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Comparing the Clinical Effectiveness of High-Dose and Low-Dose Statin Therapy in Patients with Atherosclerotic Coronary Artery Disease (CAD)

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ABSTRACT

Coronary artery disease is associated with the circulatory system and leading cause of death around the globe, **Objective:** To compare the mean changes in low-density lipoprotein cholesterol with high and low doses of statin therapy. **Methods:** A non-randomized controlled trial at the Department of Cardiology, Fauji Foundation Hospital Rawalpindi was conducted from January 26-2023 to July 25-2023, among patients aged 45-75 years of both genders with ST-elevation myocardial infarction or non-ST-elevation myocardial infarction. Patients were divided into groups using a convenience sampling technique. Patients in Group A were given high-dose statin therapy atorvastatin 40mg orally daily. While Group B received low-dose statin therapy atorvastatin 20mg orally daily. The low-density lipoprotein cholesterol level was repeated after 3 months. Data were entered and analyzed using SPSS version 23. **Results:** The mean age of Group A was 56.14 ± 8.9 years and Group B was 57.5 ± 9.7 years, as per gender distribution group A showed 57.1% and Group B 68.6%, whereas, the females in Group A, were calculated as 42.9% and in Group B 31.4%. The mean changes observed in low-density lipoprotein cholesterol were significantly higher in groups in comparison to the group with low-dose statin therapy. The changes observed were significant at 35 ± 27.8mg/dl in higher statin therapy versus 21.4 ± 20 mg/dl with a p-value of 0.024. **Conclusions:** It was concluded that high-dose statin causes a greater reduction in low-density lipoprotein cholesterol levels. The high-dose therapy could be a great option in treating the low-density lipoprotein in initial management.

INTRODUCTION

Coronary artery disease (CAD) is a disease of the cardiovascular system and one of the major causes of death among underdeveloped countries [1]. According to an estimate, the deaths recorded in 2019 were 17.9 million which represented 32% of total deaths globally [2], whereas 85% of deaths were recorded from other heart diseases and associated risk factors, such as obesity, smoking, alcohol, and high blood pressure [3]. The main cause of CAD is atherosclerosis, which is a plaque development in the arteries, whereas the plaque development is majorly due to fat accumulation, cholesterol, waste products of calcium, and the clot-making substance fibrin [4]. Low-density lipoprotein (LDL) reduction is associated with a significant decrease in mortality in patients with CAD and statins represent the most effective drugs to achieve this. Statins are the type of medication used to treat artery diseases, in-lowering cholesterol, and preventive therapies for cardiovascular diseases. Statins include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and

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simvastatin [5]. These effects include attenuation of vascular inflammation, improved endothelial cell function, and atherosclerotic plaque stabilization. Statins not only reduce the risk of atherosclerotic coronary disease but also reduce total mortality in secondary prevention [6]. A researcher studied the level of Low-Density Lipoprotein Cholesterol (LDL-C). After administration of atorvastatin 10 mg and 80 mg respectively [7]. The result of their study showed a significant reduction of LDL with a low dose of statin therapy. The mean LDL was lower in low-dose statin therapy i.e.12.51 ± 4.80 and higher in high-dose statin therapy with a mean standard deviation was 29.16 ± 10.5 [8]. CAD and atherosclerosis are among the most common causes of mortality among men and women in the United States, and atherosclerotic changes affect the walls of coronary arteries. The CAD is progressive and generally begins in late childhood and clinically manifests in the middle of adult ages. An update of American Heart Association guidelines presented for the preventative strategies of cardiovascular diseases among women recommended that risk assessment at each stage of women's life and specifically during pregnancy to avoid the rising complications of pregnancies, along with the constant post-partum consultation with cardiologists [9] in late 2013 the American heart association college of cardiology (AHA/ACC) presented the new treatment guidelines that no longer specify LDL and non-HDL cholesterol targets for primary and secondary prevention of CAD. Among patients with metabolic syndrome, the combination of low HDL levels and high triglyceride levels is more effective among patients with co-morbid conditions with CAD. The Asian region has been documented and declared to have a higher burden due to CAD compared to Western countries probably due to the high economic impact of disease burden in the South Asian region, Pakistan is among the underdeveloped countries with limited data on record. The current study aims not only to assess the current scenarios but will be helpful to clinically understand and scientifically proven therapeutic outcomes and to help develop the appropriate strategies regionally to prevent CAD [10].

