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Original Research Article

Comparative Study of Efficacy of Atorvastatin versus Atorvastatin with Vitamin D3 in Patients with Dyslipidemia Attending Tertiary Care Hospital

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Conflict of interest: Nil

Abstract:

Introduction: Hyperlipidemia is a well-known risk factor for atherosclerosis, accounting for a significant proportion of ischemic strokes and heart disease globally. Vitamin D supplementation paired with atorvastatin has been shown in studies to have synergistic effects in lowering serum cholesterol levels and treating statin-induced myalgia and myopathies. The study was done to determine the effect of a fixed dose combination of 1000 I.U of Vitamin D3 and Atorvastatin 10mg per day on serum HDL, VLDL, and Triglyceride values in hyperlipidemic individuals compared to those on Atorvastatin 10 mg per day for six months.

Materials and Methods: This prospective randomized comparison study took place in a tertiary care hospital's outpatient general medicine department for six months. A total of 100 patients with dyslipidemia were selected. Out of 100 patients, 50 were given atorvastatin 10 mg, and the other 50 were given atorvastatin 10 mg and 1000 IU of Vitamin D3 orally. Patients were monitored monthly for six months, and their lipid profiles were examined at the beginning and end of the study. The data was entered into a Microsoft Excel worksheet and then imported into the SPSS version 23.0 software for analysis. An unpaired t-test was used to assess differences in changes between the two treatment groups.

Results: Total cholesterol, Low Density Lipoproteins, very Low Density Lipoproteins & Triglycerides were significantly reduced and the High Density Lipoproteins significantly increased in atorvastatin and Vitamin D3 group than in atorvastatin group at the end of 6 months.

Conclusion: Both groups showed significant changes in their plasma lipid profiles. However, the atorvastatin and vitamin D3 group performed better than the atorvastatin-treated group.

Keywords: Atorvastatin. Vitamin D, Lipid Profile, Dyslipidemia, CAD.

Introduction

Dyslipidemia, defined as low levels of high-density lipoprotein (HDL) cholesterol or high levels of total or low-density lipoprotein (LDL) cholesterol, is a significant risk factor for coronary heart disease (CHD) and stroke.[1] Cardiovascular diseases (CVD) are currently the leading cause of death in India, much like in Western countries. According to an Indian Council for Medical Research (ICMR) survey, 79% of the people examined had at least one lipid issue, with variances depending on the locality. [2]

Lowering blood cholesterol is one of the most important strategies for managing and preventing CAD.[3] Encouraging healthy lifestyle changes is the first and most significant step toward preventing atherosclerotic vascular disorders. It is recommended that they limit their intake of foods high in trans fats and calories. They should accomplish 150 minutes of moderate-intensity physical activity every week.[4]

Despite the fact that statins are primarily used to treat cardiovascular disorders, statin-induced myopathy is a significant contributor to patient nonadherence and statin cessation. Vitamin D deficiency, which weakens muscles, may worsen statin-induced myopathies. Increasing vitamin D levels may aid with statin tolerance. [5] Despite being a bright, tropical country, India has the highest prevalence of vitamin D deficiency (70%) among all countries.[6] The study was done to determine the effect of a fixed dose combination of 1000 I.U of Vitamin D3 and Atorvastatin 10 mg

per day on serum HDL, VLDL, and Triglyceride values in hyperlipidemic individuals compared to those on Atorvastatin 10 mg per day for 6 months.

Materials and Methods

The prospective randomized comparative study was conducted for 6 months in the outpatient department of General Medicine at Medical College & General Hospital, Kurnool, following permission by the institutional ethical committee.

Inclusion criteria: Patients aged 30-70, either gender, with dyslipidemia, and willing to participate.

Exclusion criteria: Patients with chronic renal failure, chronic liver illness, bone ailments, or thyroid problems. Hyperlipidemic patients on various cholesterol-lowering medications.

Patients who require or are currently taking vitamin D with or without calcium for bone disease prevention or treatment. A valid written informed consent was taken from patients after explaining study to them. Out of 100 patients, 50 received atorvastatin 10 mg/day orally, whereas the remaining 50 received atorvastatin 10 mg and 1000 IU of Vitamin D3 orally.

A case record form was utilized to gather demographic data, medical history, and treatment details. Blood samples were taken at two points in time: baseline and three months. Blood samples were taken and tested in the Department of Clinical Biochemistry in accordance with clinical guidelines. Following a 12-hour overnight fast, blood was drawn from an antecubital vein and placed in Vacutainer tubes. Triglyceride levels were determined by enzyme colorimetry [7]. The cholesterol esterase method [8] was employed to measure total cholesterol (C.V. 14.1%) and HDL cholesterol, the latter being precipitated from serum using phosphotungstic acid and magnesium ions [9]. The concentration of very low density lipoprotein (VLDL) cholesterol was determined by dividing the triglyceride level by five [10]. Then calculate the LDL cholesterol concentration using the Friedewald et al. [11] formula: LDL cholesterol (mg/dl) = total cholesterol - (HDL cholesterol).- T.G/5.

