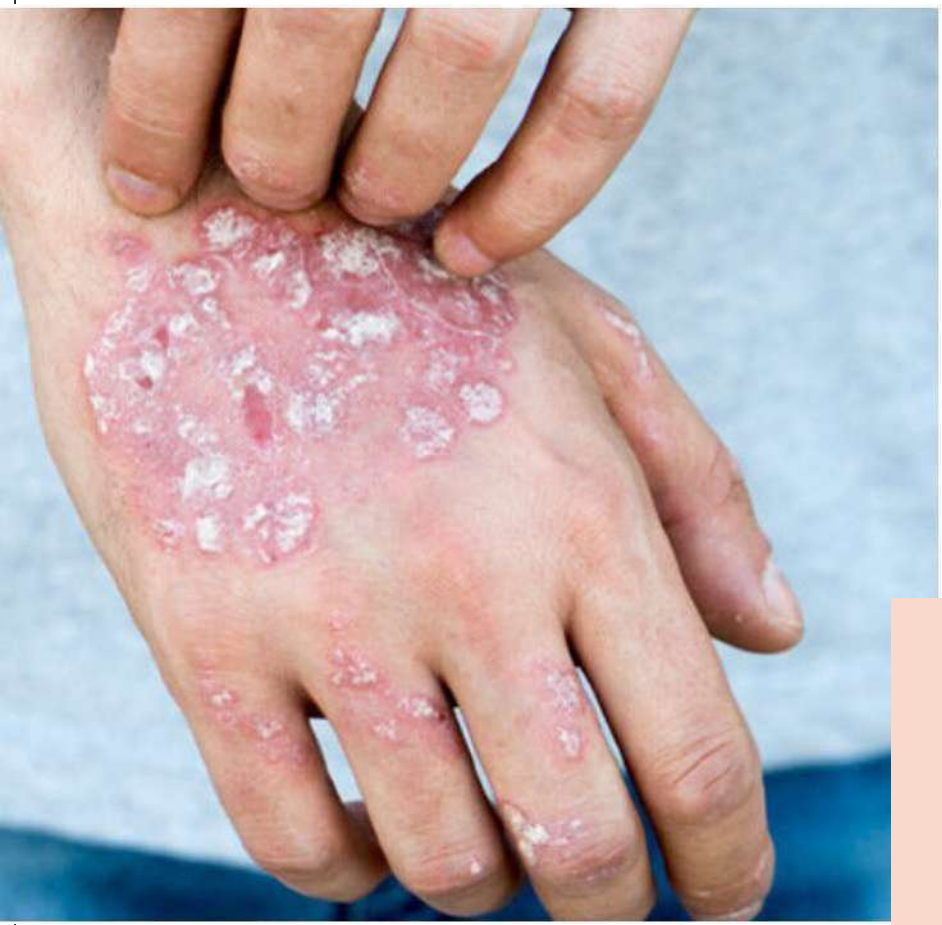
DAILY ORAL D3 IN PSORIASIS



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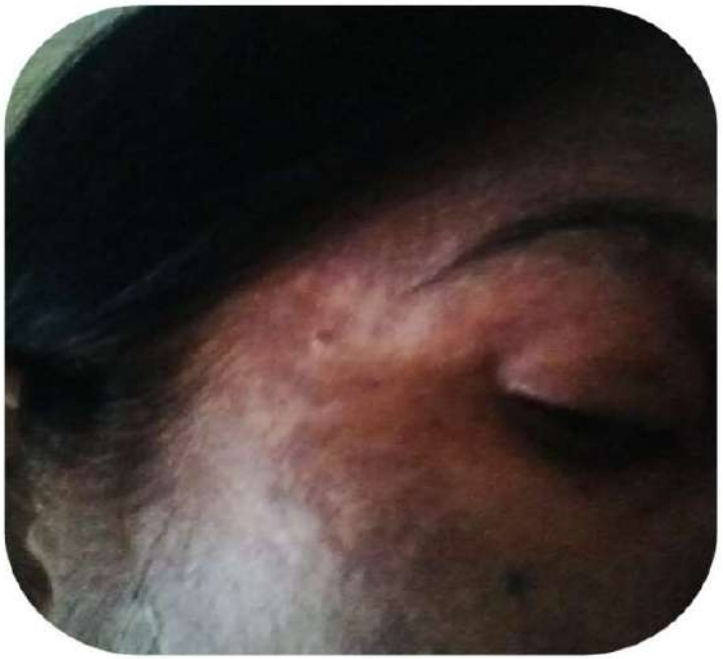

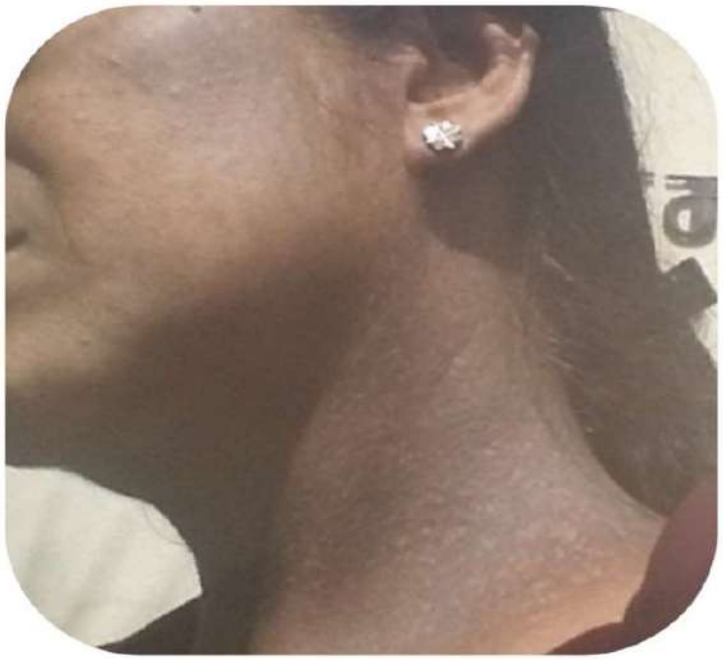

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Prof. Dr. Cícero Galli Coimbra

MD, PHD Neurologist, Internal medicine
Federal University of São Paulo, Brazil

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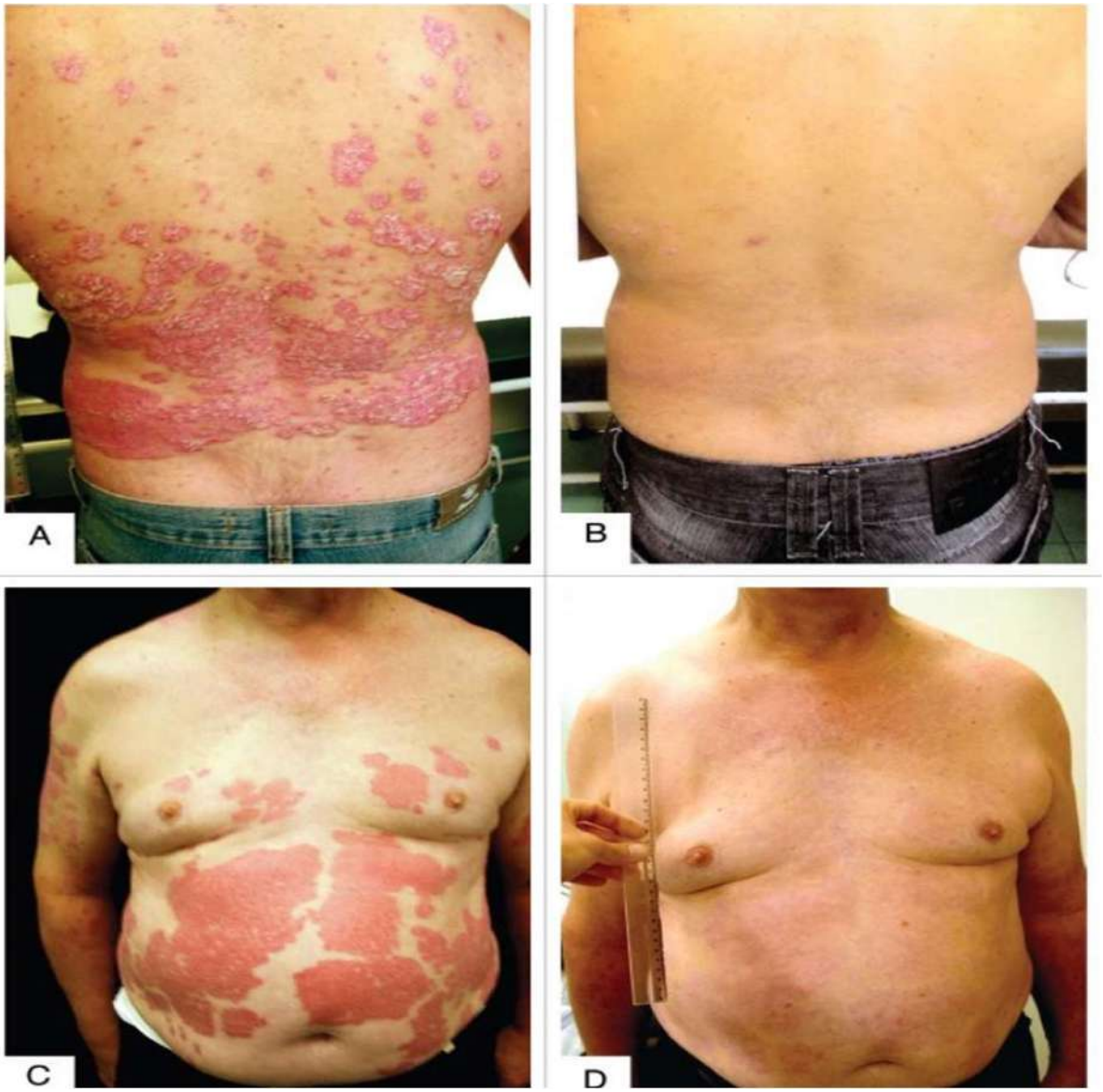
Psoriasis



