25(OH)_2D$ are therefore temporally and spatially limited to the sources of inflammation and do not interfere with circulating serum levels of $1,25(OH)_2D$. It is clear that local synthesis of $1,25(OH)_2D$ requires that its precursors – 25(OH)D and especially cholecalciferol – are locally bioavailable: this depends both on their circulating levels and their tissue stocks.

This new paradigm – which is, then, quite different from what occurs in the endocrine system – in particular requires that the extra-skeletal effects of vitamin D also depend on the tissue reserves of vitamin D metabolites which are locally produced or inactivated. Given this paradigm, it should be clear that obtaining circulating levels of 25(OH)D in the systemic circulation is necessary but not sufficient, if at the tissue level adequate concentrations of active vitamin D metabolites are not obtained for some reason (insufficient induction? excessive catabolism? lack of cholecalciferol or of precursor metabolites?)

And yet, in present trials we evaluate only (and not even all the time!) circulating levels of 25(OH)D though not those of $1,25(OH)_2D$, let alone tissue concentrations, which are the functional ones, especially for extra-skeletal effects. You'll appreciate that this new paradigm, discovered a century after the endocrine system, opens the way to new and intriguing lines of research, such as the possibility that local administration of cholecalciferol or 25(OH)D may at times turn out to be a better option than oral supplementation in obtaining some extra-skeletal benefits. Might, for example, transcutaneous application of vitamin D at the breast level be more efficient than oral intake in preventing and treating breast cancer? Or might we even come to discourage covering the breasts to favor local cutaneous production of cholecalciferol?

What do you think?

I hope you enjoy reading this issue.

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UPDATE ON VITAMIN D IN PEDIATRIC PATIENTS

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INTRODUCTION

Vitamin D is essential for humans. In addition to its recognized roles in calcium and phosphorus metabolism and bone mineralization, vitamin D is also known for its activity at the extra-skeletal level, as many cells throughout the body express the vitamin D receptor and the 1α-hydroxylase enzyme. Extra-skeletal actions of vitamin D are significant in pediatric patients because they have an impact on the normal processes of a child's development, including those of the immune system, thus promoting good health.

In a review which I prepared in 2017, these were the conclusions I drew on vitamin D in pediatric patients:

- the action of vitamin D may have beneficial effects in the prevention and cure of chronic diseases;
- vitamin D can play a synergic role in the maintaining and developing a child's immune system;
- it is crucial to maintain normal vitamin D serum levels for clinical efficiency apart from those required for bone metabolism. Even if roughly one-third of the population of western countries, Italy included, has insufficient levels of vitamin D (serum levels < 20 ng/nL - 50 nmol/L), it has been suggested that efficient levels needed to sustain an appropriate response of the immune system should be higher (equal to or higher than 30-40 ng/m - 75-100 nmol/L) (Fig. 1).

Note that these statements are all hypothetical ("can", "it is possible", etc.). The aim is to establish the role of vitamin D in chronic diseases, a very controversial and debated topic for which we find contrasting and equivocal data in the literature. Observational studies in adults affected by various pathologic conditions have shown that these diseases are more severe in those subjects with low vitamin D levels. However, very often studies on vitamin D supplementation have produced negative and controversial results and have even provided documented evidence on the inefficiency of vitamin D supplementation in subjects with cardiovascular and oncological diseases. The Vitamin D and OmegA-3 TriaL (VITAL), which investigated whether taking supplements of vitamin D (2.000 IU/day) and omega-3 fatty acids (1 gram/day) would reduce the incidence of cancers or cardiovascular diseases over 5 years, showed that there was no difference between subjects taking the supplement and those taking the placebo. This study suggests a difference between association data compared to those obtained by supplementation [1,2].

The aim of this review is, first, to provide a reasoned update of what the literature tells us about the role of vitamin D in pediatric patients; second, to show that levels of dietary vitamin D intake are almost always insufficient at all ages [3]; and, third, to show that supplementation is the way to obtain adequate levels of vitamin D. It is yet not clear, though, whether achieving adequate levels of vitamin D is associated with a significant clinical improvement.