This study aims to assess and compare the mean changes in LDL cholesterol with high and low-dose statin therapies.

METHODS

A non-randomized control trial designed study was conducted at Fauji Foundation Hospital Rawalpindi from January 26, 2023, till July 25, 2023. A sample size of 70 was calculated through the M Calculator [11]. Each group was allotted 35 patients using a convenience sampling technique. Keeping a 5% level of significance and 80% power of study with mean difference for Group A was 12.5 ± 4.80 and for Group B was 29.16 ± 10.57. All patients with ST-elevation myocardial infarction (STEMI) or non-ST-elevation myocardial infarction (NSTEMI) whether male or female with LDL level >190 mg/dl, HDL level <40 mg/dl, or total cholesterol level >240 mg/dl were included in the study. However, patients aged >75 years or less than 45 years, with chronic kidney disease, and patients with chronic liver disease were excluded from the study. After getting ethical approval from the hospital research committee & Research Evaluation Unit of the College of Physicians & Surgeons, Pakistan (CPSP/REU/MED-2020-122-16329), 70 patients who fulfilled the study inclusion criteria were enrolled from the indoor/outdoor of the General Medicine Department of Fauji Foundation Hospital, Rawalpindi. Written informed consent explaining the research objectives was signed by the patients. All patients were assessed through history, physical examination, and lab investigation, including lipid profile, serum creatinine, serum ALT, and urine RE at baseline and post-treatment. Group A received high-dose statin therapy atorvastatin 40 mg orally daily. While Group B received low-dose statin therapy atorvastatin 20 mg orally daily. Outcomes were measured after 12 weeks through the comparison of pre- and post-treatment LDL. Demographic details of the patient along with study findings were recorded in the specially designed proforma. Collected data were entered and analyzed on SPSS version 23. Mean ± SD was calculated for quantitative variables like age, BMI, pre-treatment LDL, post-treatment LDL level, and mean change in LDL with low and high-dose statin therapy. Frequency and percentage were calculated for qualitative variables like gender. The mean change in LDL was compared in both groups using an independent t-test with the value of $p<0.05$. However, the dominant variables like BMI, age, and gender of patients were compared by using data stratification. Mean, and standard deviation was calculated by analyzing the data in SPSS.

RESULTS

In the study, 70 patients were enrolled 35 patients in each group, there were 57.1% males in Group A and 68.6% in Group B, females were 42.9% in Group A and 31.4% in Group B shown in table 1.

Table 1: Gender Distribution in Patients (Groups A and B)

Groups With Statin Therapy		Gender		Total	p-value
		Male	Female		
Group A (High Dose Statin Therapy)	Count	20	15	35	0.322
	% Within Group	57.1%	42.9%	100.0%	
Group B (Low Dose Statin Therapy)	Count	20	15	35	
	% Within Group	57.1%	42.9%	100.0%	

The Mean age was 56.14 ± 8.9 years in Group A and 57.5 ± 9.7 in Group B. The Mean BMI was 28.5 ± 5.7 kg/m2 in Group A and 30.1 ± 5.9 in Group B as shown in table 2.

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Table 2: Age and BMI of the Population Pre-Treatment and Post-Treatment LDL-C in Both Groups

Variables	Group	N	Mean ± SD	Std. Error Mean	p-value
Age (Years)	Group A (High Dose StatinTherapy)	35	56.14 ± 8.961	1.515	0.542
	Group B (Low Dose Statin Therapy)	35	57.51 ± 9.736	1.646	0.001
45-60 Years	Group A (High Dose Statin Therapy)	25	33.80 ± 26.937	-	0.001
	Group B (Low Dose Statin Therapy)	19	18.16 ± 19.236		0.281
61-75 Years	Group A (High Dose Statin Therapy)	10	38.00 ± 31.464	-	0.454
	Group B (Low Dose Statin Therapy)	16	25.31 ± 22.096		0.353
BMI (kg/m^2)	Group A (High Dose Statin Therapy)	35	28.5971 ± 5.7429	0.97073	
	Group B (Low Dose Statin Therapy)	35	30.1200 ± 5.96814	1.00880	
Pre-treatment LDL (mg/dl)	Group A (High Dose Statin Therapy)	35	179.00 ± 29.074	4.914	
	Group B (Low Dose Statin Therapy)	35	173.57 ± 31.238	5.280	
Post-treatment LDL (mg/dl)	Group A (High Dose Statin Therapy)	35	144.00 ± 37.275	6.301	
	Group B (Low Dose Statin Therapy)	35	151.86 ± 33.652	5.688	

