

Effectiveness of Atorvastatin in the Management of Hypercholesterolemia

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ABSTRACT

Introduction- India is currently undergoing a significant transformation in its epidemiological landscape as a result of variables such as population growth, economic progress, urbanization, and an aging population, all of which contribute to alterations in risk factors. The increase in cardiovascular risk and hypercholesterolemia is associated with the adoption of unfavorable lifestyles. Statins are used very commonly as lipid-lowering medications.. Although statins have proven to be helpful, additional research is required to fully comprehend their efficacy, potential negative effects, and long-term toxicity. **Methodology-**A study was carried out at SS Hospital, IMS, BHU, Varanasi to evaluate the impact of Atorvastatin treatment on Hypercholesterolemia. This study focused on persons who were visiting the outpatient department (OPD) of the Modern Medicine hospital. The intervention was conducted within the hospital setting. **Result and Discussion-** The consistent and comparable triglyceride/LDL cholesterol reduction was observed after treatment with Atorvastatin. No major side effects were observed on biochemical tests, like LFT and KFT over 90-day follow up. A long term follow up and histological examination, either invasive or non-invasive, is required to give conclusive report.

Keywords-High Cholesterol, hypercholesterolemia, lipid profile, Atorvastatin, Clinical trial,

Introduction

India is currently experiencing a swift shift in its epidemiological situation due to factors such as a growing population, economic development, urbanization, and an aging population, which in turn leads to changes in risk factors¹.The occurrence of cardiovascular risk and hypercholesterolemia is linked to the adoption of un-favourable lifestyles, including increased smoking and tobacco use, changes in dietary habits with higher consumption of unhealthy foods, and a rise in sedentary behaviour^{2,3}. The INTERHEART study has found that apolipoproteins, specifically high levels of ApoB and low levels of ApoA1, along with elevated total and LDL cholesterol, are the primary risk factors for coronary heart disease (CHD) on a worldwide scale, including South Asian countries.⁴ During clinical trials, it has been regularly seen that medications aimed at reducing cholesterol levels effectively reduce the risk of stroke.⁵ In Allopathy statins is very common for lowering the cholesterol level.

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Statins exhibit great efficacy in decreasing LDL levels and moderate efficacy in increasing HDL levels. The reduction of triglycerides is directly proportional to both the initial number of triglycerides and the effectiveness of the medicine in lowering LDL cholesterol. ⁷⁻⁸ Statins, as a class, are generally well tolerated and there are no known discrepancies in terms of safety. The most detrimental consequences include hepatotoxicity and myotoxicity. The occurrence of transaminase elevation larger than three times the normal level is 1% for all statins and is directly related to the dosage. ⁹ The major adverse effect of statins is myopathy, defined as muscle pain or weakness associated with Creatine Kinase (CK) levels higher than 10 times the upper limit of normal. ¹⁰

Statins are highly effective in reducing cholesterol levels; however, further investigation is required to better understand their efficacy and potential adverse effects in the human body.

Methodology

Planning of the Study: A Hospital-based Intervention Study was planned to determine the efficacy and adverse effect of atorvastatin on High Cholesterol patients in SS Hospital, IMS, BHU, Varanasi.

Research Strategy: Interventional Study

Research Setting: This was a hospital-based study conducted in the SS Hospital, IMS, BHU, Varanasi.

Diagnostic Criteria: Where the participants had total cholesterol levels >200 mg/dL (5.2 mmol/L) or Low density lipoprotein cholesterol (LDL C) levels >130 mg/dL (3.4 mmol/L) or Triglycerides < less than 150 mg/dl or HDL < 40mg/dl.

Sample Size: Total Sample Size = 35

Inclusion Criteria

1. People with abnormal cholesterol levels
2. Participants should be in stable health without any acute medical conditions, significant comorbidities, or recent cardiovascular events (e.g., heart attack, stroke) within the past three months.

Exclusion Criteria

1. The patient not giving consent to participate in the study.
2. People whose blood sugar is uncontrolled.

A total of 35 patients with a diagnosis of High Cholesterol were enrolled in the study. The cases were randomly allocated regardless of their age, sex, religion, socio-economic status, etc. 35 clinically diagnosed and registered patients of Deranged Lipid Profile were treated by- Atorvastatin 10 mg OD tab – 90 days.