The recent *Nota 96*, issued by the Italian Medicine Agency (AIFA) to introduce new regulatory criteria on whether the National Health Service (SSN) will reimburse vitamin D costs for the adult population, does not apply to patients of pediatric age (0-18 years old). For these subjects, reimbursement of vitamin D continues to be completely covered by the SSN (*Nota 96, Gazzetta Ufficiale*, general series no. 252, 26 Oct. 2019). This regulation could be explained by the higher vulnerability of children with insufficient vitamin D status, a circumstance that necessitates greater elasticity in coverage criteria.

ACTION ON BONE TISSUE

Let me begin by discussing new developments with regard to bone metabolism. In pediatrics, it is necessary to consider the primary role played by vitamin D in bone mass formation immediately from birth. Vitamin D can

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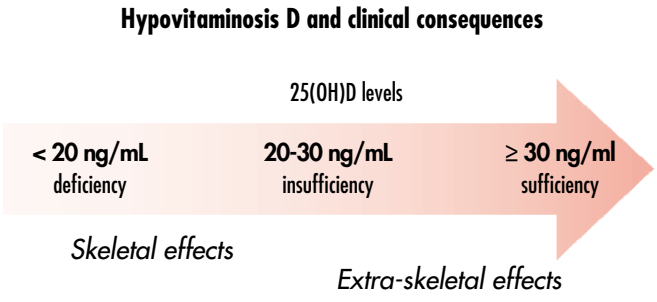

FIGURE 1.
Vitamin D values.

cause hypercalcemia that starts at the intestinal level, where it triggers calcium (Ca) and phosphorous (P) absorption, increasing the expression of Ca channels on the surface of enterocytes. Vitamin D deficiency is associated with an increase in parathormone (PTH), which in turn causes an increase in bone turnover and a reduction in bone density. This action favors the onset of both rickets during childhood and osteomalacia during adolescence and adulthood [4]. In this regard, an English article from 2018 warns about the increased incidence of cases of rickets where neonatal and infantile vitamin D supplementation is not mandatory [5]. Moreover, the increase in these cases in the UK is due to the fact that fortified dietary intake of vitamin D alone does not completely protect against significant vitamin D deficiency. This circumstance, associated with risk factors for hypovitaminosis, such as ethnicity, dark skin color, religious practices, and lifestyles, entails increased risks that need to be taken into account, leading these authors to urge changes to current preventive health policies [5].

VITAMIN D DURING PREGNANCY AND LACTATION

More and more scientific evidence indicates the importance of adequate levels of vitamin D during pregnancy and lactation, for mothers, fetuses, and newborns.
Nota 96, published by the AIFA in October 2019, introduced new regulatory criteria regarding reimbursement of vitamin D costs by the SSN for the adult population and officially recognized the importance of vitamin D during pregnancy and lactation, assuring the reimbursement of its costs by the SSN regardless of 25(OH)D level.
During pregnancy, vitamin D metabolism is modified in response to the increased Ca needs required for fetal skeletal mineralization, leading to an increase in 1,25(OH)2D levels in maternal plasma. Calcitriol plays a fundamental role in the modulation of calcium-phosphorus homeostasis in both the mother and the fetus, increasing intestinal Ca absorption [4]. The fetus is almost completely dependent on the mother for its 25(OH)D levels. In fact, maternal and fetal 25(OH)D levels are strictly related, as shown by the positive association between maternal 25(OH)D levels evaluated during pregnancy or near term and those in the fetal cord or the newborn. A high incidence of hypovitaminosis D in pregnant women is very common. An Italian study [4] evaluated 25(OH)D plasma levels in pregnant Italian women at term and found that roughly 60% had vitamin D plasma levels < 20 ng/mL.
Regarding breast feeding, maternal milk certainly represents the best food for the baby. However, as we know, it contains low quantities of vitamin D (< 50 IU/L), levels which are not in line with those recommended by the International Scientific Society for this age range (400 IU/day) (Table I). Furthermore, the literature has highlighted that vitamin D levels in maternal milk are directly related to those of the mother, with the same seasonal trends (high levels in summer, influenced by the mother's exposure to the sun) [6]. These results confirm the importance of promoting adequate levels of vitamin D not only in infants but also in mothers during the period of breastfeeding.
In this regard, a study showed that a mother who is breastfeeding has a fourfold higher risk of being vitamin D deficient compared to women who are not, especially during winter and spring [7].
In addition, women who breastfeed have a high risk of bone fragility fractures because of the loss of bone mass. During lactation, some hormonal variations, independent of calcium absorption, can cause the loss of about 5-10% of bone mineral content in order to ensure calcium intake in the mother's milk [8]. Indeed, women who breastfeed secrete about 210 mg of Ca/day into their milk and experience long periods of postpartum amenorrhea, during which plasma estrogen levels are drastically reduced. During breastfeeding, therefore, important metabolic changes occur at the maternal skeletal level, both because calcium is passed onto the baby and because of high bone turnover due to a drastic decrease of postpartum estrogens.

