

Price Dispersion of Vitamin D Supplements Over Time: An Initiative for Prescriber Education

Preeta K. Chugh, Aashima Dabas¹

Department of Pharmacology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, ¹Department of Paediatrics, Maulana Azad Medical College and Associated of L.N. Hospital, New Delhi, India

Abstract

Objectives: High prevalence of vitamin D deficiency mandates prescribing an appropriate form of vitamin D that allows attainment of sufficiency in a cost-effective manner. We aimed to compare vitamin D products in Indian market in terms of composition and cost in 2020 with 2013 to understand price dispersion over 7 years. **Methods:** Constituents, formulations, and prices of 'branded' and generic vitamin D products were sourced from various drug information compendia and online sources. Price per defined daily dose (DDD), percentage cost variation, and change in prices over 7 years (2020 vs. 2013) was determined. **Results:** There has been a disproportionate increase in the number of brands and cost variation of cholecalciferol and calcitriol in the last 7 years. The percentage cost variation increased almost 10 times for calcitriol and 4.4 times for alfacalcidol tablets and cholecalciferol granules. An analysis of >1,100 products in 2020 showed that the predominant form was calcitriol which was combined with calcium in >90% of the products with huge cost variation (>3000%). Ergocalciferol and cholecalciferol were available in 22 and 15 different strengths respectively. Median price/unit of cholecalciferol (60,000IU) was lower for tablets/capsules compared to other formulations; but with >1000% cost variation. **Conclusion:** A wide cost variation exists with the use of different vitamin D brands and preparations with conventional cholecalciferol tablets and capsules being a low-priced alternative. Quality control measures and strict enforcements of existing regulations are essential to ensure that competitive prices of branded generics are translated into availability and affordability for the population.

Keyword: Brand, cost analysis, generic drugs, nutritional supplements, treatment, vitamin D deficiency, vitamin D

INTRODUCTION

Vitamin D deficiency has been reported in both developed and developing nations across various age groups, gender and illnesses in both hospital-based studies (50-94%) and community settings (37-99%).^[1,2] Fortification of food and vitamin D supplementation are the primary preventive and cost-effective interventions to reduce the burden of vitamin D deficiency.^[1-5] Food fortification is an effective population-based strategy that mandates government initiative on a large-scale for effective implementation.^[5] Supplementation programs have lowered the incidence rates of rickets in children^[6] and shown reduction in falls, fractures; improvement in musculoskeletal health with additional cost-benefits in elderly.^[7,8] Despite the cost-effectiveness of this intervention, monitoring their intake for overdose, adherence especially in high-risk groups and mass-outreach are concerns with supplementation.

Globally, with considerable research on vitamin D, high prevalence of vitamin D deficiency, greater prescriber and population awareness, and recommendations for routine supplementation without pre-screening in certain population groups, has led to a considerable rise in the number of prescriptions of vitamin D.^[9-12] It is estimated that the global vitamin D therapy market size is expected to grow at a compound annual growth rate (CAGR) of 11.70% from \$2,020.30 million in 2019 to \$3,925.67 million by the end of 2025 across the West and Asia Pacific countries including India.^[13] Similar data shows that market size in India rose

Address for correspondence: Dr. Preeta K. Chugh,

Department of Pharmacology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi - 110 029, India.

E-mail: docpreeta@yahoo.com

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from 2.98 billion (Indian National rupees, INR) in 2014 to 5.38 billion in 2018.^[14]

However, variations in dose and duration of vitamin D supplementation as per recommendations put an onus on the prescribing physician to facilitate a rational and cost-effective prescription. An understanding of the various products could aid in an informed decision-making process to prescribe an appropriate cost-effective formulation, in adequate quantity (international unit (IU) per dose and dosing frequency).^[10] At present, there are numerous 'branded generics' of vitamin D in different forms, strengths and vehicles for delivery in the Indian market that mandates a structured analysis to rationalize prescribing decision.^[15-17] In low-and middle-income countries (LMICs), low levels of health insurance coverage combined with households spending 50-80% of their total health expenditure on medicines, make high drug prices an important impediment to access and compliance.^[15] We aimed to assess the composition and the price variations among various vitamin D supplement products available in the Indian market and estimate price dispersion over 7 years (2013–2020).