Result

The study assessed the impact of Atorvastatin on several lipid parameters over three visits: baseline (first visit), after 30 days (second visit), and after 90 days (third visit). Regarding total cholesterol, there was a notable enhancement in number of normal patient converting from abnormal value. As the proportion of patients with levels below 200 mg/dL rose from 28.57% initially to 60% after 30 days, and subsequently to 82.86% after 90 days. The proportion of patients with triglyceride levels below 150 mg/dL increased from 37.14% at the beginning to 51.43% after both 30 and 90 days. The LDL levels showed significant improvement, with the proportion of patients with LDL levels below 100 mg/dL increasing from 37.14% at the beginning of the study to 48.57% after 30 days, and further to 57.14% after 90 days. The levels of high-density lipoprotein (HDL) also showed improvement, with the percentage of patients having HDL levels

above 60 mg/dL increasing from 20% at the beginning of the study to 34.29% after 30 days, and further increasing to 51.43% after 90 days. The trends of improvement in lipid profile i.e. decrease in Total cholesterol, triglyceride and LDL; and increase in HDL is being seen.

Fig. – 1: Number of patient sin Normal Range (Lipid Profile) before and after treatment

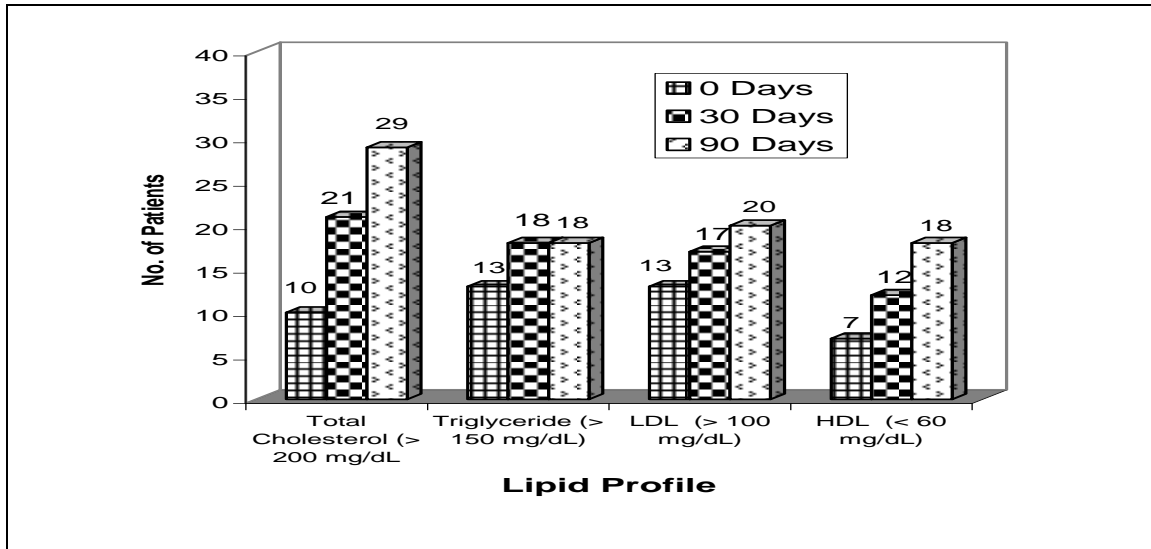


Table -1: Changes in a diagnostic test value at each level of treatment (0 days vs 30 days vs 90 days)