EXTRA-SKELETAL EFFECTS

In the last few years, many effects of vitamin D at the extra-skeletal level have been identified. Among these, an important role is played by the regulation of immune system response. For many years, it has been known that vitamin D carries out important functions on many cells of the innate and adaptive immune system: it produces defensins and cathelicidin, which contribute to providing children with immediate defenses; it provides dendritic cells (DC) with greater tolerance; it has an anti-inflammatory effect, suppressing Th lymphocytes and increasing the number of the regulatory T cells (TREG); it reduces the production of the pro inflammatory cytokines from Th1 lymphocytes; and it is able to regulate the intestinal barrier, which is still immature in the newborn, by increasing the development of epithelial cells, triggering the formation of tight-junctions, and developing immune system cells present in the intestine.

THE ROLE OF VITAMIN D IN INFECTIONS

Many studies have shown a relationship between vitamin D levels and respiratory infections. Specifically, a higher incidence of respiratory infections in children with rickets has been observed. Camargo et al. found a higher risk of respiratory infections at three months after birth for infants with vitamin D values < 10 ng/mL in their cord blood compared to those with values > 30ng/mL [9]. Belderbos et al. reached the same conclusions regarding a higher incidence of bronchiolitis in babies with vitamin D deficiency [10].

THE ROLE OF VITAMIN D IN WHEEZING AND ASTHMA

Regarding the prevention of these diseases, Danish studies showed that high doses of vitamin D starting from the 24th week of gestation were not associated with a reduction in the risk of asthma in children at 6 years of age [11]. On the other hand, other studies have observed a positive effect of vitamin D supplementation on pulmonary functionality in newborns. Many studies have shown that

TABLE I.
Treatment recommended by International Scientific Organizations for prevention and treatment of vitamin D deficiency.

	Prophylaxis with D_3 or D_2	Treatment with D_3 or D_2
0-12 months	400-1,000 IU/day regardless of type of feeding	2,000 IU/day for 6 weeks or 50,000 IU/week for 6 weeks < 1 month: 1,000 IU/day for 1-3 months 1-12 months: 1,000-3,000 IU/day (depending on weight) for 1-3 months
Preterm with net weight < 1,500 g	200-400 IU/day	
Preterm with net weight > 1,500 g	400-600 IU/day	
1-18 years	600-1,000 IU/day, at least during months with low exposure to sun; double or triple doses are recommended for patients with risk factors	2,000 IU/day for 6-8 weeks or 50,000 IU/week for 6-8 weeks
1-18 years with risk factors: obesity, liver pathology, malabsorption syndrome [inflammatory bowel disease (IBD), celiac disease, cystic fibrosis], treatment with anticonvulsants, corticosteroids, antiretroviral or antifungal medications	1,000-1,500 IU/day, at least during months with low exposure to sun	4,000-6,000 IU/day