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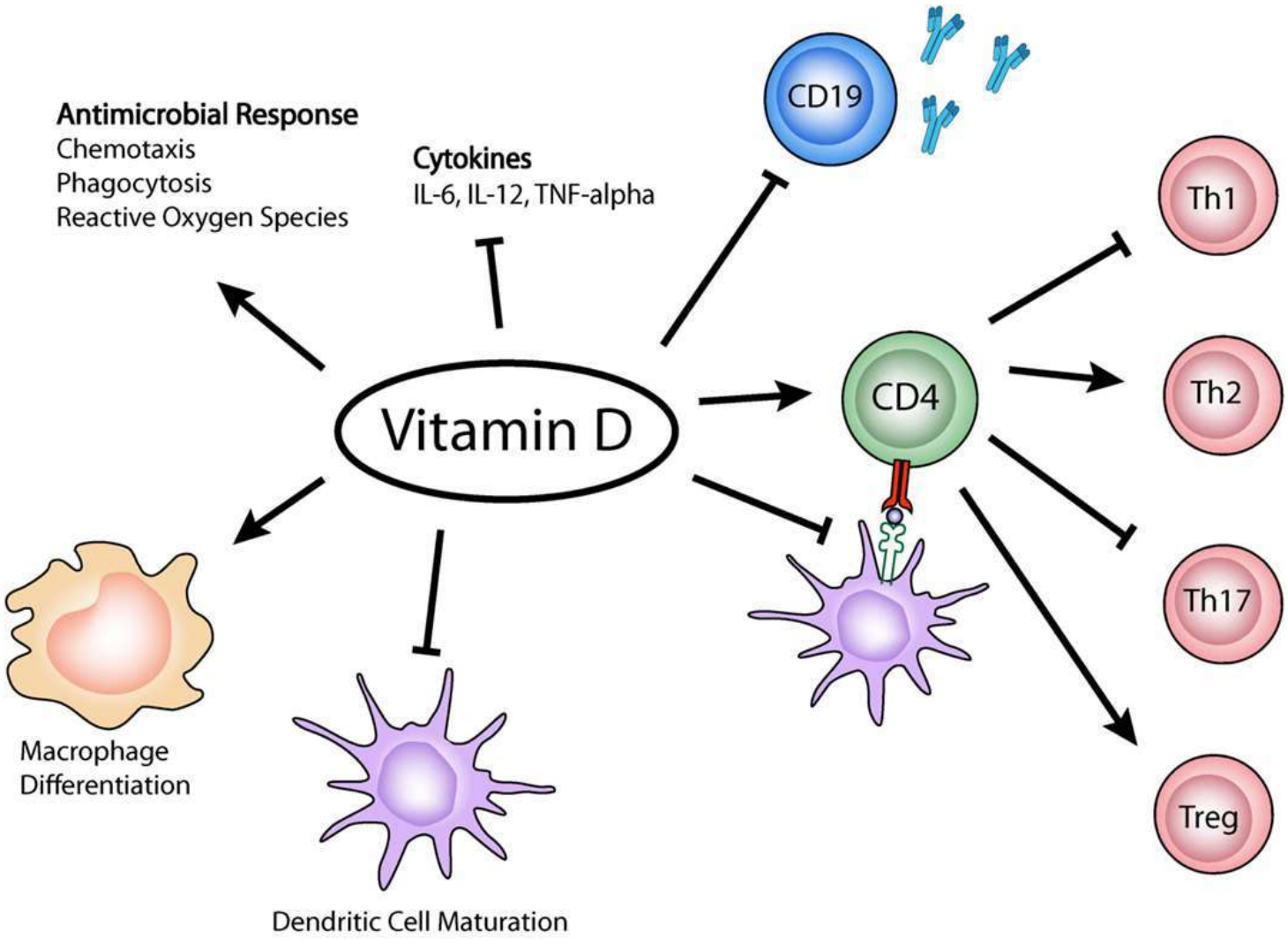
Vitamin D as Immune-modulator



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Vitamin D on Adaptive Immune Response

Vitamin D - **powerful regulator** of the immune system modulates this process by -

- **Promotes a timely shift from Th1 to Th2** cell immune profile (Cell-mediated to Antibody-mediated immunity)
- It **suppresses the Th17 reaction** caused by over production of the 'immune messenger' cytokine called interleukin 17
- It **facilitates differentiation of the T regulatory cells** that balance the immune response.

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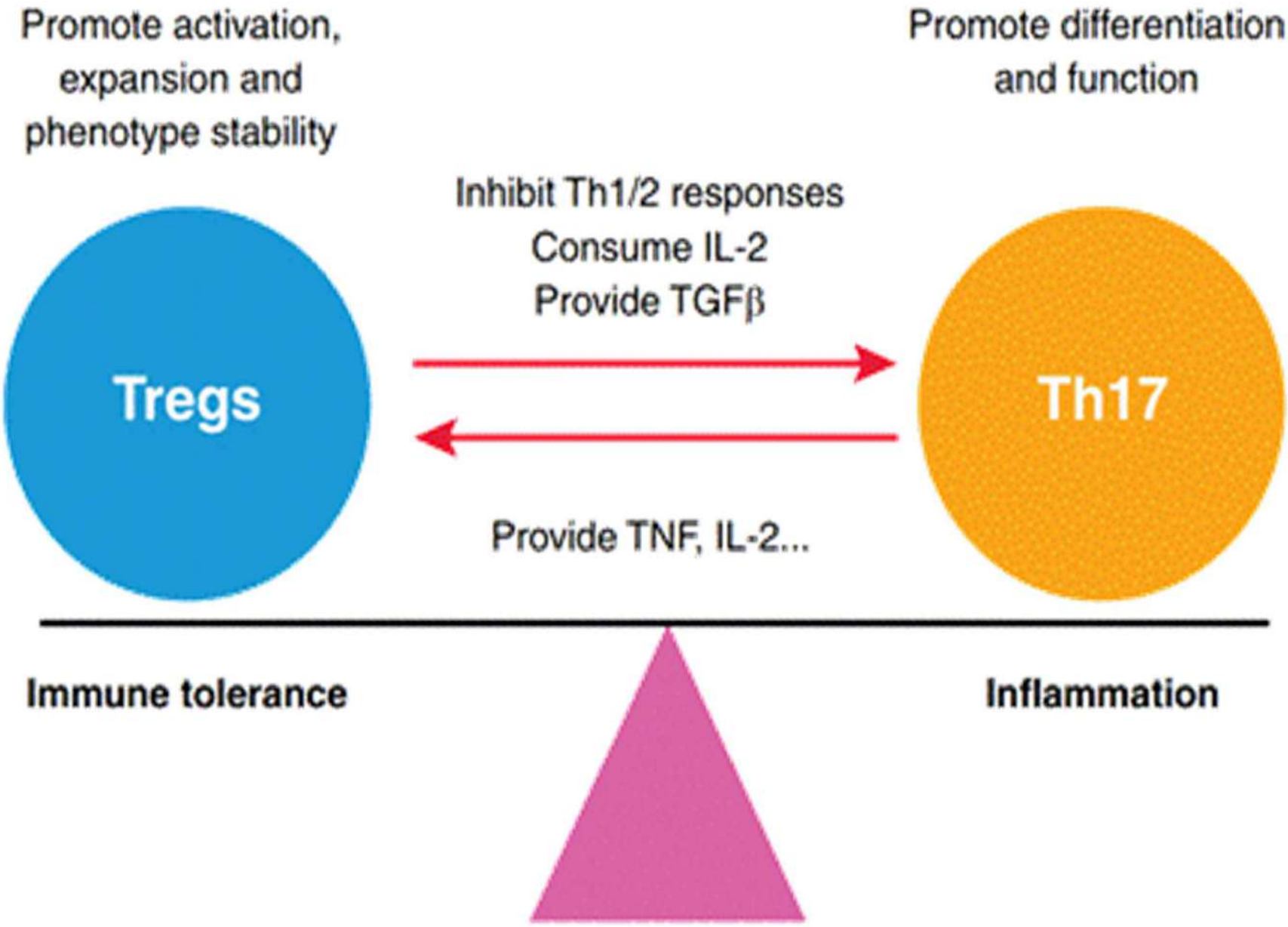

Vitamin D Receptor Polymorphism is Associated with Psoriasis

Byung-Soon Park, Jeong-Soo Park,* Dong-Youn Lee, Jai-Il Youn, and In-Gyu Kim*

Departments of Dermatology and *Biochemistry and Molecular Biology, Seoul National University College of Medicine, Seoul, Korea

Vitamin D receptor is a trans-acting transcriptional factor that mediates 1α,25-dihydroxyvitamin D_3 action in the regulation of target gene expression. Recent studies have shown that clinical response of psoriasis to 1α,25-dihydroxyvitamin D_3 is correlated with the vitamin D receptor mRNA expression level, which may be influenced by the genotype of the vitamin D receptor. In this study, we have explored a possible association between psoriasis and the polymorphism in the gene encoding the vitamin D receptor. We examined the allelic frequencies of the vitamin D receptor in psoriasis patients (n = 104) and in healthy controls (n = 104) by analyzing the restriction pattern of the polymerase chain reaction products. A significant increase in the frequency of the A allele (absence of the restriction site at intron 8) by *Apa*I restriction fragment length polymorphism was observed in psoriasis patients compared with that of the control group, and the tendency was more accentuated in early onset psoriasis. Odds ratios (95% confidence interval) for psoriasis of AA and Aa genotypes were 5.0 (1.3–19.1) and 2.4 (1.3–4.3), and odds ratios for early onset of AA and Aa genotypes were 6.4 (1.6–25.0) and 3.1 (1.7–5.9), respectively. Allele frequencies for A and a alleles were 0.317 and 0.683 in the psoriasis group and 0.168 and 0.832 in the control group ($p = 0.001$). A significant association between vitamin D receptor genotypes and the mean age at onset was observed ($p < 0.05$). Our findings suggest that allelic variance in the vitamin D receptor gene itself or other genes in linkage disequilibrium with this gene, could predispose to the development of psoriasis. *J Invest Dermatol 112:113–116, 1999*

frontiers in Immunology

HYPOTHESIS AND THEORY
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Vitamin D Resistance