Parameter	Basic line	After 30 Days	After 90-Days	Within-group comparison (Repeated Measures ANOVA One Way) and Friedman Test for non-parametric
	1 st Visit	2 nd Visit	3 rd Visit	
BP(Systolic)	138.15 ± 30.52	127.11 ± 15.86	127.31 ± 15.93	F=2.611; P=.089
BP(Diastolic)	83.94 ± 28.27	82.51 ± 21.14	83.31 ± 15.57	F=0.099;P=0.906
Weight(kg)	65.37 ± 14.29	65.6 ± 13.92	67.97 ± 17.82	F=1.181;P=.320
BMI	26.27 ± 5.88	26.36 ± 5.7	27.36 ± 7.68	F=1.078;P=0.352
Platelet Count (Lac/Cumm) Day	175.01 ± 73.61	182.56 ± 54.46	189.63 ± 48.33	F=1.709;P=0.202
Total Bilirubin (mg/dl) ^a	0.65 ± 0.29	0.69 ± 0.35	0.68 ± 0.27	χ ² = 12.02;p=0.002
Direct Bilirubin (mg/dl) ^a	0.28 ± 0.21	0.31 ± 0.21	0.3 ± 0.15	χ ² = 11.748;P=0.003
Indirect Bilirubin (mg/dl) ^a	1.13 ± 4.51	0.38 ± 0.29	0.37 ± 0.28	χ ² = 1.068; P=.586
AST (SGOT) (U/L) ^a	35.12 ± 18.67	36.51 ± 14.12	37.41 ± 17.38	χ ² = 17.73; p=0.000
ALT (SGPT) (U/L) ^a	36.58 ± 18.72	37.01 ± 12.73	40.62 ± 16.44	χ ² =10.824; p=0.004
Alk. Phosphatase (U/L) ^a	182.82±105.75	177.66 ± 78.48	187.91 ± 96.06	χ ² =8.809; p=0.12
Albumin(g/dl) ^a	4.27 ± 0.49	4.33 ± 0.52	4.33 ± 0.56	χ ² =.311; p=0.856
Serum Urea Day	27.37 ± 14.8	27.5 ± 14.5	27.3 ± 14.23	F=.548; P=0.584
Serum Creatinine Day ^a	0.89 ± 0.3	1.44 ± 3.33	0.79 ± 0.17	χ ² = 1.083; P=.306
Total Cholesterol Day	225.15 ± 53.22	189.72 ± 45.1	175.56 ± 31.93	F=26.552; P=0.00
Triglyceride Day ^a	226.34±166.52	181.4 ± 92.52	165.33 ± 70.91	χ ² = 37.222; P=0.000
LDL Day	117.89 ± 48.39	103.15 ± 37.45	93.37 ± 28.67	F=12.65; P=0.00
HDL Day	49.68 ± 15.29	52.76 ± 17.82	55.52 ± 15.61	F=5.550; P=0.008

a= Within group comparison more than two measurements (Friedman Test)

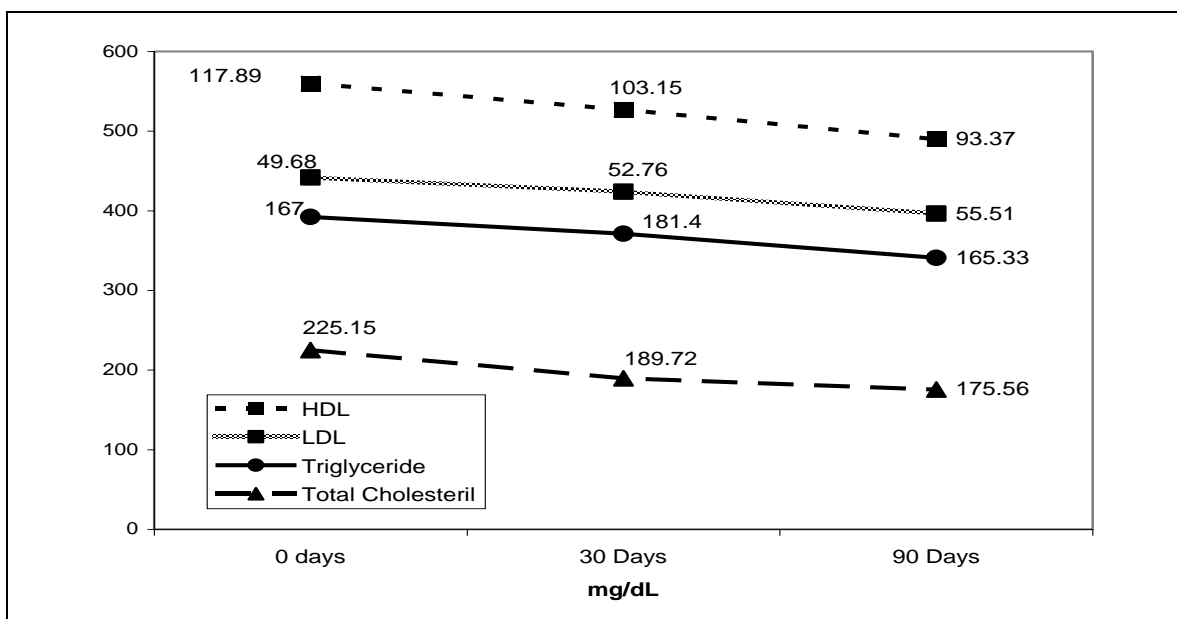
The table presents the results of parameters measured at three specific time points: the initial visit, 30 days later (second visit), and 90 days later (third visit). The measurements were assessed using Repeated Measures ANOVA One Way and the Friedman Test to examine comparisons within the groups, with the latter being especially for non-parametric data.