vitamin D deficiency in pediatric patients is linked to a higher number of respiratory infections and therefore to more hospital visits, more hospitalizations, and greater use of oral cycles of corticosteroid therapy [12]. Other trials, such as the current DIVA study, will probably be able to clarify whether high doses of vitamin D supplementation can reduce the frequency of asthma exacerbations and lead to better control of the pathology [12]. DIVA is a multicentric, placebo-controlled Canadian study: preschool aged children affected by wheezing caused by viral infections will receive two high doses of vitamin D (100,000 IU) at an interval of two months, followed by a daily dose of 400 IU during the winter.
Currently available evidence shows that vitamin D supplementation decreased the risk of exacerbations (fewer systemic steroids and fewer visits to the ER) but was less effective in reducing the severity of the asthma [13]. According to a meta-analysis, the greatest benefit is achieved in patients with very low baseline 25(OH)D levels (< 10 ng/mL) and in those who followed therapy with daily or weekly doses of vitamin D [14]. However, these effects are less evident in children between 1 and 5 years of age, probably because the obstructive respiratory disease is characterized by different causes and a different physiopathology.

THE ROLE OF VITAMIN D IN AUTOIMMUNE DISEASES

Many studies have shown a correlation between hypovitaminosis D and the risk of developing such autoimmune diseases as diabetes mellitus type 1 (DM1), Crohn's disease and Rheumatoid Arthritis (RA). In fact, an adequate supply of vitamin D in the first years of life is associated with a reduction in the risk of developing DM1 in the following years. This reduced risk is directly proportional to the administered dosage of vitamin D [15, 16]. In particular, the protective effect was measured at 27% in the U.K. However, other studies did not find the same positive effects in terms of protection against the risk of developing these diseases, whether supplementation was given during pregnancy or during infancy. It should be noted, though, that very few controlled randomized studies have been conducted.
RA mainly increases in cases of hypovitaminosis D. However, results on vitamin D supplementation are still very controversial: supplementation could have an impact on the severity of the disease especially when vitamin D levels are low. Again, more studies need to be carried out in this field.

OBESITY AND METABOLIC SYNDROME

Available data show an association between obesity and hypovitaminosis D (insufficient levels > 50% in obese children). On the other hand, the biological effect of vitamin D deficiency on insulin resistance, hypertension, hyperlipidemia, and progression to Type 2 Diabetes is probably of little relevance, which could explain why results on vitamin D supplementation are mixed [3].

CONCLUSIONS

In conclusion, vitamin D has biological effects that go far beyond skeletal ones. While it is important to maintain adequate levels of vitamin D for healthy bone structure, the same recommendation may also apply to a variety of systems and organs.
However, intervention studies conducted to evaluate the effect on the prevention or improvement of pathologies attributed to vitamin D deficiency are often contradictory, at least for the moment. More research data need to be collected to determine the dosages, therapy duration and serum vitamin D levels which are optimal for obtaining positive clinical and biological outcomes.

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VITAMIN D IN THE PREVENTION OF CEREBROVASCULAR PATHOLOGIES: RESULTS OF NEW CLINICAL TRIALS IN LIGHT OF UNEXPECTED DEVELOPMENTS AND PROBABILITIES

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INTRODUCTION

Ischemic stroke is the main cause of long-term disability and the fourth cause of mortality globally. The World Health Organization (WHO) estimates that approximately 15 million new cases of stroke occur each year, of which 5 million have fatal outcomes and another 5 million produce serious and permanent disability, with significant social costs. It is believed that over the next few years aging populations and the reduction of mortality by stroke will lead to a progressively increasing prevalence of this pathology. Researchers have attempted to create validated systems of risk calculation: they aim to identify both high-risk patients in order to reduce the possibility of the onset of stroke and risk thresholds that make possible the implementation of effective preventive therapies [1,2].

Alongside the study of noted risk factors for cerebrovascular pathologies – hypertension, diabetes, dyslipidemia, smoking, and atrial fibrillation – in the last few years particular attention has been paid to identifying new potential risk factors, among which nutritional and dietary factors have become especially important.