METHODOLOGY

Data source

This was a cross-sectional cost analysis for the assessment of vitamin D products using both online and text sources of drug information. Various text compendia [*Current Index of Medical Specialities (CIMS)* Reference Guide (July-Sep 2020) and *Drug Today* (July-October 2020)] and online sources (CIMS website) that detailed products, their medicinal formulations- constituents and dosage, and maximum retail prices (MRP) prices in the Indian Rupee (INR) were utilized.^[18-20]

The MRP of the product was also considered with its generic price and ceiling price as fixed by the Government of India. Under the Essential Commodities Act, drug prices have been controlled using a series of Drugs Price Control Orders (DPCOs), beginning in 1970.^[21] In 1997, India established the National Pharmaceutical Pricing Authority (NPPA), an organization that reviews and fixes pharmaceutical prices using market-based mechanisms.^[15] The prevailing DPCO, 2013 had set ceiling prices for essential drugs from the National List of Essential Medicines (NLEM), a list of medications based on the World Health Organization's (WHO) list of essential medicines.^[22] Ceiling price are set using price to retailer, which is the price the pharmacist pays for medication, in contrast to MRP that is printed on the medication package.^[15] As the NLEM includes only cholecalciferol, the ceiling prices were available only for this product and was used for comparison with MRP.^[23] Price of generic products was taken from the official site of the Bureau of Pharma PSUs of India (BPPI) and Government of India that aims to provide quality generic medicines at an affordable price across the country.^[24]

Due to differences in nomenclature (both branded and generic), packing sizes, pricing and customary dosages, WHO has

developed the Anatomical Therapeutic Chemical (ATC)/ Defined Daily Dose (DDD) methodology to facilitate the presentation and comparison of drug consumption statistics at international, national and regional levels. WHO defines a technical unit of measurement DDD as an assumed average maintenance dose per day for a drug for its principal indication in an adult.^[25] Cholecalciferol (D3) and ergocalciferol (D2) are the inactive forms of vitamin D from animal and plant source, respectively. Alfalcidol and calcitriol are the biologically active forms that have a DDD of 1 mcg. Given that both are available as 0.25 mcg oral strengths, four unit products would be required to attain DDD.

Data analysis

Unit price of each product was calculated by dividing the given price (MRP) with the available pack size of that particular strength. The cost per DDD was calculated by multiplying the number of units needed to attain the DDD with the unit price of the drug of a particular strength. Percentage cost variation was calculated for a particular strength and formulation of vitamin D as follows: $[(\text{MRP of most expensive brand} - \text{MRP of least expensive brand}) / \text{MRP of least expensive brand}] * 100$. Cost ratio was defined as the ratio of cost of the most expensive and least expensive brand product.

Statistical analysis

Data (product details; composition and price) were entered in Microsoft Excel and analyzed using the same software. Descriptive analyses were performed to calculate and compare costs/DDD (minimum and maximum cost), percentage cost variation, and the cost ratio for different products. A comparison was also drawn with our previous analysis of 2013 to understand the price variation of these products over time.^[17]

RESULTS

Among a total of 1115 products, vitamin D3 is commonly available as calcitriol (n = 502; 45.02%) and cholecalciferol [Table 1, Figure 1]. Majority of calcitriol preparations were combined with calcium and other micronutrients (94.42%). Cholecalciferol (n = 457; 40.98% of the total products) was available in strength of 60,000IU in 63.47% of cholecalciferol brands and as a single product in 88.81% preparations [Table 1]. Cholecalciferol (DDD-800IU/20 mcg) was available in very few products (5.03%) limiting the estimation of cost per DDD. Among various alfalcidol brands, median price per DDD and cost ratio of tablets and capsules was comparable as shown in Table 2. Though the median price per DDD of calcitriol tablet and capsule was comparable, there was a wide variation in calcitriol tablets (3633%) and capsules (729.23%). The median price per unit of 60,000 IU cholecalciferol was comparable in tablets, capsules, and granules; making them economical alternatives for treatment of deficiency. The oral solutions (nano-emulsions) were the most expensive products (unit price range INR 45-260) [Table 2]. The percentage cost variation was more than 1000% for calcitriol

Table 1: Vitamin D products in the Indian market

	Calcitriol	Cholecalciferol	Alfacalcidol	Ergocalciferol	Total
Total number of products (%) [#]	502 (45.02%)	457 (40.98%)	124 (11.12%)	32 (2.86%)	1115 (100%)
Number of strengths available	2	15	4	22	43
Number of constituents (range)	1-9	1-5	1-6	1-41	1-41
Number of products-single ingredient- vitamin D (%) [@]	28 (5.57%)	421 (92.12%)	24 (19.35%)	1 (3.12%)	474
Number of products with calcium (%) [@]	474 (94.42%)	17 (3.38%)	99 (79.83%)	28 (87.5%)	618

[#]This percentage is calculated as the selected number of vitamin D products in the numerator and total vitamin D products (1115) in the denominator. For example, in case of calcitriol, 502/1115=45.02% calcitriol products of the total vitamin D products. [@] This percentage is calculated as the number of particular vitamin D products in the selected option as numerator and the particular vitamin D product in the denominator. For example, in case of calcitriol, 28/502=5.57% calcitriol products contain single ingredient- vitamin D.