There were no notable changes in the blood pressure readings, including both systolic and diastolic measurements, during the duration of the study. The weight and BMI exhibited a slight rise, however, the alterations were not statistically significant.

The levels of bilirubin showed significant change, with total bilirubin fluctuating significantly and direct bilirubin increasing significantly with time. Specifically, AST (SGOT) and ALT (SGPT), exhibited a significant rise over a period of time.

There were no significant elevations in serum urea. There were variations in the levels of serum creatinine, but these differences were not statistically significant. The study revealed a significant decline in overall cholesterol, triglycerides, and LDL levels as time progressed. Furthermore, there was a substantial rise in HDL levels.

Figure-1.1: Lipid Profile changes before and after treatment



The findings indicate that Atorvastatin effectively reduces total cholesterol levels resulting in a notable decrease in Total Cholesterol and LDL and TG. HDL is showing increase in value.

This table provides a proportion of adverse events in patients. Gas was reported by 6 (17.15%) persons of the total. Eye itching and skin were recorded 1 (2.85%) and 1 (2.85%) respectively of the total. Significantly, the group, consisting of 27 individuals (77.15%), did not encounter any negative effects.

Table- 3: Side Effect of Atorvastatin

Side Effect	No.	%
Gas	6	17.15
Eye Itching	1	2.85
Skin Rashes	1	2.85
No side effect	27	77.15
Total	35	100

Discussion

Statin is a useful medicine for controlling total Cholesterol, Triglyceride, LDL, and HDL. Atorvastatin is a prevalent and significant medication used to reduce cholesterol levels. Statin is a useful medicine for controlling total Cholesterol, Triglyceride, LDL, and HDL. The atorvastatin dose-ranging study.¹¹ employed a broad range of doses, from 5 to 80 mg/dL, with 13 to 16 individuals in each group showed good result of stain.

The result of this study emphasizes the substantial effectiveness of atorvastatin in treating hypercholesterolemia in patients, which is consistent with the findings reported in prior studies. Atorvastatin significantly decreased overall cholesterol, LDL cholesterol, and triglyceride levels, while simultaneously increasing HDL cholesterol levels. This indicates that atorvastatin has the ability to improve lipid profiles and hence lower the likelihood of cardiovascular events. The study also noted no negative consequences (for 90 Days), which further reinforces the safety of atorvastatin.

This study is showing the findings, which is in agreement with the many of studies conducted to show the effectiveness of atorvastatin. But, these encouraging findings do not ensure that Statins are the best drug for management of dyslipidemia. Because several questions still need to be answered with surety. Mechanism of action of statin is to move the cholesterol from peripheral blood to liver. Liver is the organ of metabolism for lipid, carbohydrate and protein as well. Notwithstanding, it is also a detoxifying organ of our body. A patient of hypercholesterolemia may need to take it for long time, even if for rest of life ¹² and this is the major limitation of statin therapy. In many of the studies, macroscopic changes are suggestive of increased grade of fatty changes of liver. Our study showed the considerable improvement in lipid markers on biochemical examination during the 90-day therapy period. Considering the duration of treatment for dyslipidemia and the burden of this disease in Indian community, a long term follow-up study is required. Histological examination, either invasive or non-invasive, is required to give conclusive report. The advent and availability of diagnostic technique like Fibroscan will improve the diagnosis of pathology, conclusively.

In India, prevalence of high cholesterol is 15-20% in rural subjects and 25-30% in Urban community¹³. Major fund of health sector are now being directed towards the management of non-communicable diseases. Ayushman Bharat is an ambitious programme to address the ailing health condition of the society. If the treatment of high cholesterol is to be taken for long duration, fund flow for PMJAY and Health & Wellness Centre will need to be increased further. This may put an extra economic burden on the Indian society. A 90 day study does not provide information to conclusively deny the absence of long term liver complications. Also, there is needed to go to look for the alternative therapy for the short term curative regimen.

Conflict of Interest- None

Ethical Approval -Yes

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