Widely used in the prevention and treatment of bone pathologies [3], in recent years vitamin D has been introduced for the possible prevention of cerebrovascular diseases as well. For over a decade, sales of vitamin D in the U.S. have grown exponentially, making it one of the most commonly used supplements [4,5]. Its potential benefits have been upheld by ecological studies – both laboratory and observational – although these data have turned out to be inconsistent and insufficient to establish a causal connection [3,6,7]. Studies on the usefulness of vitamin D in preventing cerebrovascular diseases, conducted together with secondary or post hoc analyses, have largely produced invalid results. Indeed, all these studies were marred by several limitations: low dosages, inadequate type of study, short duration, and less than optimal verification of the endpoints [3]. No large-scale studies with significantly high doses of vitamin D have been carried out whose primary endpoint is the prevention of cerebrovascular diseases. For this reason, the Institute of Medicine [3] and the Preventive Services Task Force in the U.S. [8] have reached the conclusion that available data do not allow us to definitively verify the efficiency of the use of vitamin D for this purpose or to establish a risk-benefit relationship. The Institute of Medicine has asked the scientific community to undertake clinical trials with high doses of vitamin D (at least double the daily dose of 600-800 IU/day recommended for bone health) in different populations, including African Americans, who tend to have less cutaneous synthesis of vitamin D through exposure to sun with respect to other ethnic groups [9].

NEW CLINICAL TRIALS (TABLE 1)

The VITamin D and OmegA-3 TriaL (VITAL) was the first trial on a large scale [10,11]. Conducted in the U.S., this was a randomized, double-blind, placebo-controlled clinical trial which evaluated the risks and benefits

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of dietary supplementation of vitamin D_3 (2,000 IU/day) and omega-3 fatty acids (1 g/day of Omacor® fish oil capsules with 840 mg omega-3 fatty acids, comprising eicosapentaenoic acid [EPA, 460 mg] + docosahexaenoic acid [DHA, 380 mg]) for the primary prevention of cancer and of cerebrovascular diseases. It involved 25,871 men and women in the U.S., aged ≥ 50 and ≥ 55, respectively. The study design called for a similar number of men and women and a broad sample of African Americans. The study lasted 5.3 years. The results of VITAL showed that vitamin D does not cause a reduction of the co-primary endpoints of cerebrovascular pathologies (consisting of heart attack, cerebrovascular stroke, and mortality; HR = 0.97 [0.86-1.08]).

Nor does vitamin D reduce the specified secondary cardiovascular endpoints, which include a wide array of major cerebrovascular events in addition to coronary revascularization (HR = 0.96 [0.86-1.08]), heart attack (HR = 0.96 [0.78-1.19]), stroke (HR = 0.95 [0.76-1.20]) and cerebrovascular mortality (HR = 1.11 [0.88-1.40]), when taken individually. Vitamin D does not affect all causes of mortality (HR = 0.99 [0.87-1.12]). Similar results were seen in analyses which excluded the first or the first two years of follow-up exams or which eliminated non-compliance. No significant increases associated with the treatment were noted with regard to the risk of hypercalcemia, renal calculi, or gastrointestinal symptoms. Vitamin D does not influence one-year changes of lipid-related or inflammatory markers. The association between vitamin D and the risk of cerebrovascular endpoints or mortality for all causes did not differ significantly for race or ethnic group, cardiovascular risk factors, serum 25(OH)D levels, simultaneous randomization for omega-3 fatty acids, or other characteristics specified as potential modifying effects: vitamin D did not significantly reduce these endpoints in any subgroup.