Table 2: Cost variation among vitamin D3 products (All prices are in INR)

Drug (DDD)	Generic Price in INR	Strength and Formulation (no of brands)	Median price (per unit)	Median price (per DDD) *	Range price (per unit)	Range price (per DDD) *	Cost Ratio	Cost Variation %
Calcitriol (1 mcg)	1.3	0.25 mcg Tab. (168)	10.5	42	2.25-84	327	37.33	3633
	1.8	0.25 mcg Cap.(321)	12	48	3.9-32.34	113.76	8.29	729.23
Alfacalcidol (1 mcg)		0.25 mcg Tab. (84)	6	24	3.5-17.4	55.6	4.97	397.14
	2.2	0.25 mcg Cap. (31)	6	24	3.1-11.7	34.4	3.77	277.41
Cholecalciferol (800IU) †	1.8	800IU Oral Liquids (Drop, Suspension) (23)	4.76	4.76	2.16-8.28	6.12	3.83	283.33
		60K Cap. (92) †	27.25		3.62-62.25		17.19	1619
	9	60K Granules (97) †	25.5		10-51		5.1	410
		60K Tab. (68) †	25		5.77-78.51		13.6	1260
		60K Solution (18) †	61		45-260		5.77	477.77
		60K Oral Strip (10) †	34.5		21-68		3.23	223.8
		60K Inj. (5) †	29.75		29.75-55		1.84	84.87

*DDD= Defined Daily Dose; Tab.= Tablet; Cap.= Capsule; Inj.= Injection; 60K=60,000IU. All prices in INR. † Price per DDD was not estimated for cholecalciferol (60,000 IU); strength commonly used for treatment of vitamin D deficiency.

tablet and cholecalciferol (60K) tablets and capsules [Figure 2]. Calcium supplements with calcitriol were priced 3 times higher than single ingredient calcitriol tablets.

A wide gap was observed on comparison of ceiling price fixed by NPPA, and maximum price per unit available in the market. This indicates that market products were priced much higher (nearly 2-3 times for cholecalciferol capsules and tablets respectively) than the ceiling price.

The generic prices were much lower than the median prices of various brand products. The median price of calcitriol brands was at least 7 times higher than the price of generics in same strength and formulation. In case of alfacalcidol (0.25 mcg capsules) and cholecalciferol 60K granules, branded products were nearly 3 times more expensive than generic products in the market [Figure 3].

The vitamin D3 brands increased 4.19 times in 7 years (18 times in case of cholecalciferol), with increase in the cost variation in most of the products [Figures 1 and 4]. The percentage cost variation increased 4.4 times in case of alfacalcidol tablets and cholecalciferol granules and nearly 10 times for calcitriol tablets [Figure 4].

DISCUSSION

In the Indian market, cholecalciferol is the most readily available, efficacious and cheap form of vitamin D that should be considered for food fortification, supplementation and treatment.^[11,26,27] It has demonstrated superior short-term and long-term outcomes such as raising serum 25-hydroxy vitamin D concentrations and mortality reduction over ergocalciferol.^[28] Conventional oral fat-soluble supplements offer a simple and low-cost option, but efficacy is limited by lipophilic character and low bioavailability in gastrointestinal tract. Newer hydrophilic micellised formulations have higher bioavailability and greater response to therapy.^[29] However, their use is limited by higher cost (nearly 12 times) which escalates the expenditure for treatment of deficiency. Serum vitamin D levels tend to decline within a year in the absence of continued supplementation.^[30] Thus, whether this greater bioavailability of expensive nano-emulsion product translates into a better and sustained clinical response needs to be studied further.

