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Original Research Article

Prospective Study Comparing the Effect of Atorvastatin and Atorvastatin with Vitamin D3 Granules on Lipid Profile of Hyperlipidemic Patients

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Abstract

Background: Lipid imbalances are considered to be a risk factor for cardiovascular diseases. Vitamin D supplementation combined with atorvastatin has been proven in studies to have synergistic effects in decreasing serum cholesterol concentrations. The current study compared the effect of combination of 1000 I.U of Vitamin D3 and Atorvastatin 10 mg per day to Atorvastatin 10 mg per day on serum total cholesterol, HDL, LDL, VLDL, and Triglyceride readings in hyperlipidemic patients.

Methodology: Between January 2022 and December 2022, 100 patients with Dyslipidemia were studied in the outpatient department at Viswabharathi Medical College & General Hospital, Kurnool. Out of 100 patients, 50 received atorvastatin 10 mg/day orally for 4 weeks, whereas the remaining 50 received atorvastatin 10 mg and vitamin D3 1000 IU/day orally for 4 weeks. The plasma lipid profile was evaluated prior to intervention, as well as at the baseline, 4th week of the treatment, at 3 months and at 6 months.

Results: The mean total cholesterol, the mean Low Density Lipoproteins, very Low Density Lipoproteins & Triglycerides were significantly reduced and the mean High Density Lipoproteins significantly increased in atorvastatin + Vitamin D3 group than in atorvastatin group at the end of 3 months.

Conclusion: Plasma lipid profile improved significantly ($P<0.05$) in both groups. However the improvement was more in the atorvastatin + vitamin D3 group compared to atorvastatin treated group.

Keywords: Vitamin D, Atorvastatin. Lipid Profile.

Introduction

Lipid abnormalities are widespread in the general population and are considered to be a modifiable risk factor for cardiovascular diseases (CVD). Low vitamin D status has recently been linked to an increased risk of developing hyperlipidemia [1, 2]. Vitamin D levels must be adequate for optimum vascular health. [3] A lack of vitamin D is linked to an increased risk of CVD. [4] The rising frequency of vitamin D insufficiency is a major public health concern. In the general population, vitamin D insufficiency is an independent risk factor for mortality [5]. Several studies have been conducted to support the importance of vitamin D in the prevention and treatment of a variety of diseases, including heart disease, hypertension, dyslipidaemia, type 2 diabetes, autoimmune diseases, TB, cancer, etc. It has also been discovered that there is a substantial link between low vitamin D levels [6]. Many doctors recommend taking 1000 IU of vitamin D every day orally in hyperlipedemia patients [7].

Statins are typically prescribed as first-line therapy for hypercholesterolemia. Vitamin D has also been shown to improve blood lipid levels [8,9]. However, its effects on people with hypercholesterolemia are unknown [10,11]. As a result, the purpose of this study was to assess the effect of combination of 1000 I.U of Vitamin D3 and Atorvastatin 10mg per day for 4 weeks with Atorvastatin 10 mg per day for 4 weeks on serum total cholesterol, HDL, LDL, VLDL, and Triglyceride readings in hyperlipidemic patients.

Methodology

After Institutional ethics committee approval and informed consent, the prospective interventional study was carried out between January 2022 to December 2022 in the outpatient department of General Medicine at Viswabharathi Medical College & General Hospital, Kurnool for a period of 3 months. Patients of either gender between 30-70 years, were included in the study. The study included 100 participants with Dyslipidemia. The persons with HIV and malignancy were excluded. Out of 100 patients, 50 were given atorvastatin 10 mg/day orally, whereas the remaining 50 were given atorvastatin 10 mg and Vitamin D3 1000 IU/day orally for 4 weeks.

Exclusion criteria

1. Patients suffering from chronic renal failure, chronic liver disease, bone diseases, or thyroid issues
2. Hyperlipidemic patients using any other cholesterol-lowering medication.
3. Patients who need or are already 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. A case record form was used to collect demographic information, medical history, and treatment specifics.

Blood samples were collected at baseline, 4 weeks, 3 months and 6 months. Blood samples were collected and analysed in the Department of Clinical Biochemistry in accordance with clinical standards. Blood samples were taken from an antecubital vein into Vacutainer tubes after a 12-hour overnight fast. Enzyme colorimetry was used to determine triglycerides [12]. The cholesterol esterase method [13] was used to estimate total cholesterol (C.V. 14 3.1%) and HDL cholesterol, the latter following precipitation from serum with phosphotungstic acid and magnesium ions [14].

The concentration of very low density lipoprotein (VLDL) cholesterol was calculated by dividing the triglyceride level by five [15] and the LDL cholesterol concentration by using the Friedewald *et al.* [16] formula: LDL cholesterol (mg/dl)= total

cholesterol-(VLDL-cholesterol+DLcholesterol). The following were considered the thresholds of normality: total cholesterol <220 mg/dl, triglycerides <150 mg/dl, HDL-cholesterol <45 mg/dl, LDL-cholesterol <130 mg/dl.

Statistical Analysis

The data was entered in Microsoft Excel worksheet and imported into SPSS version 18.0 software for analysis. Differences between changes in the two treatment groups were compared using an unpaired t-test and ANOVA.