Vitamin D Resistance as a Possible Cause of Autoimmune Diseases: A Hypothesis Confirmed by a Therapeutic High-Dose Vitamin D Protocol

OPEN ACCESS

Edited by:
Kutty Selva Nandakumar,
Southern Medical University, China

Reviewed by:
Carsten Carlberg,
University of Eastern Finland, Finland

Dirk Lemke[1*‡], *Rainer Johannes Klement*[2*†‡], *Felix Schweiger*[3], *Beatrix Schweiger*[3] *and Jörg Spitz*[4]

[1] *Praxis Dr. Beatrix Schweiger, Bensheim, Germany,* [2] *Department of Radiotherapy and Radiation Oncology, Leopoldina Hospital Schweinfurt, Schweinfurt, Germany,* [3] *Praxis Dr. Beatrix Schweiger, Waldkirch, Germany,* [4] *Akademie für menschliche Medizin und evolutionäre Gesundheit, Schlangenbad, Germany*

ABNORMAL VITAMIN D METABOLISM

Vitamin D deficiency and/or Resistance

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Coimbra Protocol

- **Vitamin D** has a potent **immune regulatory** role
- Autoimmunity is found to be associated with **resistance to effects of vitamin D due to genetic polymorphism**
- To compensate for the resistance to its effects-
  - **Higher levels of Vitamin D needed**
  - **Has to be taken on daily basis**
- Individual requirement of Vitamin D varies based on the **degree** of vitamin D resistance
  - Vit D & PTH (Parathyroid Hormone)
  - Ionised Calcium
-

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Dermato-Endocrinology 5:1, 222–234; January/February/March 2013; © 2013 Landes Bioscience

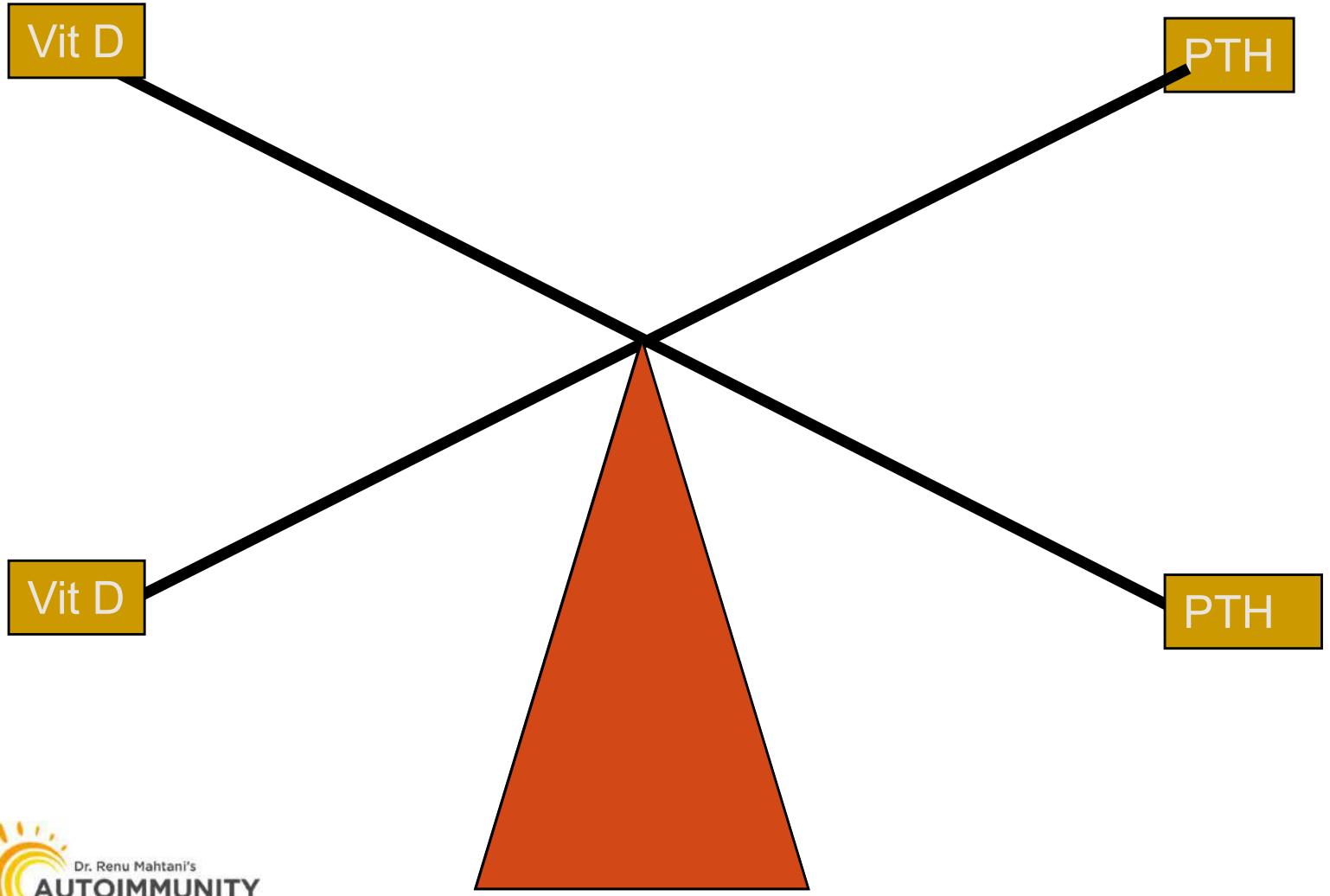
A pilot study assessing the effect of prolonged administration of high daily doses of vitamin D on the clinical course of vitiligo and psoriasis

Danilo C. Finamor,[1] Rita Sinigaglia-Coimbra,[1] Luiz C.M. Neves,[2] Marcia Gutierrez,[3] Jeferson J. Silva,[1] Lucas D. Torres,[1] Fernanda Surano,[1] Domingos J. Neto,[5] Neil F. Novo,[6] Yara Juliano,[6] Antonio C. Lopes[4] and Cicero Galli Coimbra[1,*]

[1]Laboratório de Fisiopatologia Clínica e Experimental; Universidade Federal de São Paulo; São Paulo, Brazil; [2]Instituto de Ciências da Saúde; Universidade Paulista; São Paulo, Brazil; [3]Farmácia Sensitiva; São Paulo, Brazil; [4]Disciplina de Clínica Médica; Universidade Federal de São Paulo; São Paulo, Brazil; [5]Hospital Heliópolis; São Paulo, Brazil; [6]Disciplina de Cirurgia Plástica; Universidade Federal de São Paulo; São Paulo, Brazil

Autoimmunity has been associated with vitamin D deficiency and resistance, with gene polymorphisms related to vitamin D metabolism frequently described in affected patients. High doses of vitamin D3 may conceivably compensate for inherited resistance to its biological effects. This study aimed to assess the efficacy and safety of prolonged high-dose vitamin D3 treatment of patients with psoriasis and vitiligo. Nine patients with psoriasis and 16 patients with vitiligo received vitamin D3 35,000 IU once daily for six months in association with a low-calcium diet (avoiding dairy products and calcium-enriched foods like oat, rice or soya "milk") and hydration (minimum 2.5 L daily). All psoriasis patients were scored according to "Psoriasis Area and Severity Index" (PASI) at baseline and after treatment. Evaluation of clinical response of vitiligo patients required a quartile grading scale. All patients presented low vitamin D status (serum 25(OH) D3 ≤ 30 ng/mL) at baseline. After treatment 25(OH)D3 levels significantly increased (from 14.9 ± 7.4 to 106.3 ± 31.9 ng/mL and from 18.4 ± 8.9 to 132.5 ± 37.0 ng/mL) and PTH levels significantly decreased (from 57.8 ± 16.7 to 28.9 ± 8.2 pg/mL and from 55.3 ± 25.0 to 25.4 ± 10.7 pg/mL) in patients with psoriasis and vitiligo respectively. PTH and 25(OH)D3 serum concentrations correlated inversely. The PASI score significantly improved in all nine patients with psoriasis. Fourteen of 16 patients with vitiligo had 25–75% repigmentation. Serum urea, creatinine and calcium (total and ionized) did not change and urinary calcium excretion increased within the normal range. High-dose vitamin D3 therapy may be effective and safe for vitiligo and psoriasis patients.

