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## **Original Research Article**

## Vitamin D: prescription audit in tertiary health care centre

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## ABSTRACT

**Background:** Vitamin-D is critically important for development, growth and maintenance of health of human being. Many evidences show association between vit-D deficiency and several serious health conditions. Data collection on use of drugs is being obtained with the aim of optimizing drug therapy. So far till date only few studies about prescription pattern of vit-D have been found. Hence it is very important to do audit of prescriptions of vit-D. The aim of the study is to provide concise and updated information about the use of vit-D in tertiary care hospital and to record demographic details of patients.

**Methods:** After ethical approval, this cross sectional study was conducted at tertiary health centre. Patient and drug data (name of drug, dose, dosage form and route of administration) was collected from the patient's prescriptions in OPD.

**Results:** Highest prescriptions of vit-D were found in orthopedic department (22% of total prescriptions of that department). Prescribing percentage of vit-D in medicine department was 4.6%, dermatology 1.5% and in psychiatry 0.8% of total prescriptions. Prescriptions of vit-D in combination with calcium were found in orthopedics (52%), medicine (7%) and obstetrics and gynecology (10%) departments.

**Conclusions:** Highest prescriptions of vit-D alone and with calcium found in orthopedic department. Periodic therapeutic audit is necessary to rationalise the use of vit D.

Keywords: Calcium, Data collection, Vitamin-D deficiency

### **INTRODUCTION**

In recent times, there has been a lot of talk over the sunshine vitamin-D. In humans vit-D is critically important for development, growth and maintenance of health. Evidences show association between vitamin deficiency and several serious health conditions. Vit-D deficiency is a major factor in the pathology of cancer, heart diseases, stroke, hypertension, autoimmune diseases, diabetes, depression, chronic pain, osteoarthritis, myopathies, birth defects, periodontal diseases and many more diseases. These diseases are beyond the known rickets and osteomalacia. Vit-D influence key biological function vital for human health. Clinicians prescribe vit-D to achieve and maintain better health.<sup>1-3</sup>

Drug utilization has been defined as a marketing, distribution, prescription and use of drug in a society with special emphasis on the resulting medical and social consequences.<sup>4,5</sup> Data collection on use of drugs in man is being obtained with the aim of optimizing drug therapy. So far till date few studies about prescription pattern of vit-D have been found. Hence it was pertinent to do data collection of prescriptions of vit-D.

The aims of the study were:

- To provide a concise and updated information about the use of vit-D in tertiary care hospital.
- To record demographic details (age, sex) of patients and its association with frequency of prescription of vit-D.

#### **METHODS**

A cross sectional study was conducted at tertiary health care centre. An inclusion and exclusion criteria was applied for benefiting study.

#### Inclusion criteria

OPD prescriptions of Departments which prescribe vitamin D.

Departments from which data noted were; Obstetrics and Gynecology, Orthopedics, Medicine and Allied psychiatry, Dermatology departments.

#### **Exclusion** criteria

Departments which do not prescribe Vitamin D. Clinical Departments were General surgery, Pediatrics, Ophthalmology, ENT.

Departments which do not prescribe drugs- Non clinical departments: Physiology, Anatomy, Biochemistry, Pharmacology, Microbiology, Pathology, Forensic medicine, Community medicine.

Inclusion and exclusion of departments were done by personal interview of senior faculty of respective department. Question was asked to them that whether they prescribe vitamin D or not. Department which had replied "Yes" were included.

Patient and drug data (name of drug, dose, dosage form and route of administration) was collected from the patients' prescriptions in outpatient department (OPD) of institute during study period.

#### Statistical analysis

Data was noted and was expressed s percentage of total prescription of respective departments.

## RESULTS

In this study prescribing practice of vit-D alone and combination with calcium including dose, type was noted.

Highest prescriptions of vit-D were found in orthopedics department (22% of total prescriptions of that department) in children, adult and elderly patients associated with fracture, joint pain etc. Prescribing percentage of vit-D in medicine department was 4.6%, especially in patients of chronic renal failure, diabetes, hypertensive, peri and post menopausal women. In dermatology 1.5% in patients of chronic psoriasis; in psychiatry 0.8% prescription of vit-D were found in patients of resistant depression. Vit-D in combination with calcium was found in orthopedics (52%), medicine (7%) and obstetrics and gynecology (10%).