Mean pre-treatment LDL-C was 179 ± 29mg/dl in Group A and 173 ± 31.2 mg/dl in Group B. Post-treatment LDL-C was 144 ± 37.2 mg/dl in Group A and 151.8 ± 33.6 in Group B. The co-morbidities among patients have been shown in Figure 1.

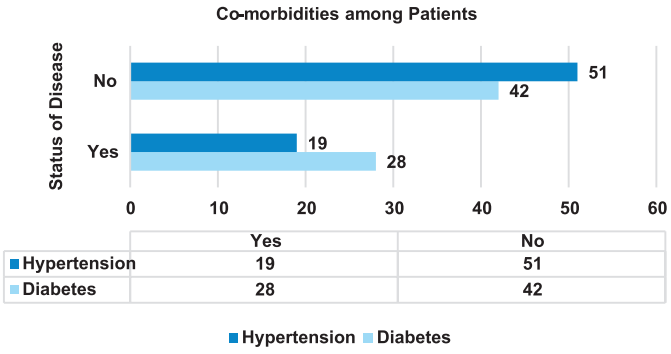

Figure 1: Co-morbidities among study participants

In our study, 70 patients were enrolled 35 patients in each group. The mean age was 56.14 ± 8.9 years in Group A and 57.5 ± 9.7 in Group B. Mean BMI was 28.5 ± 5.7 kg/m2 in Group A and 30.1 ± 5.9 in Group B shown in table 3.

Table 3: Data Stratification for Both Groups according to BM

Body Mass Index (BMI)	Groups	N	Mean ± Std. Deviation	p-value
Equal to or Less Than 30kg/m^2	Group A (High Dose Statin Therapy)	20	42.50 ± 30.371	0.001
	Group B (Low Dose Statin Therapy)	16	14.06 ± 9.525	
	Total	36	29.86 ± 27.294	
More Than 30kg/m^2	Group A (High Dose Statin Therapy)	15	25.00 ± 21.213	0.039
	Group B (Low Dose Statin Therapy)	19	27.63 ± 25.242	
	Total	34	26.47 ± 23.242	

Mean pre-treatment LDL-C was 179 ± 29mg/dl in Group A and 173 ± 31.2 mg/dl in Group B. Post-treatment LDL-C was 144 ± 37.2 mg/dl in Group A and 151.8 ± 33.6 in Group B. There were 57.1% male in Group A and 68.6% in Group B, female was 42.9% in Group A and 31.4% in Group B in table 4.

Table 4: Gender-Based comparison of both study groups among study participants

Gender	Group	N	Mean ± Std. Deviation	p-value
Male	Group A (High Dose Statin Therapy)	20	32.25 ± 25.260	0.041
	Group B (Low dose statin therapy)	24	21.04 ± 21.818	
	Total	44	26.14 ± 23.842	
Female	Group A (High Dose Statin Therapy)	15	38.67 ± 31.593	0.001
	Group B (Low dose statin therapy)	11	22.27 ± 18.623	
	Total	26	31.73 ± 27.675	

Mean change in LDL-C was significantly higher in high-dose statin as compared to low-dose statin i.e. 35 ± 27.8 versus 21.4 ± 20 mg/dl, p-value 0.024. The mean change in LDL-C was significantly higher in high-dose statin as compared to low-dose statin i.e. 35 ± 27.8 versus 21.4 ± 20 mg/dl, p-value 0.024 shown in table 5.