Individual tailoring of doses based on the extent of PTH inhibition



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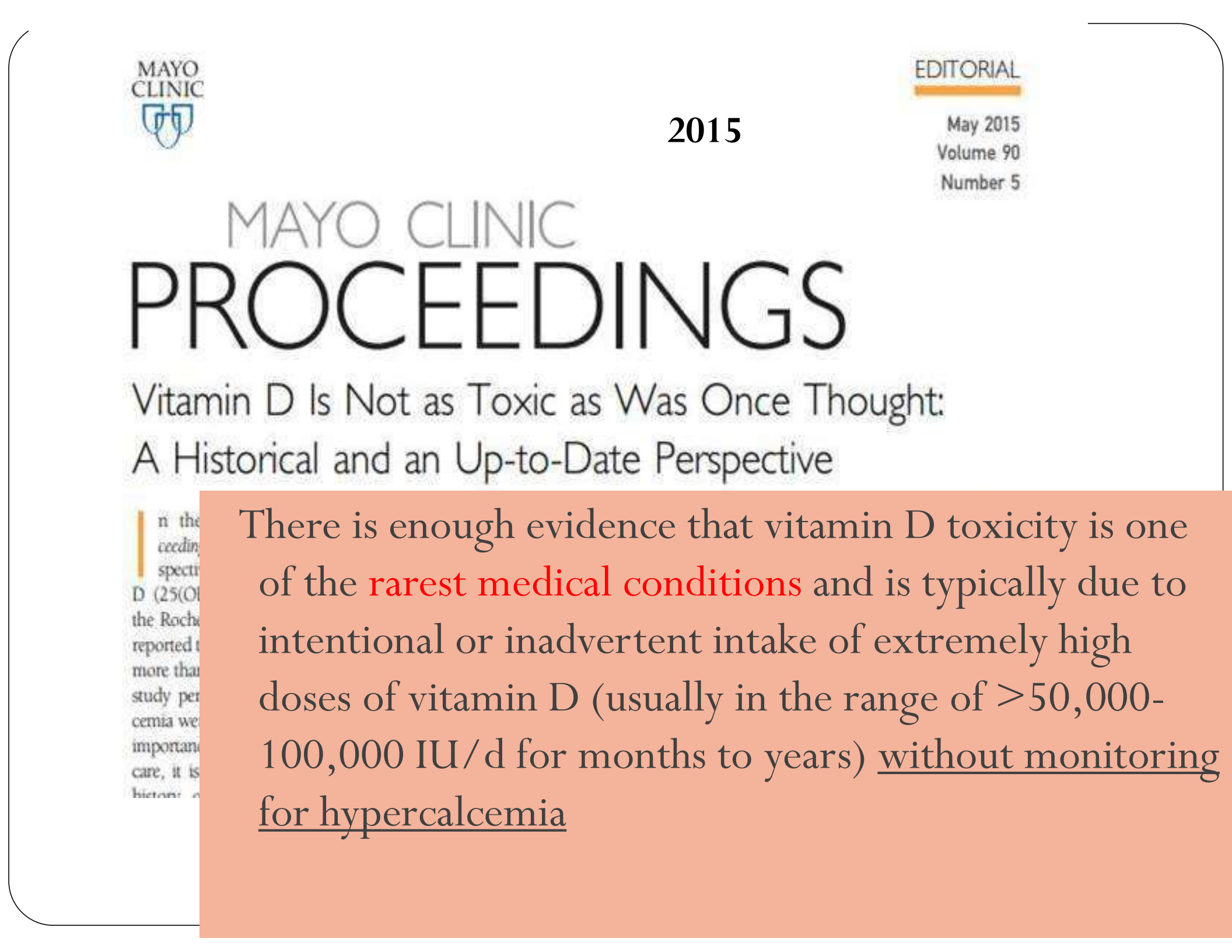
PTH suppression by Vitamin D: Index of vitamin D utilisation

- How much vitamin D is used by the body is important rather than how much is supplemented
- If PTH levels are not dropping – the body is not making proper use of vitamin D due to Vit D resistance
- Shows the individual level of Vitamin D resistance

PTH level monitoring

- Within the reference range but not yet at the lowest value – vit D dose can be increased
- At the lowest value but still within the reference range – maintain the same dose of vit D
- Dropped to below the normal lowest reference value – vit D dose should be reduced



2015

There is enough evidence that vitamin D toxicity is one of the rarest medical conditions and is typically due to intentional or inadvertent intake of extremely high doses of vitamin D (usually in the range of >50,000-100,000 IU/d for months to years) without monitoring for hypercalcemia

Micronutrients to improve efficacy of vitamin D and dose reduction

- Vital Minerals
  - Magnesium
  - Selenium
  - Zinc
- Riboflavin B2
- Methyl-cobalamin - B12
- Omega 3 Fatty Acid

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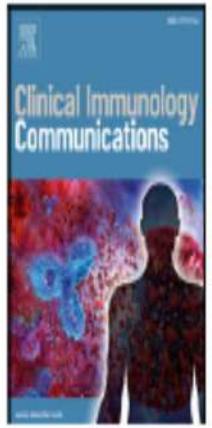


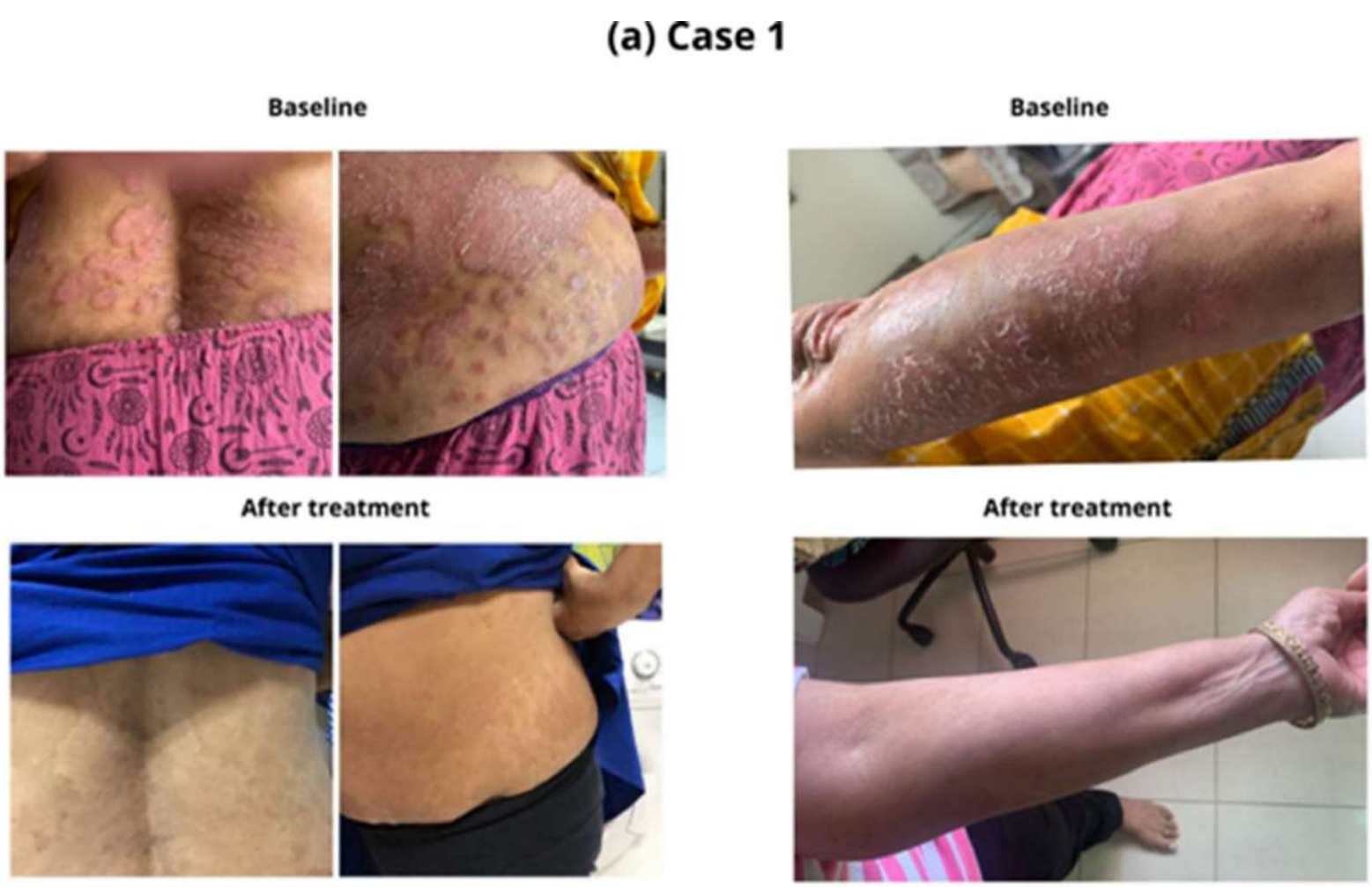
Daily oral vitamin D3 without concomitant therapy in the management of psoriasis: A case series

Renu Mahtani[a], Pradeep M.K. Nair[b,*]

[a] Dr. Renu Mahtani's Param Health - Autoimmunity Treatment Centre, Pune, India
[b] Sant Hirdaram Medical College of Naturopathy & Yogic Sciences, Sant Hirdaram Nagar, Bhopal 462020, India

- The role of vitamin D3 as an immune-modulator, especially in autoimmune disorders has been evidenced.
- The genetic polymorphisms of the vitamin D receptors have been found to induce a high level of vitamin D resistance in autoimmune diseases warranting higher doses of vitamin D to combat this resistance and achieve meaningful clinical effects.
- Monitoring parathyroid hormone levels in the serum can be used as the best biological indicator to estimate the optimal therapeutic doses of vitamin D3 in treating psoriasis
- Studies suggest that Vitamin D3 concentrations in serum lower than 300 ng/mL do not induce any toxicity
- Calcium restricted diet and monitoring for hypercalcemia is mandatory

- 6 cases of psoriasis were treated with daily oral Vitamin D3 (cholecalciferol) in doses ranging from 30,000 IU to 60,000 IU over a period of 2 to 6 months and then followed by lower daily maintenance dose.
- The dose of vitamin D3 was adjusted based on the drop in the level of parathyroid hormone as the ionized calcium levels were also periodically monitored to prevent hypercalcemia.
- Significant control of psoriasis was observed within a span of 2–6 months, which was measured by Psoriasis Area and Severity Index (PASI) and a symptom Visual analog scale.



5 min D level 11 ng/ml, PTH value of 66 pg/ml. After the loading dose of 60000 IU of Vitamin D3 she was put on 30000 IU of Vitamin D3 daily for 2 months. The PTH levels reduced to 37.5 pg/ml indicating vitamin D3 response and significant clinical improvement was also noticed. Therefore, the vitamin D3 dose was reduced to 25000 IU per day. The ionized calcium was 4.26 mg/dL indicating normocalcemia. By three months, the patient presented with complete control of the disease (PASI= 0.4) with no itching (VAS=0) The patient is currently on a maintenance dose of 20000 IU per day with PTH and ionized Calcium levels well in range.