The wide cost variation of cholecalciferol tablets and capsules (>1000%) indicates the impact of choice of brand

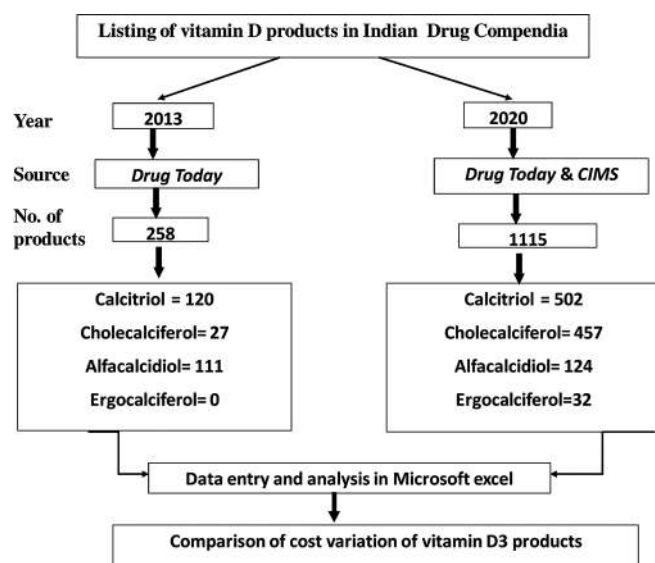


Figure 1: Flowchart for the analysis of vitamin D products in 2013 and 2020

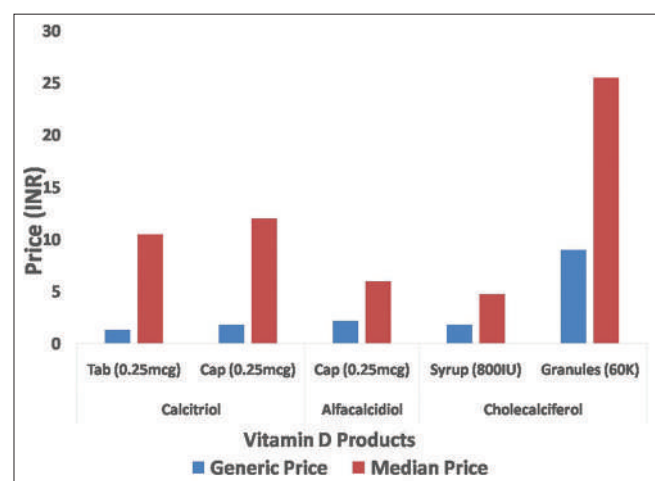


Figure 3: Comparison of generic price and median price of various vitamin D products

in relation to expense for the treatment of deficiency. Alfalcidol and calcitriol are the active and more potent formulations that are reserved for patients with chronic renal and hepatic disease.^[26] However, the present study showed that calcitriol was the most commonly available D3 analog which was combined with calcium in >94% of the products. These combined supplements were 3 times more expensive than calcitriol (single-ingredient) tablets and can significantly raise expenditures and risk of adverse reactions; thus impacting compliance when prescribed for long-term use. With regards to pediatric population, cholecalciferol was available in various strengths and formulations like syrups and drops. As milk remains a poor source of vitamin D, the Indian pediatric guidelines recommend daily supplementation of 400-600 IU of vitamin D in infancy and older children and 60,000 IU monthly in adolescence with emphasis on calcium intake.^[31] The use of cholecalciferol instead of calcitriol in most pediatric

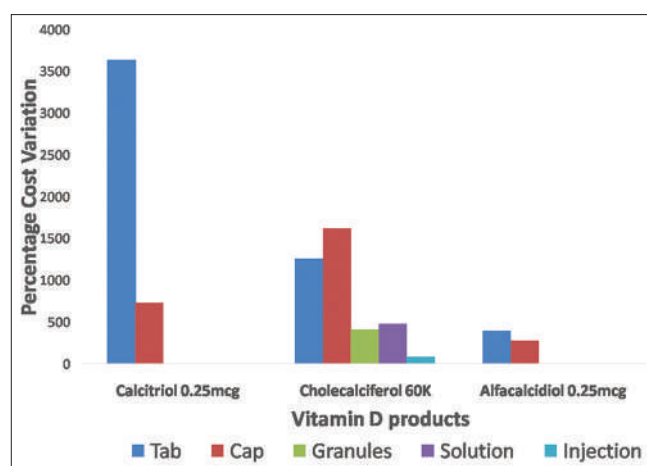


Figure 2: Comparison of mean cost variations of various vitamin D3 products. Legend: Percentage cost variation = [(MRP of most expensive brand – MRP of least expensive brand)/MRP of least expensive brand]*100