Results

A total of 100 patients were enrolled in the study. All the patients were followed up till the completion of the study. Among the 100 patients analyzed, 54% were male and rest were female (46%). (Fig 1). The age of patients ranged from 30 yrs to 70 yrs. Average patient age was 53.43 yrs.

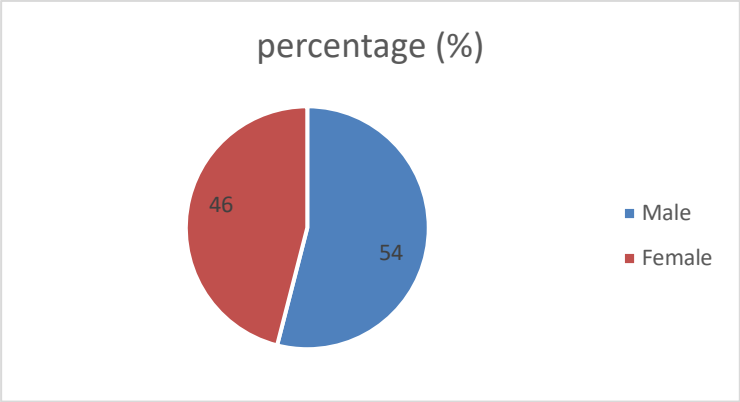

Figure 1: Gender distribution of patients with Dyslipidemia

Table 1: Effect of Atorvastatin on lipid profile of hyperlipidemic patients (Atorvastatin group)

Parameter	Baseline	4 weeks	3 months	6 months
Total Cholesterol mg/dl	202.6±43.5	198.3±42.2	197.2±41.3	192.5±39.8
LDL mg/dl	132.5 ±33.6	130.6±31.5	129.1±30.2	129.2±28.4
HDL mg/dl	38.9± 12.4	39.2±12.6	39.3±12.8	39.4±13.1
VLDL mg/dl	31.6±8.2	30.4±8.4	30.9±8.2	28.2±8,1
TG mg/dl	131.5±54.1	128.4±51.2	129.8±52.3	124.3±50.2

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 4 weeks, 3months & 6 months of treatment. (Table 1).

Table 2: Effect of Atorvastatin and vitamin D3 on lipid profile of hyperlipidemic patients (Atorvastatin and vitamin D3 group)

parameter	Baseline	4 weeks	3 months	6 months
Total Cholesterol mg/dl	206.8±43.2	196.6±42.5	183.7±41.3	169.6±39.5
LDL mg/dl	134.5 ±32.1	126.6±29.3	112,7±27.5	98.4±23.1
HDL mg/dl	39.2±12.1	42.2±12.2	44.6±12.3	50.7±11.8
VLDL mg/dl	32.7±7.9	28.4±7.2	26.8±7.4	20.8±6.9
TG mg/dl	138.6±58.1	126.4±52.1	122.9±42.2	116.4±32.2

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. (Table 3).

Table 3: Comparison of Atorvastatin and Atorvastatin with Vitamin D3 on lipid profile at the end of 6th month.

parameter	Atorvastatin group (n=50)	Atorvastatin and vitamin D3 group (n=50)	P value
Total Cholesterol mg/dl	192.5±39.8	169.6±39.5	<0.001
LDL mg/dl	129.2±28.4	98.4±23.1	<0.001
HDL mg/dl	35.2±13.1	50.7±11.8	<0.001
VLDL mg/dl	28.2±8,1	20.8±6.9	<0.001
TG mg/dl	124.3±50.2	116.4±32.2	<0.001

Discussion

Before beginning pharmacological therapy, plasma lipid profiles were performed, and treatment efficacy in both groups was measured by measuring plasma lipid profiles at the first, third, and sixth months. Both groups' plasma lipid profiles improved significantly. However, the improvement in the atorvastatin vitamin D3 group was much greater than in the atorvastatin treated group. JB Schwartz discovered that vitamin D supplementation reduced LDL cholesterol and total cholesterol levels. They came to the conclusion that vitamin D supplementation reduced serum lipid profiles [17]. Ahmed *et al*., from the Jewish Hospital of Cincinnati's cholesterol unit in Cincinnati, Ohio, discovered that vitamin D3 increased statin tolerance by lowering myalgia [18].

In our study, it was discovered that the Atorvastatin-Vitamin D3 treated group had a larger percentage elevation in HDL cholesterol levels at 3 months than the Atorvastatin treated group. There were no serious adverse effects reported. Several studies have revealed a link between Vitamin D3 and HDL cholesterol. Maki *et al.* found a substantial association between Vitamin D3 and HDL-C after controlling for established HDL-C determinants, such that for every 10 ng/mL increase in Vitamin D3 there is a 4.2-mg/dL increase in HDL-C concentration. [19] Rasa *et al*. discovered that high serum Vitamin D3 levels are related with more HDL particles in another investigation. They determined that vitamin D3 protects the heart by boosting the production of more HDL particles, which aid in reverse cholesterol transfer. [20]

Conclusion

Both groups of plasma lipid profiles improved significantly. However, the improvement in the atorvastatin + Vitamin D3 group was much greater than in the atorvastatin treated group.

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