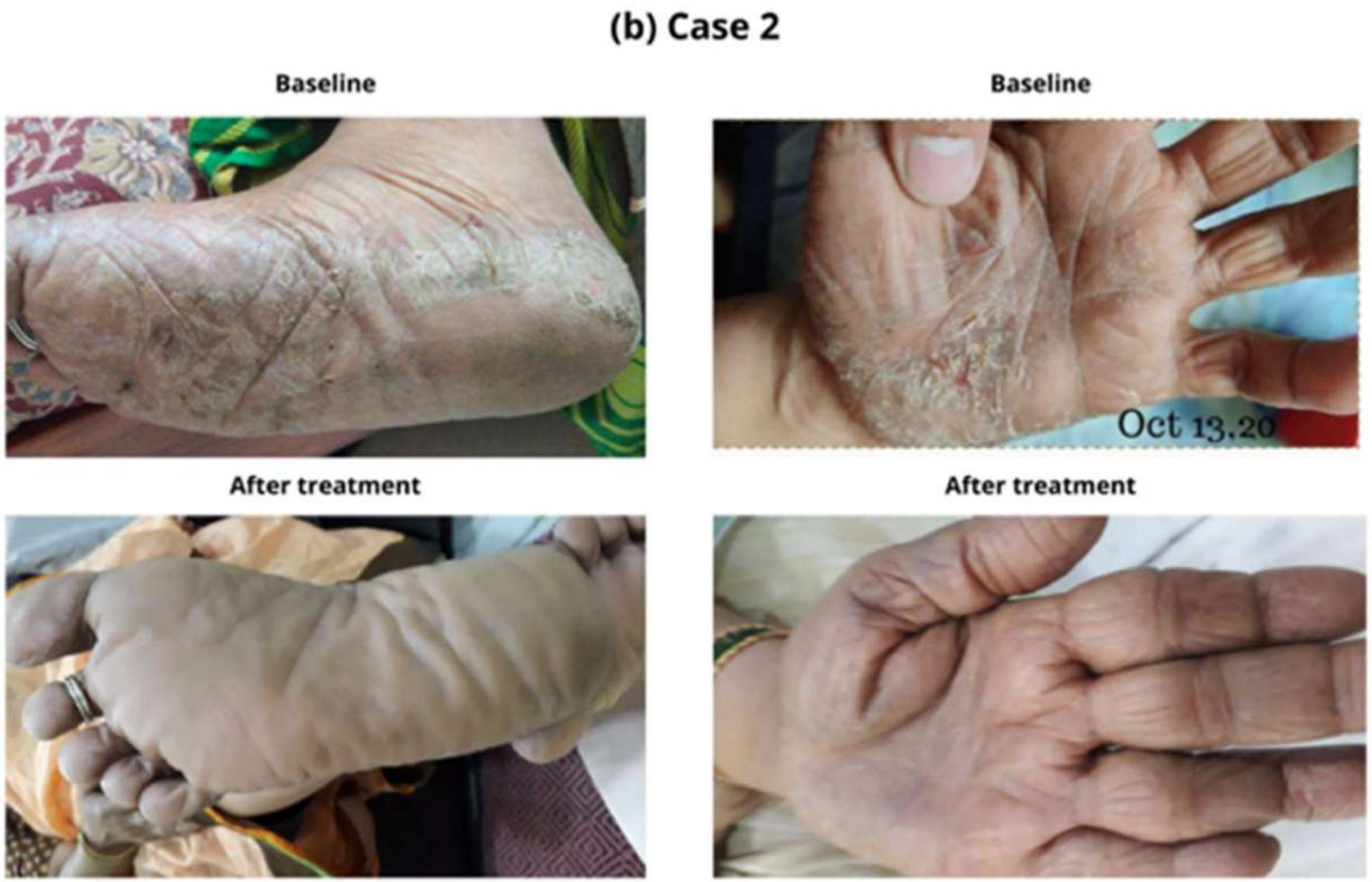
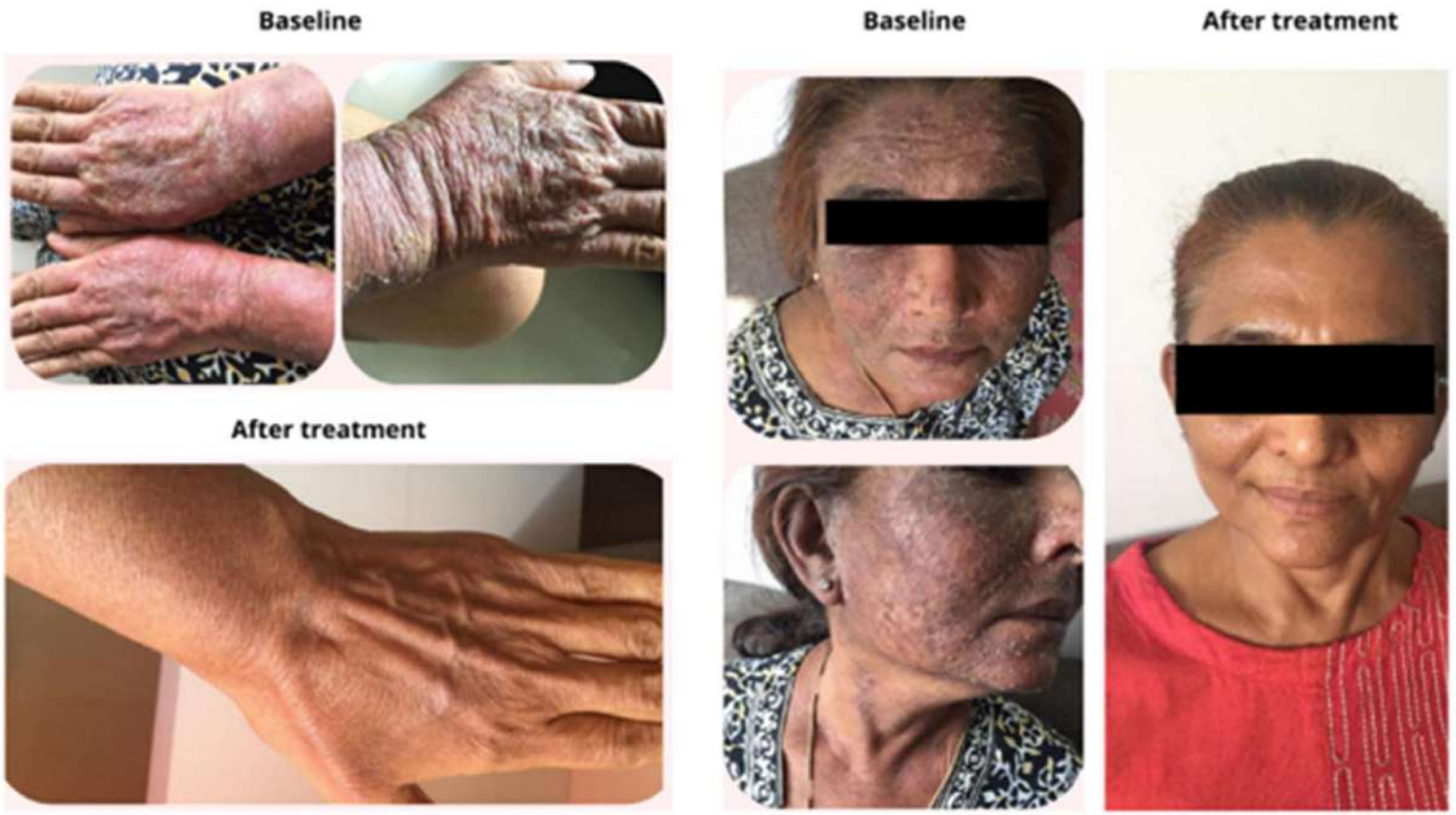


Fig. 1. Baseline through follow-up changes in the psoriatic lesions of cases 1and 2.

63-year-old woman, psoriasis for 4 years, itching and thick scaly eruptions largely involving the palms and plantar region. The Vitamin D level at the onset was 45 ng/ml and PTH level was 37.5 pg/Ml. She was treated with Vitamin D3 doses of 30000 IU daily for a period of 3 months. Her PTH level came down to 21.2 pg/ml whereas the ionized calcium remained within normal range (1.25 mg/dl). She showed complete control of disease by the end of the 3rd month PASI score (0) and VAS score (0). Since the 4th month she is on a maintenance dose of 20000 IU daily and no relapse of symptoms at the end of the one year follow-up.