The Vitamin D Assessment Study (ViDA) was a randomized, double-blind, placebo-controlled trial conducted in New Zealand [12]. The 5,110 participants were divided into two groups, the first (n = 2,558) receiving an initial dose of vitamin D of 200,000 IU, followed a month later by a monthly dose of 100,000 IU, and the second (n = 2,552) receiving a placebo, for a median duration of 3.3 years (range = 2.5-4.2 years). No significant percentage difference was observed in the range of the above-mentioned cerebrovascular events between the vitamin D (11.8%) and the placebo (11.5%) groups (HR = 1.02 [0.87-1.20]). Likewise, sub analysis for heart attack (RR = 0.90 [0.54-1.50]) and stroke (RR = 0.95 [0.55-1.62]) did not produce significant results. The same results were obtained in the subgroup of vitamin D deficient participants (HR = 1.00 [0.74-1.35]) and when participants were divided for previous vascular events. No difference was noted between the vitamin D and placebo groups at the time of the first vascular event or in the frequency of secondary, pathology-specific outcomes. Like the VITAL study, the ViDA trial showed that vitamin D does not reduce the risk of mortality for all causes.

The short duration of the study and the bolus administration of vitamin D (100,000 IU/month) represent important limitations of this trial.

The Women's Health Initiative (WHI) was a randomized double-blind trial with placebo which involved 36,282 postmenopausal women between the ages of 51 and 82 from 40 clinical centers in the U.S. [13] The participants were divided into two groups, the first receiving 1,000 mg of calcium carbonate + 400 IU of vitamin D_3/day and the second a placebo. The average follow-up period was 7 years. The results of this study for coronary heart disease (HR = 1.04 [0.92-1.18]), stroke (HR = 0.95 [0.82-1.10]), and death for vascular diseases (HR = 0.92 [0.77-1.10]) were not statistically significant.

The RECORD Trial (Randomized Placebo-Controlled Trial of Vitamin D_3 and/or Calcium) was a pragmatic, randomized, placebo-controlled and factorial design study of supplementation with calcium and/or vitamin D_3 for the secondary prevention of bone fragility fractures [14]. The research was conducted on 5,292 subjects with an average age of 77 years. The average duration of the follow-up exam was 6.2 years. Participants were vitamin D deficient at the start of the trial and were divided into four groups, which received vitamin D_3 (800 IU/day), calcium (1,000 mg/day), both, or a placebo. The main outcomes were death for all causes, death for vascular pathologies, death for neoplasms, and incidence of neoplasms. The hazard ratios for heart attack (HR = 0.97 [0.75-1.26]), stroke (HR = 1.06 [0.85-1.32]), and vascular mortality HR = 0.91 [0.79-1.05]) were not significant. A post hoc statistical analysis adjusted for compliance and which therefore had a lower number of participants showed accentuated trends for reduced mortality in the group treated with vitamin D and increased mortality in that taking calcium only, even if the overall results did not attain statistical significance.

Trivedi et al. conducted a study to determine the effect of vitamin D supplementation every four months on the fracture rate in men and women aged ≥ 65 years [15]. This randomized double-blind trial involved administration of 100,000 IU/die of vitamin D_3 or of a placebo every four months for a period of five years. Participants numbered 2,686 (2,037 men and 649 women) aged between 65 and 85 years. The hazard ratios for incidence of coronary disease (HR = 0.94 [0.77-1.15]), coronary mortality (HR = 0.84 [0.56-1.27]), incidence of cerebrovascular pathologies (HR = 0.90 [0.77-1.06]), and vascular mortality (HR = 0.84 [0.65-1.10]) did not reach statistically significant levels.

The Finnish Vitamin D Trial (FIND) for the primary prevention of neoplasms and cerebrovascular pathologies, lasting five years, saw the participation of 2,495 subjects (men aged ≥ 60 years and women ≥ 65 years) [16]. Participants were divided into three groups, which received 1,600 or 3,200 IU/day of vitamin D or a placebo. Initially, researchers planned to involve 18,000 participants, but the study group was later reduced because of recruiting difficulties and funding limitations. The primary outcomes included incidence of neoplasms and vascular pathologies. The results of the trial were expected for June 2018 but have not been published yet.

At present, the VITAL trial is the only one that was conducted on a broad population sample and whose primary endpoints were cancer and cerebrovascular pathologies. Indeed, the other two studies conducted on a vast scale – the Australian D-Health [17] and the British Vitamin D and Longevity (VIDAL) [18] trials – which planned to involve 25,000 and 20,000 participants, respectively, posit total deaths and incidence of neoplasms as their endpoints. Only the D-Health study is studying the incidence of cerebrovascular pathologies: results of this trial are expected in 2021.