Preferred route of administration of vit-D was oral route (98%) as compared to parenteral route (intramuscular 2%).

In oral route different dosage forms like tablets (49%), sachets (32%) and syrup (17%) were used.

Strength of vit-D in sachet and tablet is 60,000IU (International Unit), in syrup it is 30000IU/5ml. In injectable preparation strength is 6 lakhs/ 3ml.

Vit-D in combination with calcium were having ranges from 500 mg to 1300mg of calcium with 200IU to 800IU vit-D; in different brands of combinations.

In all vit-D prescriptions, prescription percentage in female was 70% as compared to male (30%). Highest prescriptions of vit-D were found in age group of 48- 64 years in both male and female. Only 11 % of patients were given the initial loading dose of vit-D followed by maintenance dose.

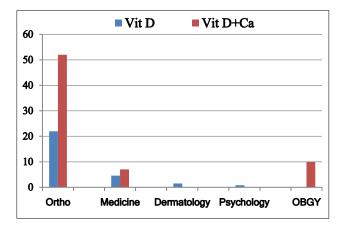
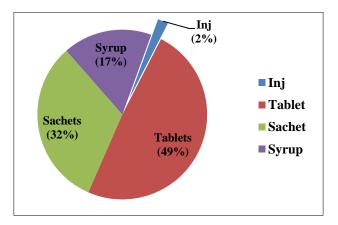
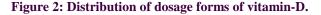


Figure 1: Department-wise prescriptions of vit-D alone and in combination with calcium.





#### DISCUSSION

Access to standardized and validated information on drug use is essential to allow audit of pattern of drug utilization, identification of the interventions. In the field of drug utilization research an internationally accepted classification for drug consumption was much needed. Norwegian researchers developed a system known as the Anatomical Therapeutic Chemical (ATC) classification. In order to measure drug use, it is important to have both a classification system and a unit of measurement. A technical unit of measurement called the Defined Daily Dose (DDD) to be used in drug utilization studies was developed. Then in 1990, WHO recognized the need to develop use of the ATC/DDD system as an international standard for drug utilization studies. International nonproprietary names (INN) are preferred for it. If INN names are not assigned, USAN (United States Adopted Name) or BAN (British Approved Name) names are chosen. WHOs list of drug terms is used when naming the different ATC levels.6

Vit-D and analogues may be regarded as hormones, but are classified in group, calcium homeostasis- H05. The DDDs are based on therapeutic use. The DDD of 20mcg cholecalciferol corresponds to 800IU.

Table 1: Vitamin D and analogues-A11CC.

Name	ATC code	DDD	Route of administration
Dihydrotachysterol	A11CC02	1mg	0*
Alfacalcidol	A11CC03	1mcg	0*
Calcitriol	A11CC04	1mcg	P*
Cholecalciferol	11 CC05	1mcg	0*
Calcifediol	A11CC06	20mcg	0*

O= Oral, P= Parenteral

There are different forms of vit-D, namely cholecalciferol, calcidiol [25(OH)D] and calcitriol [1,25(OH)<sub>2</sub>D]. Choleclciferol is the naturally occurring form of vit-D. Choleclciferol is made in large quantities in skin when it is exposed to sunlight. After it is made in the skin or taken by mouth, cholecalciferol is transported to the liver where it is metabolized into calcidiol. Calcidiol follows one of two pathways, one responsible for bone and other for cellular effects. In kidney calcidiol is turned into calcitriol. Calcitriol the active form of vit-D and has now been shown to have anti cancer properties. <sup>(1,3)</sup> Calcipotriol (Calcipotriene) is a synthetic derivative of calcitriol with modified side chain. This has been used as a treatment for psoriasis topically.<sup>7</sup>

Studies from different parts of India indicate the wide prevalence of vit-D deficiency in our country. Deficiency was reported in all age groups including toddlers, children, pregnant women, adult males and females residing in rural and urban India.<sup>8</sup> Vit-D deficiency is highly prevalent with 30%-50% of adults at risk. Risk factors for vit-D deficiency include dark skin, advanced age and limited exposure to sun, use of sun screen lotions or extensive covering of the skin by clothing.<sup>9</sup>