(c) Case 3



55 year old woman, psoriasis for 12 years, exacerbation since 2 years, whole body involvement, severe eruptions and erythematous scaly plaques. Very low vitamin D levels at onset 9.44 ng/ml and PTH levels was 52.2 pg/mL . Her PASI scores (44.2) indicated severe psoriasis along with extreme itching (VAS=9). She was given a single dose of 600000 IU of Vitamin D3 followed by 30000 IU daily. After 2 months, the PTH was recorded as 35.38 pg/mL and ionized calcium levels were 1.20 mg/dL. As there was no improvement and the PTH levels were still not at the lowest, the dose of Vitamin D3 was escalated to 45000 IU from the third month. The patient continued the therapy under monitoring, until complete control (PASI=0.8; VAS=1) was achieved by the end of 6th month (PTH 29.6 and Ionised Calcium 1.2). The Vitamin D3 dose was then progressively reduced and now the patient is under a maintenance dose

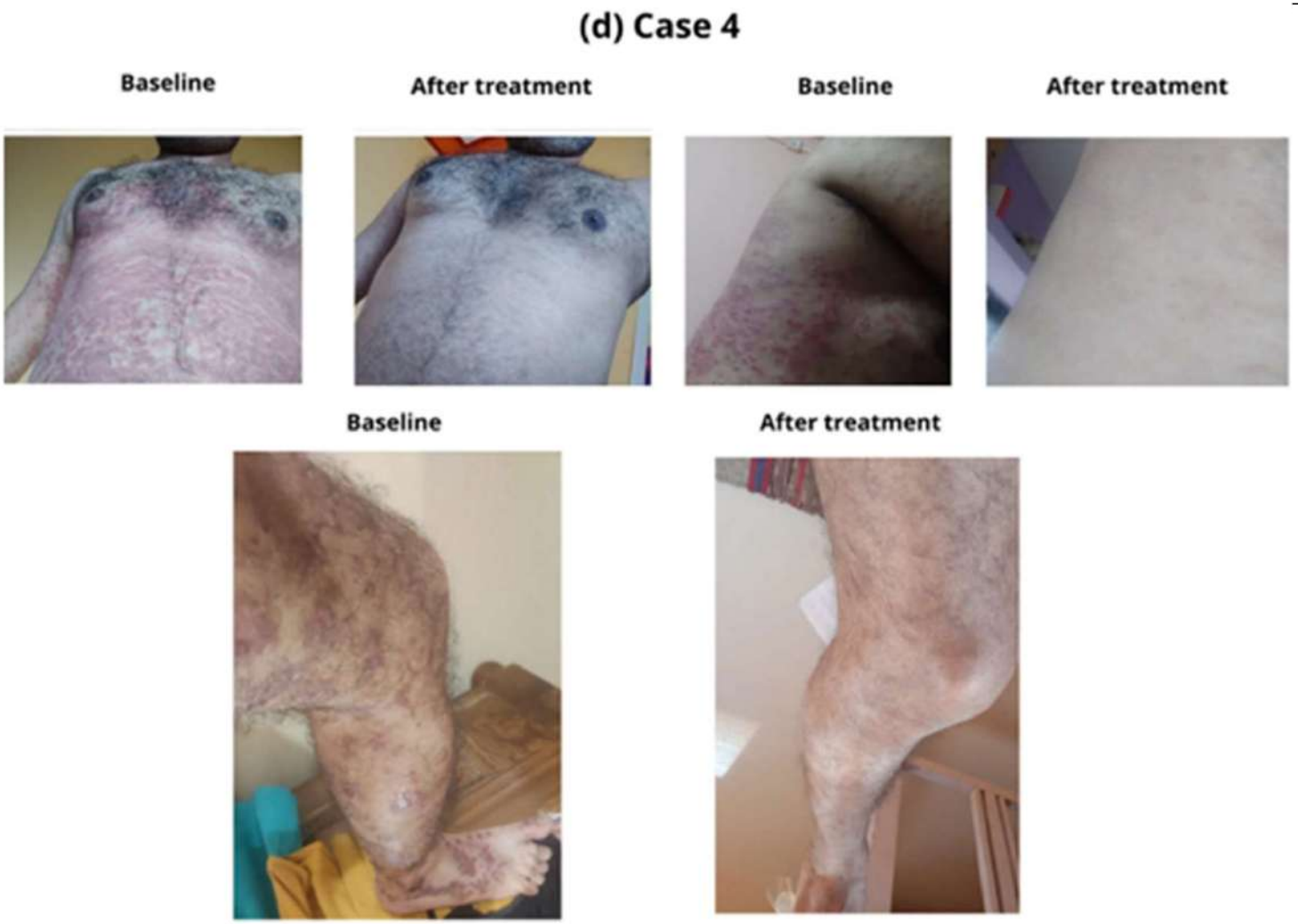
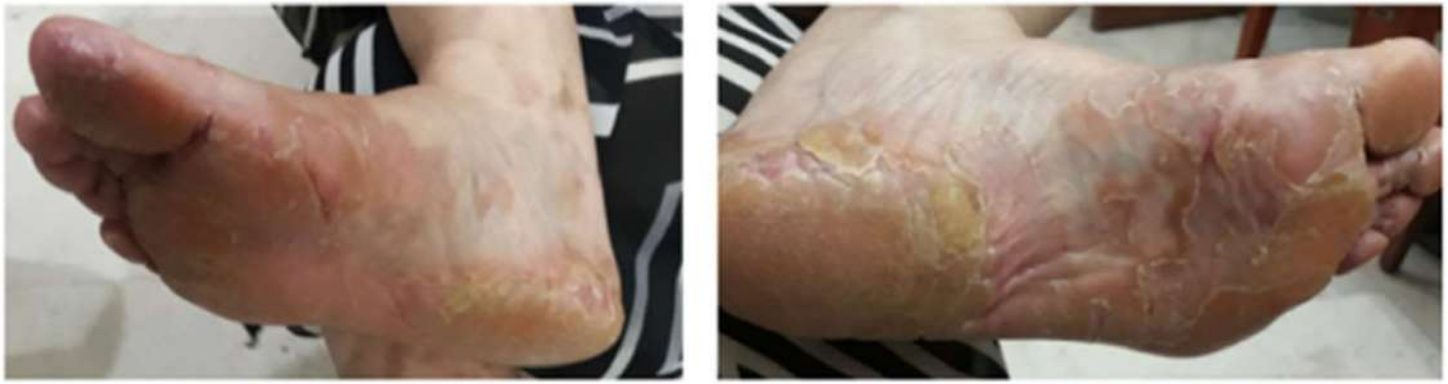


Fig. 2. Baseline through follow-up changes in the psoriatic lesions of cases 3 and 4.

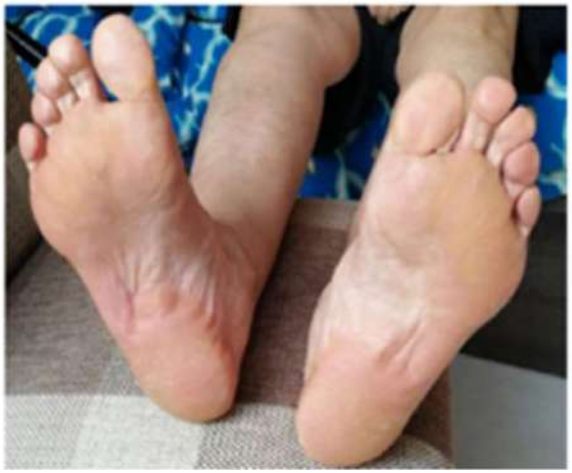
A 37 year old male with 8 years history of psoriasis. His Vitamin D and PTH levels were 61.5 ng/ml and 24 pg/mL respectively. He was started on the initial daily dose of 30000 IU for the first 2 months. Considering the clinical improvement and lowering of PTH levels (7.76 pg/ml), the dose of Vitamin D3 was reduced to 20000 IU daily from the 3rd month onwards. Complete control of the disease was achieved by the end of 4th month (PTH 18.3 pg/ml, ionised calcium 1.16 mg/dL). Presently, the patient is on a maintenance dose of 15000 IU daily and complete remission with PASI (0) and VAS score (0).

(e) Case 5

Baseline



After treatment



A 48-year-old female presented with erythematous and pruritic plaques in the palmar and plantar region for 2 years. Her laboratory reports revealed Vitamin D3 levels of 21.3 ng/ml and high level (113 pg/mL) of PTH. She was started on 30000 IU of vitamin D3 daily, which was reduced to 15000 IU daily after 2 months owning to 90 percent subsidence in the progression of disease (PTH 83.3 pg/ml and ionized Calcium 1.33). The dose was further reduced to 10000 IU daily by the end of 4th month as there was complete remission (PASI=0.4) and the itching was also under control (VAS=1). No further relapse was reported and the patient is under a stable dose of 60k of Vitamin D3 once a week.