Statistical Analysis: The data was entered into a Microsoft Excel worksheet and then imported into the SPSS version 23.0 software for analysis. An unpaired t-test was used to assess differences in changes between the two treatment groups.

Results

A total of 100 patients were enrolled in the study Among the 100 patients analyzed, 54% were male and rest were female (46%). The age of patients ranged from 30 yrs to 70 yrs. Average patient age was 53.43 yrs. The baseline characteristics of patients in the two treatment groups are shown in Table 1.

Table 1: Demographic characteristics of the two treatment groups

Variables	Atorvastatin (n=50)	Atorvastatin and vitamin D3 (n=50)
Gender		
Male	28	26
Female	22	24
Age (years)	55.42±7.4	54.65±7.2

Reduction in the total cholesterol. LDL cholesterol, VLDL cholesterol & TG and increase in the HDL cholesterol was observed in the Atorvastatin treatment group after 6 months of treatment as shown in Table 2

Table 2: Effect of atorvastatin on lipid profile in group A, (n=50).

Lipid profile	Before AVS	After AVS
Total Cholesterol mg/dl	212.12 ± 16.23	185.64± 17.76
LDL mg/dl	148.32 ± 13.78	118.76 ±12.92
HDL mg/dl	37.43 ± 2.83	40.25± 2.93
VLDL mg/dl	38.34 ±8.24	29.23 ± 8.12
TG mg/dl	171.62 ± 43.62	158.26 ± 42.12

Reduction in the total cholesterol. LDL cholesterol, VLDL cholesterol & TG and increase in the HDL cholesterol was observed in the Atorvastatin and Vitamin D3 treatment group after 6 months of treatment as shown in Table 3

Table 3: Effect of atorvastatin on lipid profile in group A, (n=50).

Lipid profile	Before AVS and Vit. D3	After AVS and Vit. D3
Total Cholesterol mg/dl	215.12 ± 18.41	168.56± 15.64
LDL mg/dl	155.45 ± 13.45	99.64 ±10.87
HDL mg/dl	36.23 ± 2.92	42.45± 3.01
VLDL mg/dl	39.56 ±8.65	27.42 ± 8.02
TG mg/dl	175.78 ± 45.56	139.86 ± 39.32

Total cholesterol. LDL cholesterol, VLDL cholesterol & TG were significantly reduced and HDL cholesterol was significantly increased in the Atorvastatin and vitamin D3 treatment than in the Atorvastatin group at the end of 6 months of treatment as shown in Table 4

Table 4: Comparison of Atorvastatin and Atorvastatin with Vitamin D3 on lipid profile at the end of 6th month

Lipid profile	Atorvastatin group (n=50)	Atorvastatin and vitamin D3 group (n=50)	P value
Total Cholesterol mg/dl	185.64± 17.76	168.56± 15.64	0.002*
LDL mg/dl	118.76 ±12.92	99.64 ±10.87	0.01*
HDL mg/dl	40.25± 2.93	42.45± 3.01	0.001*
VLDL mg/dl	29.23 ± 8.12	27.42 ± 8.02	0.01*
TG mg/dl	158.26 ± 42.12	139.86 ± 39.32	0.02*

***significance**

Discussion:

Before beginning pharmacological therapy, plasma lipid profiles were performed, and treatment efficacy in both groups was measured by measuring plasma lipid profiles at sixth month. Both groups' plasma lipid profiles improved significantly. However, the atorvastatin and vitamin D3 group showed greater improvement than the atorvastatin-treated group.

Schwartz observed that vitamin D supplementation lowers LDL and total cholesterol levels. They concluded that vitamin D supplementation lowered blood lipid profiles [12]. Ahmed et al. at the Jewish Hospital of Cincinnati's cholesterol section in Cincinnati, Ohio, reported that vitamin D3 improved statin tolerance by reducing myalgia [13]. In the Abhima et al 2020 trial, a fixed dose combination of vitamin D3 1000 IU and atorvastatin 10 mg per day for three months resulted in a substantial mean percentage increase in HDL levels as compared to the atorvastatin group. [14]]

According to Ahmed et al. study from the Jewish Hospital of Cincinnati, vitamin D relieved statin-induced myalgia. Failure to comply is caused by one of the statins' negative effects.[13] A study conducted by Harold E Bays using Atorvastatin 10mg for 8 weeks revealed a median percentage increase in HDL Cholesterol of 10, which was larger than the data in our study.[15]

According to Rasa et al., vitamin D protects the heart by encouraging the production of large HDL particles, which aid in the reverse transfer of cholesterol. [16] Maki et al. found a strong association between 25(OH)D and HDL-C after controlling for established HDL-C determinants, such that for every 10 ng/mL increase in 25(OH)D, HDL-C concentration increased by 4.2 mg/dL. [17]

Conclusion

When vitamin D3 supplementation is combined with atorvastatin, patients with dyslipidemia show improved lipid profile responses as compared to when atorvastatin is taken alone.

There seems to be an additional effect of vitamin D supplementation on cholesterol levels.

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