A recent meta-analysis of vitamin D trials [19], which also included the VITAL and ViDA studies, showed that vitamin D does

TABLE I. New clinical trials.

Trial	Sample	Age range	Duration (years)	Vit. D dose	Outcomes
Vitamin D and Omega-3 Trial (VITAL), USA	25.875	≥ 50 men ≥ 55 women	5	2.000 UI/day	Neoplasms, vascular pathologies
Vitamin D Assessment Study (ViDA), New Zealand	5.110	50-84	3.3 (median)	100.000 UI/month	Vascular pathologies
Women's Health Initiative (WHI)	36.282	51-82	7 (average)	400 UI/die	Femur fractures, other fractures, colorectal cancer, total mortality and by cause
Randomized Placebo-Controlled Trial of Vitamin D_3 and/or Calcium (RECORD)	5.292	77 (average)	6.2 (average)	800 UI/day	Total mortality, by vascular cause and by neoplasms, incidence of neoplasms
Trivedi et al.	2.686	65-85	5	100.000 UI every 4 months	Incidence of fractures, total mortality
Finnish Vitamin D Trial (FIND), Finland	2.495	≥ 60 men ≥ 65 women	5	1.600 UI/day or 3.200 UI/day	Neoplasms, vascular pathologies
D-Health, Australia	21.315	60-84	5	60.000 UI/month	Total mortality, neoplasms
Vitamin D and Longevity (VIDAL), UK	20.000	65-84	5	100.000 UI/month	Total mortality, neoplasms

not reduce the risk of major adverse cardiovascular events (10 trials, 6,243 events, 79,111 participants; RR = 1.00 [0.95-1.06]), of heart attack (18 trials, 2,550 events, 82,576 participants; RR = 1.00 [0.93-1.08]), of stroke (15 trials, 2,354 events, 82,239 participants; RR = 1.06 [0.98-1.15]), or of cardiovascular mortality (10 trials, 2,202 events, 76,783 participants; RR = 0.98 [0.90-1.07]).

CONCLUSIONS

The results of in vitro and in vivo experimental studies suggest that $1,25(OH)_2D$ inhibits the proliferation of vascular smooth muscle cells and vascular calcification, has a beneficial impact on the homeostasis of blood volume and pressure by regulating the renin-angiotensin-aldosterone system, reduces inflammation, and improves insulin sensitivity [20-23]. In prospective observational studies, 25(OH)D levels are inversely correlated to risk factors and to cerebrovascular events [24-26]. Nonetheless, the results of currently available clinical trials have generally failed to demonstrate significant improvement in endpoints of preventing vascular pathologies. This contradiction in the results, however, rather than casting a shadow over the matter, provides the premises for further study on the role of vitamin D in preventing cerebrovascular pathologies. Indeed, analysis of outcome data from the trials does not allow us to definitively exclude the possible beneficial effect of vitamin in the prevention of cerebrovascular diseases. It is possible to identify a threefold order of factors responsible for the negative results: study populations which did not show high cerebrovascular risk, which were not vitamin D deficient, and which had co-factors that were not adequately assessed.

For these reasons, it is necessary to identify populations with vascular risk factors which could effectively benefit from vitamin D. It is possible to hypothesize that protective levels of vitamin D for vascular pathologies are lower than those for other pathologies, such as neoplasms. It is quite probable that in clinical trials whose principal endpoints are the incidence of neoplasms and vascular conditions patients already had a protective base level of vitamin D for these pathologies. In this light, it would be necessary to focus attention on population subgroups with high cerebrovascular risk and severe vitamin D deficiency (≤ 10 ng/mL).

Rather than a single risk factor, vitamin D deficiency should be considered from the point of view of a complex nutritional alteration which causes some dysfunction – at the endothelial level – of the homeostasis of blood circulation and coagulation as well as of glucose and lipid metabolism, with the resulting possibility of an increase in the risk for major vascular diseases.

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