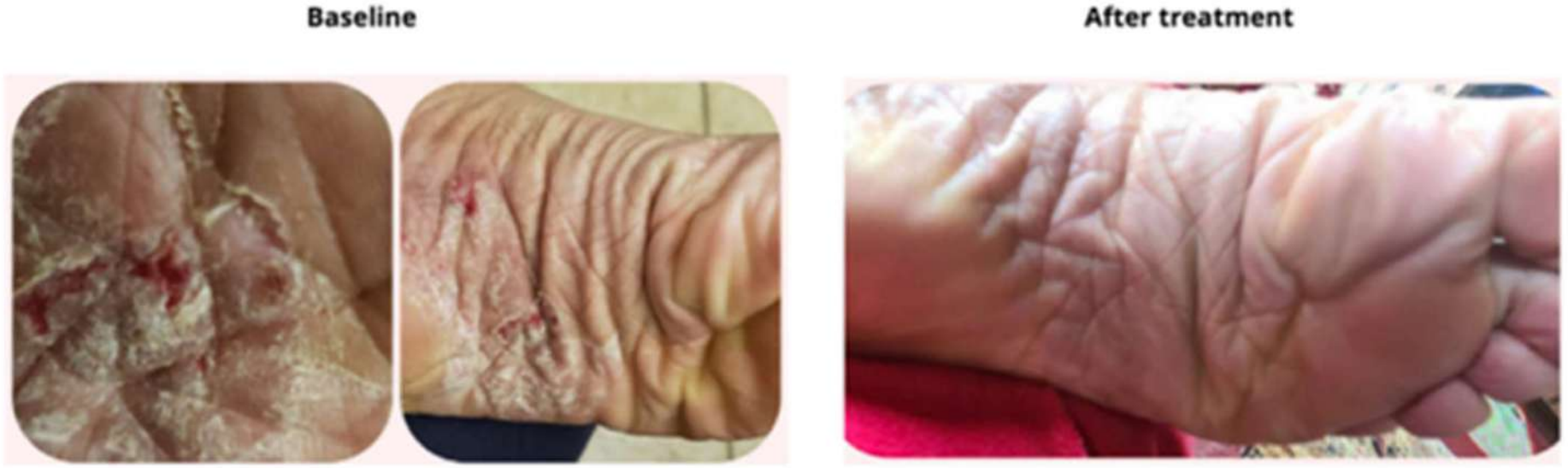
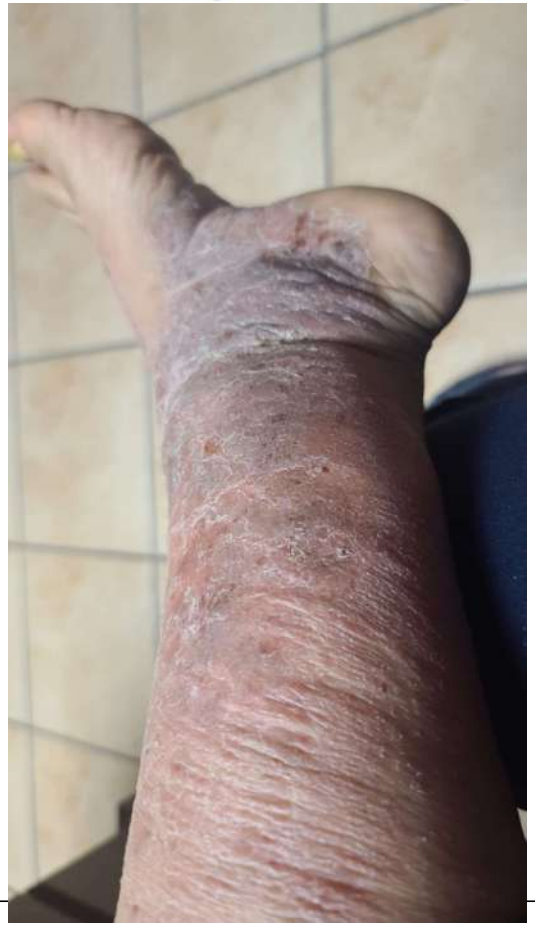
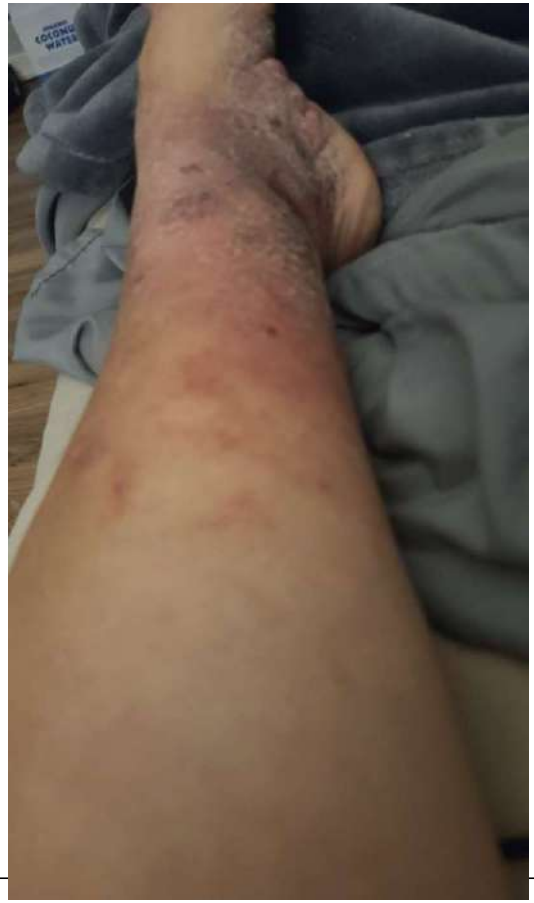


Fig. 3. Baseline through follow-up changes in the psoriatic lesions of cases 5 and 6.





- A 55-year-old (Mexican origin) female with 8 years history of psoriasis presented with severe itching and erythrodermic lesions involving the palms and plantar and leg region. Her vitamin D levels - 39 ng/ml and PTH levels - 26 pg/mL. She was put on 30000 IU vitamin D3 daily, but as her BMI was > 35, the vitamin D3 dose was increased to 40000 IU within a week.
- The dose was further increased to 50000 IU daily after 30 days. PTH values checked after 2 months of therapy, showed a marginal reduction from 26 pg/ml to 22 pg/ml, indicating a high degree of vitamin D resistance. The ionized calcium levels were maintained in the normal range. Therefore, from the third month, the vitamin D dose was further increased to 60000 IU daily with strict restriction of calcium rich foods. PTH checked after a month of 60000 IU daily was 19 pg/ml and ionized calcium levels within normal range.
- The same dose was continued for another one month owing to a marginal improvement. By then, the PTH had reached its lower limit of normal ranges i.e. 15 pg/ ml. Then, the dose of vitamin D3 was reduced at a rate of 10000 IU per month i.e. 50000 IU daily during 5^{th} month and 40000 IU daily during the 6^{th} month. By the eighth month, the patient achieved a complete control of the disease with PASI and VAS scores as 0.8 and 1 respectively. Similarly laboratory reports revealed a stable PTH level of 24 pg/mL and ionized calcium level of 5 mg/dL. The patient was on a maintenance dose of 40000 IU daily
- Addition - She got back the psoriasis after 6 months. The vitamin D dose has been increased under monitoring and she is 80% better with 70000 IU daily.

- The observations from this case series demonstrate –
- Promising and durable control of the signs and symptoms in psoriasis, with no adverse events or relapse with regular oral individualised dosesVitamin D3.
- It can be given safely as an effective therapeutic modality for treating psoriasis.
- The findings of this case report need further evaluation through well designed large scale randomised trials

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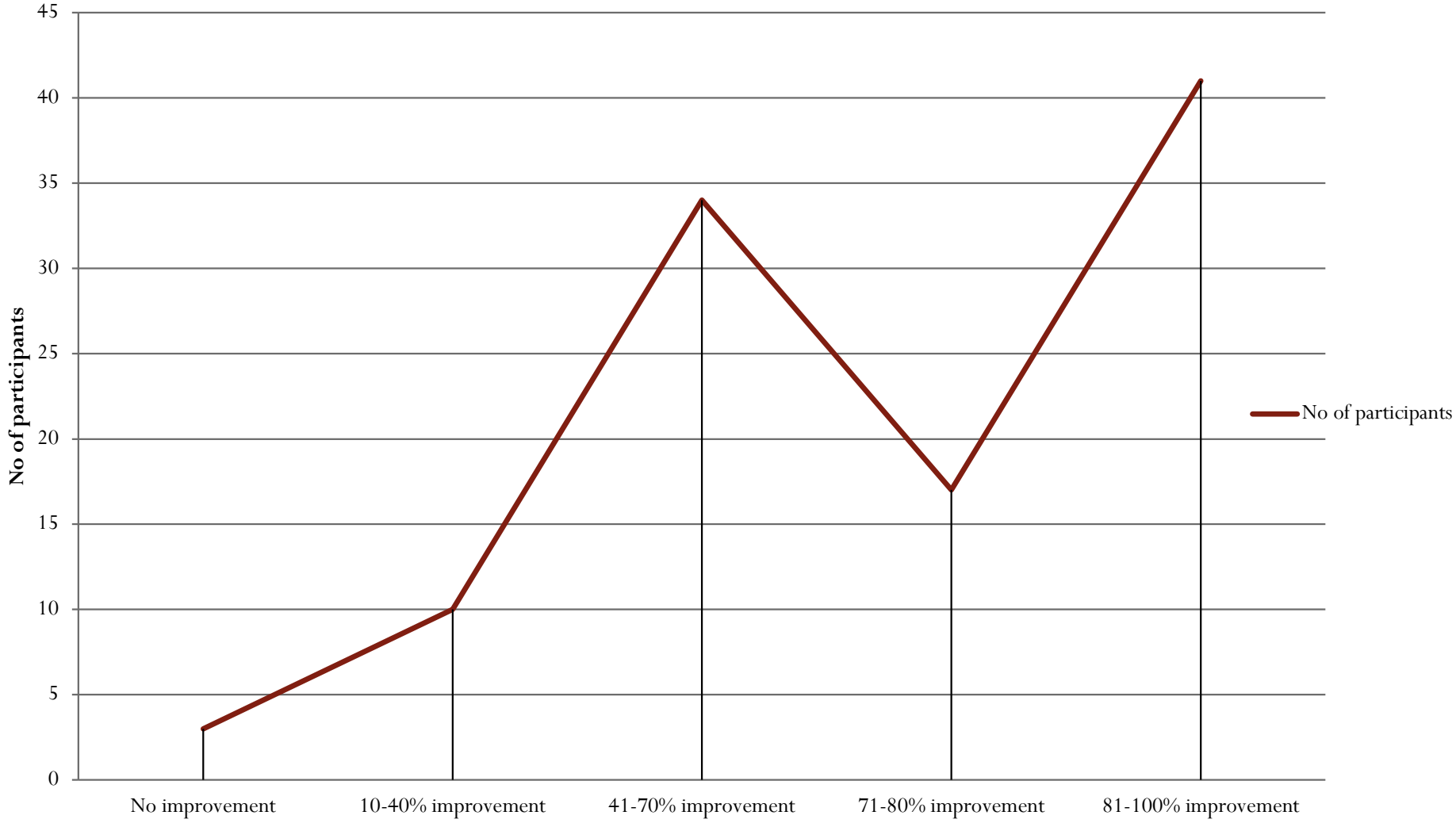
Percentage Improvement Score