Vit-D is necessary for the absorption of calcium and also has a role in the regulation of insulin secretion from pancreatic beta cells.<sup>10</sup> It is thought that vit-D may be involved in stimulating glucose transport and preventing systemic inflammation, which is associated with insulin resistance.<sup>11,12</sup> Low vit-D levels have been associated with abdominal obesity, hypertension and dyslipidemia.<sup>13</sup>

Intention of giving vit-D to patients is to reduce morbidity associated with vit-D deficiency. The type of vit-D, dose, frequency and duration of treatment is based on the goal of correcting vit-D deficiency for individual patients. Patients characteristics should be considered when prescribing a treatment, including skin colour, age and BMI.<sup>14</sup> In present study there was variability in the prescriptions of vit-D in different departments of tertiary health care centre. There was high prescription of vit-D in orthopedics and other departments. High percentage of prescriptions of vit-D reflects the increased awareness of the possible consequences of poor vit-D status.

Standardizing treatment approaches at a given clinical setting would improve care processes. Patient's vit-D level before treatment would be a logical starting point; according to it treatment regimen can be planned.<sup>15</sup>

The best way for estimating vit-D status is the measurement of serum 25(OH)D;<sup>1,7</sup>

- < 25nml/L is deficient
- 25-50nmol/L is border line.
- >50nml/L is adequate.

It is expensive test and many patients cannot afford it so they are advised to change lifestyle and supplement dose of vit-D without measuring serum 25(OH)D level. A loading dose regime consists of vit-D given over 6-8 weekly doses.300, 000IU; followed by maintenance therapy, consisting of vit-D in 800-2000 IU daily or intermittently (4000 IU).

Evidence from meta-analysis showed that serum 25(OH)D levels achieved better with cholecalciferol (D3) over ergocalciferol. (D2).<sup>1</sup> Oral vit-D<sub>3</sub> is the preferred choice in vit-D deficiency. In present study also oral route (98%) is preferred as compared to parenteral route (2%). Oral treatment is believed to be better absorbed than intramuscular route.<sup>16</sup>

In present study orthopedics, medicine and obstetrics and gynecology department prescribed calcium and vit-D combinations. Calcium is a mineral that is found naturally in foods. Calcium is necessary for many normal functions of body, especially bone formation and maintenance. Vit-D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body. Calcium and vit-D combination is used to prevent or to treat a calcium deficiency.<sup>17</sup>

Vit-D is actually a hormone rather than vitamin. Vit-D traditionally was viewed as permissive factor in calcium metabolism because it was thought to permit efficient

absorption of dietary calcium. Administration of 400-800 IU/ day of vit-D to elderly men and women has been shown to improve Calcium absorption, bone remodeling, protect bone mass and reduce fracture incidence.<sup>18</sup>

The clinical syndrome of vit-D deficiency can be a result of deficient production of vit-D in skin, lack of dietary intake, accelerated losses of vit-D, impaired vit-D activity or resistance to the biological effects of  $1,25(OH)_2D$ . Regardless of the cause, the clinical manifestation of vit-D deficiency are largely a consequence of impaired intestinal calcium absorption.<sup>7</sup> Based on the Institute of Medicine 2010 report, the recommended daily intake of vit-D is 600 IU from 1 to 70 years of age, and 800 IU for those over 70; based on the observation that 800 IU of vit-D , with calcium supplementation, decreases the risk of hip fractures in elderly women. For controlling calcium balance in adult, the recommended daily intake of calcium is 1000-1200 mg Thus, it is standard practice to ensure an adequate calcium and vit-D intake in patients with osteoporosis.<sup>7</sup> This will be helpful to maintain serum 25(OH)D above 30ng/ml.

## CONCLUSION

Highest prescriptions of Vit-D alone and with calcium found in orthopedic department. Most of the patients receive maintenance therapy after initial loading doses of Vitamin D supplement.

#### **Recommendations**

Periodic therapeutic audit is necessary to rationalize the use of vit D. Supplement doses in elderly can serve the purpose but serum levels assist in confirming causality and defining proper dose. Thus target concentration intervention has to be individualized.

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