Retrospective review of Vitamin D treatment at Veterans Affairs Medical Center.

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INTRODUCTION

•There are a number of conflicting views published on the treatment regimens for Vitamin D deficiency as well as recommended daily intake. [1-2]

•The frequency of laboratory monitoring and desired goals for patients taking Vitamin D vary among published guidelines and recommendations. [3]

•A recent study evaluating patients at a Veterans Affairs (VA) facility found inadequate monitoring and therapeutic endpoints of those with Vitamin D deficiencies. Upon receiving treatment, the authors also found that 22% of those patients remained at an insufficient Vitamin D level at follow up testing, while only 31% received follow up testing at all.[4]

•Results of this study may help guide clinical practice in order to assess and increase the quality of care provided to our veterans.

OBJECTIVE

•The primary objective was to describe the therapeutic regimens and laboratory monitoring of Vitamin D used in an outpatient setting of a VA facility. Quantification of adherence to published recommendations and/or guidelines was also assessed. Study endpoints included Vitamin D replenishment regimen, Vitamin D maintenance regimen, baseline and follow up serum 25-OH-D levels and timeframes.

METHODS

•A computer generated list of all outpatient prescriptions for Vitamin D 50,000IU filled between October 1st, 2009 and September 30th, 2011, was used..

•Charts were then reviewed to determine eligibility for participation in the study according to the following:

- •Inclusion criteria:
  - •Outpatient prescribed Vitamin D 50,000IU for at least 3 months
- •Exclusion criteria:
  - •Patients under the care of an outside provider.
  - •Patients receiving calcitriol or other prescription Vitamin D related drugs outside of the primary objective.
  - •Patients treated for Vitamin D deficiency related to parathyroid disorders or chronic kidney disease.

•The following data was collected: age, gender, height, weight, race, documented reason for Vitamin D therapy, therapy regimen, maintenance dose regimen, baseline and follow up 25-OH-D results and dates, date of prescription origination, documentation of specific disease states (diabetes, osteopenia, osteoporosis, Vitamin D deficiency, multiple sclerosis, other skeletal disorders)

RESULTS

- There were 804 prescriptions for Ergocalciferol (D2) 50,000IU and 1,511 prescriptions for Cholecalciferol (D3) 50,000IU during the study period. Due to the unexpected number of D3 prescriptions and time constraints of the student researcher, only the D2 prescriptions were evaluated. Only 355 prescriptions were reviewed after applying the inclusion/exclusion criteria. Table 1 summarizes the demographics of the patient population.

- Table 2 describes the initial and maintenance therapy prescribed. Nearly all patients were on a weekly 50,000 D2 to raise serum values to normal range. However, many patients did not complete the suggested 8 weeks of therapy before switching to a lower maintenance dose. Adherence of initial versus maintenance phase was not collected separately, but anecdotally it did seem as though many patients were prescribed 4 or 5 capsules to be taken weekly and had a remaining refill go unused. Appropriately so, adherence scores were lowest in the 4 and 5 week duration groups.

- Table 3 lists the results of serum Vitamin D monitoring. While 97.4% of patients had baseline serum monitoring on file, only 39.7% of patients had a follow up lab. Of these 141 patients, only 53.2% reached a sufficient Vitamin D level of ≥30ng/mL. The change from baseline to follow up had a mean of 16.1ng/mL but a SD of ±14.8ng/mL.

Table 1. Demographics.

Characteristic	Mean ±SD or %
Race	
Caucasian	70.1%
African American	21.4%
Pacific Islander	1.1%
Native American	0.3%
Declined	7.1%
Gender	
Male	94.1%
Female	5.9%
Age in years	64.1 ±13.1
Body Mass Index	30.6 ±6.8
Selected disease states	
Diabetes	34.4%
Osteopenia	1.1%
Osteoporosis	2.8%
Multiple Sclerosis	0.0%
Vitamin D Deficiency	19.7%
Other Skeletal Disorders	31.3%

Table 2. Vitamin D Regimens.

Vitamin D Regimens	*Rx's*	Adherence	Daily Dose
Replacement therapy regimens			
1 every month	1.9%	71.4%	1666
1 twice a week	0.8%	100%	14,285
2 capsules a week	0.3%	100%	14,285
1 every other week	0.3%	100%	3571
1 weekly	96.6%	57.4%	7142
Weekly replacement duration			Σ Dose
4 weeks	33.2%	32.2%	200k
5 weeks	10.4%	27%	250k
6 weeks	0.6%	50%	300k
8 weeks	16.9%	70%	400k
9 weeks	9.9%	88.6%	450k
10 weeks	9.6%	79.4%	500k
12 weeks	30.9%	63.6%	600k
13 weeks	3.9%	92.8%	650k
≥16 weeks	9.0%	87.5%	≥800k
Maintenance regimens			
D3- 800 Q Day	52.1%	45.6%	
D3 – 1,000 Q Day	18.8%	59.7%	
D3 – 5,000 Q 2 Weeks	0.3%	100%	
D2 -50,000IU Q Month	9.9%	74.3%	
D2 – 50,000IU Q Week	0.3%	100%	
None	18.6%	N/A	

Table 3. Laboratory Monitoring.

Vitamin D Levels (ng/mL)	Mean ±SD or %
Baseline serum 25,OH-D	15.8±5.9
Total	97.4%
Deficient <20	76.9%
Insufficient 20-29.9	19.7%
Sufficient ≥30	0.8%
Follow-up serum 25,OH-D	31.7±13.8
Total	39.7%
Deficient <20	9.9%
Insufficient 20-29.9	36.7%
Sufficient ≥30	53.2%
Change in 25,OH-D	16.1 ±14.8
Weeks between baseline & follow-up serum 25,OH-D	49.1 ±28.5

LIMITATIONS

•Not all patients had baseline and follow up 25-OH-D levels.

•An additional 1511 prescriptions for Cholecalciferol 50,000IU (Vitamin D3) were reported alongside the 804 Ergocalciferol 50,000IU prescriptions, but the timeframe of the study did not allow for those prescriptions to be included. Further study in that direction is warranted to get a more complete picture of prescribing practices for Vitamin D replacement therapy at this facility.

•This study was not designed to prospectively or retrospectively judge the efficacy of various treatment regimens.

•Adherence was marked as 'No' if a patient either failed to use all refills of the initial Vitamin D replacement therapy *or* failed to refill their maintenance regimen fewer than three times.

•46% of the patients in this population were obese and there has been some evidence in the guidelines that two to three fold higher doses of Vitamin D are necessary in this population to achieve appropriate endpoints. [2]

CONCLUSIONS

•Only 39.7% of patients prescribed D2 had follow up monitoring performed. Of those with follow up data, only 53.2% reached a sufficient therapeutic level of serum 25-OHD.

•Additional action is warranted to ensure follow up labs are ordered for patients on Vitamin D to reduce the number of veterans who may have need Vitamin D regimen adjustments or adherence counseling.

•Due to the composite means by which adherence was assessed, no determination can be made about the impact it had on therapy.

•The two most common replacement regimens were 50,000IU of D2 weekly for 4 weeks (34%), and the same for 8 weeks (17%). The 4 and 5 week regimens had adherence rates of 32.2% and 27% respectively, which may play a large role in the number of patients who failed to achieve a sufficient Vitamin D level at follow up.

•While nearly all replacement regimens meet the current guidelines for replacement therapy of a minimum daily equivalent dose of 6000IU, 44% of the regimens do not meet the minimum 8 weeks suggested. [2]

REFERENCES

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