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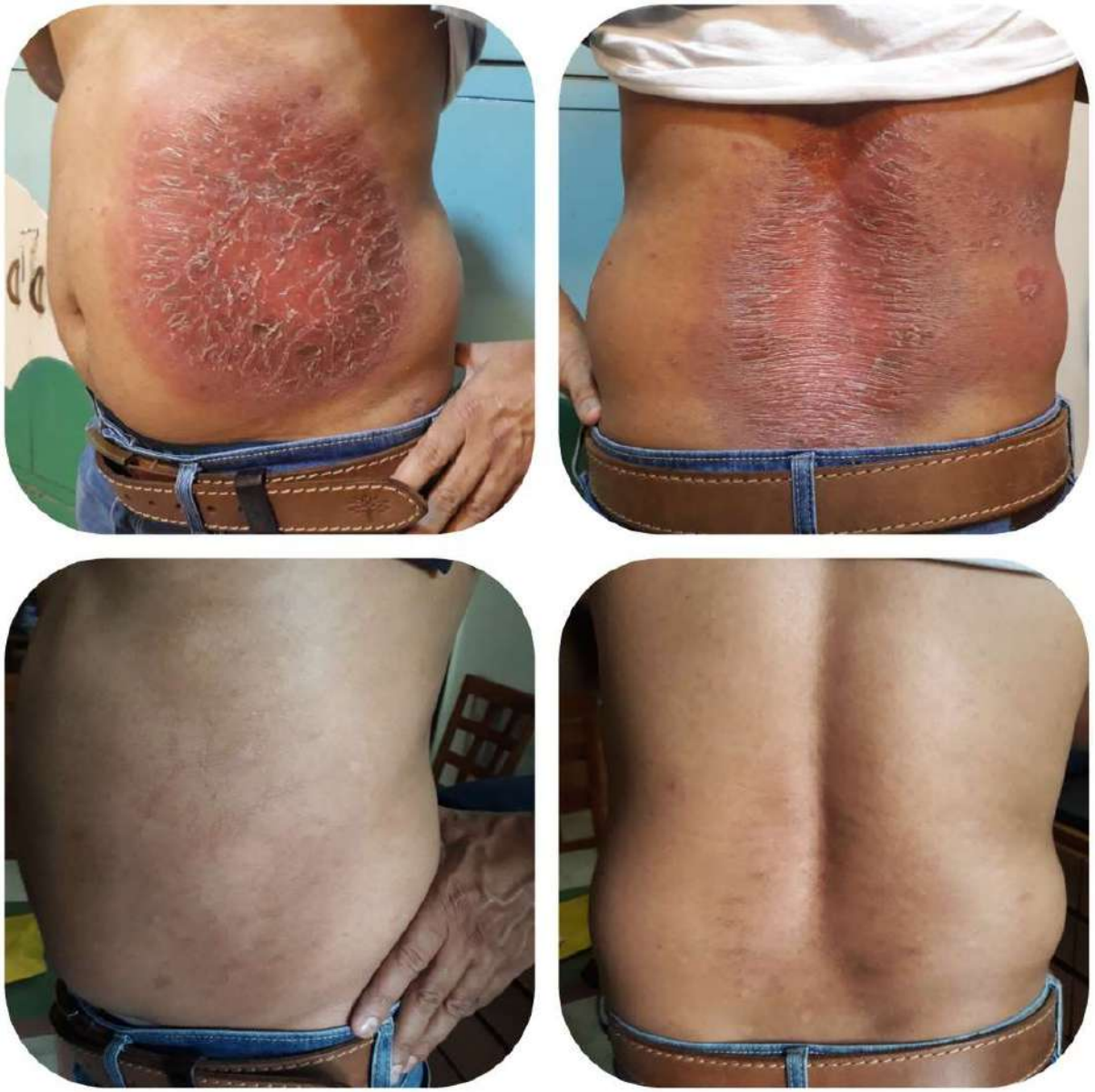
Observations

- Permanent remission –30%
- Provided that keep taking the appropriate, person specific dose of vitamin D
- Remaining get partial relief – 50%
- Control of
  - progression
  - reoccurrences (frequency and intensity)



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nutrients

MDPI

Article

Safety Data in Patients with Autoimmune Diseases during Treatment with High Doses of Vitamin D3 According to the "Coimbra Protocol"

Ulrich Amon [1,*], Raul Yaguboglu [1], Madeleine Ennis [2], Michael F. Holick [3] and Julian Amon [1]

1 International Centre for Skin Diseases DermAllegra, Coimbra Protocol Certified Center, Am Markgrafenpark 6, 91224 Pommelsbrunn-Hohenstadt, Germany; yaguboglu@dermallegra.de (R.Y.); julian.amon@aol.com (J.A.)

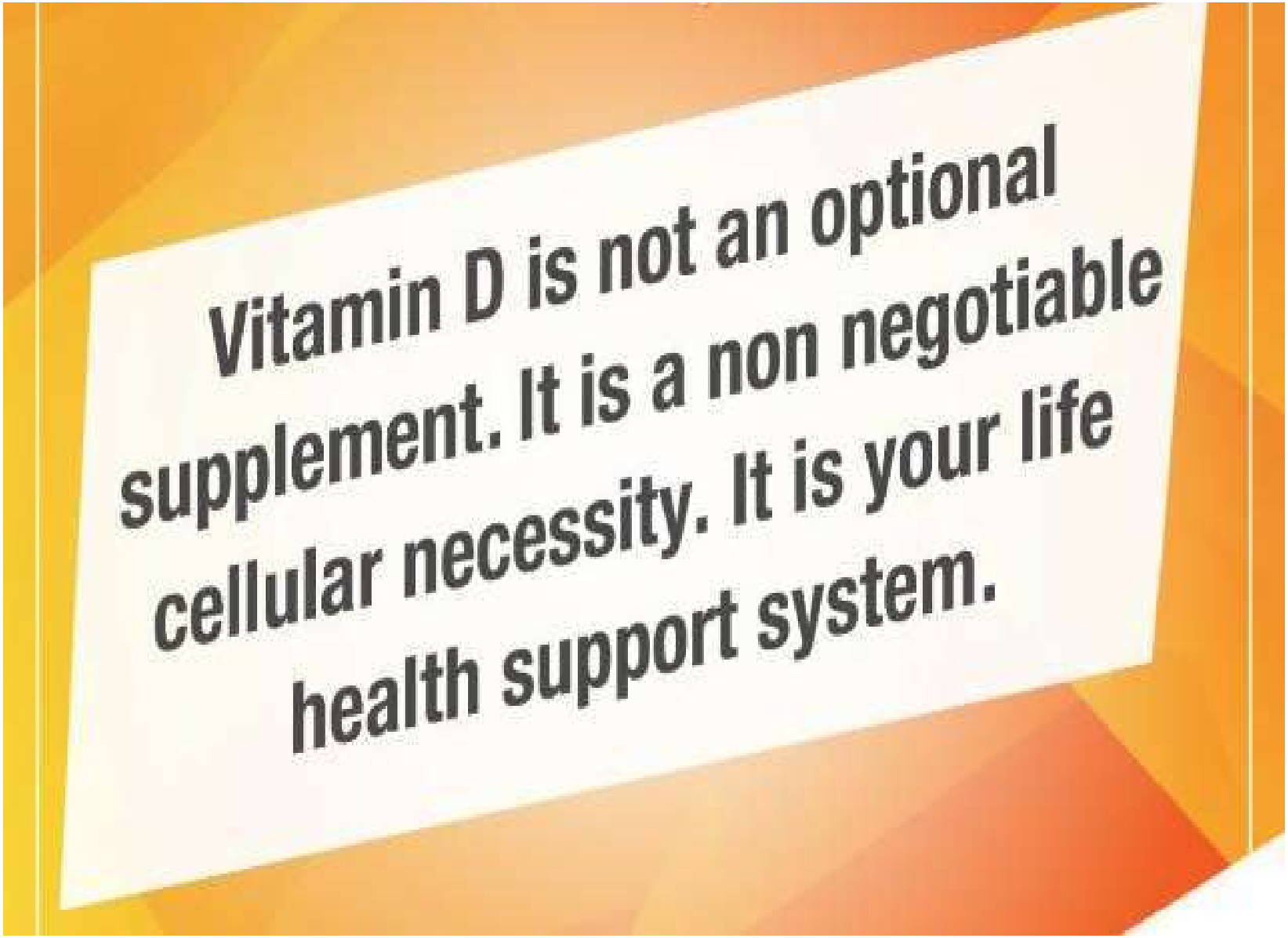
2 The Wellcome-Wolfson Institute for Experimental Medicine, Queens University of Belfast, Belfast BT7 1NN, UK; m.ennis@qub.ac.uk

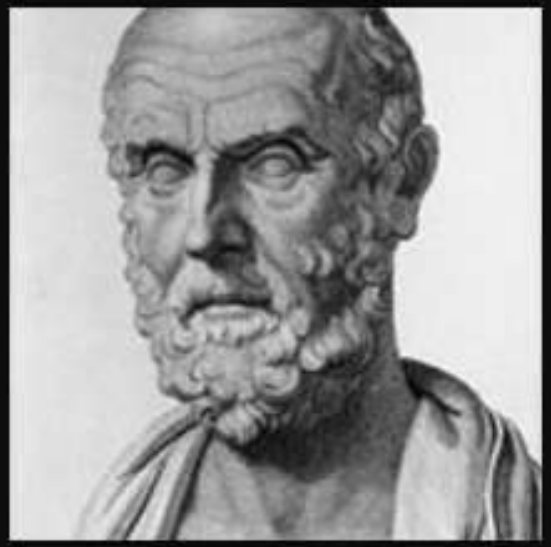
3 Endocrinology, Diabetes, Nutrition & Weight Management, Department of Medicine, Boston University School of Medicine, Boston, MA 02118, USA; mfholick@bu.edu

* Correspondence: dermallegra@aol.com; Tel.: +49-9154-914056; Fax: +49-9154-914058

319 patients over 3.5 years

300 -1000 IU vit D/kg /day


Vitamin D is not an optional supplement. It is a non negotiable cellular necessity. It is your life health support system.



Wherever the art of Medicine is loved, there is also a love of Humanity.

~ Hippocrates

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