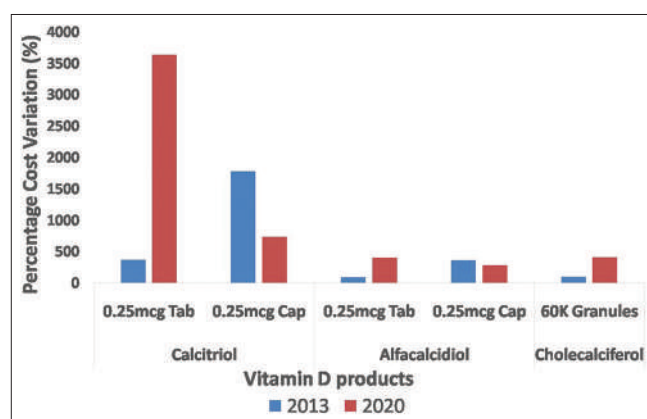


Figure 4: Comparison of percentage cost variation of vitamin D products over 7 years

formulations was reassuring. Apart from tablets and capsules, cost-variation of D3 drops was also significant suggesting indirect economic burden which may result in poor compliance to routine supplementation of D3 during infancy.

In the last decade, there has been a progressive increase in the prescriptions of vitamin D supplements.^[6,9-12] In 2017, vitamin D expenditure in Italy was reported to be €180 million, positioning it at the first place for consumption in DDD.^[10] Physicians may be unaware of the price of the prescribed drugs and may inadvertently prescribe a more expensive product.^[32] In addition, most of the patients are usually hesitant to admit their unaffordability to purchase medicines. In such a case, it is believed that patients usually forego the use of 'non-essential' drugs or the ones they perceive to be of least value compared to the essential ones used in the management of chronic conditions.^[33] A patient is likely to discontinue vitamin supplements which can have serious consequences in vulnerable groups like infants and elderly. The assessment of cost-effectiveness of supplementation in older adults

highlighted that reduction of health and social care expenditure was from avoidance of long-term care following a fall in those aged > 70 years. It is known that generic drug competition is the principal method to contain the rapid growth in pharmaceutical expenditures. However, our analysis indicates that despite an expansion of 'branded generics' market over time, a wide price gap remains in the majority of products. This gap has increased nearly ten times in case of cholecalciferol, the recommended agent for supplementation. This is a cause for concern as cholecalciferol is the only D3 analog included in NLEM and DPCO to ensure affordability for the masses. This undermines the purpose of these regulations that ensure access to affordable medicines. It is noteworthy to understand why a causal relationship between price and the number of drug competitors is difficult to establish in the Indian market. The market is dominated by "branded generics" wherein manufacturers of generic drugs compete on brand name as opposed to price. Lack of adequately conducted bioequivalence studies for most generics, ineffective enforcement of good manufacturing practices and rules and regulations has led to a proliferation of 'substandard' medications that are usually cheaper than their high-priced counterparts. In contrast, certain products establish a reputation for quality with patients and physicians and are preferred in spite of their rising prices. Thus, despite being one of the world's most competitive generics market, certain segment of population like cost-conscious consumers are ready to pay for a higher price 'branded generic' even though they are largely paying for medications out-of-pocket.^[15]

The present scenario highlights the need for an integrated approach to ensure rational and cost-effective prescribing of vitamin D supplements. Though physicians in India are encouraged to prescribe generics, patients end up purchasing 'branded generics' at the pharmacy due to their non-availability at many centres. At the prescriber level, the prescriptions should clearly indicate the product (cholecalciferol), its formulation, strength and frequency of administration. Prescribing can achieve its goal only if cost awareness is linked to therapeutic reasoning. Our study serves as a scaffold to support training of future prescribers such that they are able to consolidate their knowledge in selection of most appropriate and affordable drug for a patient.^[34,35] Understanding the needs for adjustments for purchasing power of a patient can enable access to affordable medicines. The pharmacist should ensure that the prescribed and dispensed drug product match as per prescription. At the regulatory level, implementation and enforcement of existing rules and regulations with curbing of unscrupulous manufacturing practices and pharmaceutical quality assurance is essential to create access to safe and effective generics for affordable healthcare.

This study provides a comparative analysis of single drug/ fixed-drug vitamin D and calcium preparations to help a physician prescribe an appropriate and cost-effective product. However, the present study does not cover any information on bioavailability of different brands, which were shown to be highly variable in a previous in-vitro study.^[16] The rationality

of vitamin D prescriptions across different age-groups and indications was outside the purview of the present study. The total out-of-pocket expenditure was also not assessed as consumption practices of consumers were not recorded.

To summarize, the present study highlights a disproportionate increase in the number of brands and cost variation of cholecalciferol and calcitriol products in the last 7 years. Quality standards of drugs have to be the primary focus area to ensure that the large number of "generic brands" can translate into affordability and accessibility for the masses. As a physician, one should be aware of the available products, their indication and cost to ensure rational and cost-effective treatment.

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Conflicts of interest

There are no conflicts of interest.

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