Table 5: Hypertension and Diabetes-Based comparison among study participants in both study groups

LDL in Hypertension and Diabetes	Groups	N	Mean ± Std. Deviation	p-value
Yes (Hypertension)	Group A (High Dose Statin Therapy)	1	20.00 ± 0.00	0.812
	Group B (Low Dose Statin Therapy)	18	16.39 ± 10.404	
No (Hypertension)	Group A (High Dose Statin Therapy)	34	35.44 ± 28.187	0.341
	Group B (Low Dose Statin Therapy)	17	26.76 ± 26.980	
Yes (Diabetes)	Group A (High Dose Statin Therapy)	12	49.58 ± 20.500	0.001
	Group B (Low Dose Statin Therapy)	16	15.00 ± 7.958	
No (Diabetes)	Group A (High Dose Statin Therapy)	23	27.39 ± 28.559	0.451
	Group B (Low Dose Statin Therapy)	19	26.84 ± 26.099	

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DISCUSSION

The current study aimed to investigate cardiovascular disease management among the Pakistani population, and the results demonstrated a high prevalence of multiple risk factors associated with cardiovascular diseases such as high blood pressure, diabetes mellitus, and BMI in the study population. The study also assessed the high-dose and low-dose statin therapy among patients with CAD [12]. This study was done to demonstrate the difference in LDL levels after the use of low statin versus high statin therapy in our population so that the beneficial effect of high-dose statin dose can be documented. In our study, 70 patients were enrolled 35 patients in each group. The mean age was 56.14 ± 8.9 years in Group A and 57.5 ± 9.7 in Group B which completely agrees with the mean age found in a study conducted on a similar pattern. The gender assessment is one of the important factors in elaborating the diseases of the cardiovascular system the study found remarkable changes [13]. There were 57.1% male in Group A and 68.6% in Group B, female was 42.9% in Group A and 31.4% in Group B. The uniformity in the pattern of risk factors needs a constant concentration to prevent the epidemic of cardiovascular disease in the South Asia region as reported by multiple studies [14-16]. The Mean BMI was 28.5 ± 5.7 kg/m2 in Group A and 30.1 ± 5.9 in Group B. Mean pre-treatment LDL-C was 179 ± 29mg/dl in Group A and 173 ± 31.2 mg/dl in Group B. Post-treatment LDL-C was 144 ± 37.2 mg/dl in Group A and 151.8 ± 33.6 in Group B. The mean change in LDL-C was significantly higher in high-dose statin as compared to low-dose statin i.e. 35 ± 2 7.8 versus 21.4 ± 20 mg/dl, p-value 0.024 [17]. Despite of knowing the increasing evidence that statin therapies improve the health outcomes of cardiovascular diseases and are known as a secondary preventive regimen for Atherosclerotic cardiovascular disease (ASCVD), these medications are still underused and less prescribed may be due to the assumption that high-intensity statins can cause certain adverse events [18]. The current study was conducted for a shorter period, yet it was well tolerated and accepted by the patients, and none of the patients withdrew from the study. The laboratory evidence was stronger for the clearer changes seen among the patients' post-therapy. The open-label studies like the current study might experience certain shortcomings at the level of selecting the patients by non-randomized design which might cause certain limitations [19]. The numerical expression of the study and the results in the numerical values are the points of concern when it comes to the reduction in the levels of LDL-C among the patients after statin therapy which represents the reduction of atherosclerotic events among the patients [20]. Our results were similar to other studies conducted on LDL-C by Priti *et al.*, in which they found the level of LDL-C After administration of atorvastatin 10 mg and 80 mg respectively [19]. The result of their study showed a significant reduction of LDL with a low dose of statin therapy. The mean LDL was lower in low-dose statin therapy i.e.12.51 ± 4.80 and higher in the patients with the larger doses administered with a mean standard deviation was 29.16 ± 10.5 [21, 22].

CONCLUSIONS

It was concluded that the efficacy of both therapies i.e., therapy among the patients with coronary artery disease. The management of LDL is an important factor in managing cardiac diseases. The high-dose therapy could be a great option in treating the LDL in initial management. The current guideline for the treatment of patients with atherosclerotic coronary artery disease is the use of high-dose statin therapy but in Pakistan, most of the patients are prescribed low-dose statin therapy. This study will provide local data on the comparison of low and high-dose statin therapy in patients with atherosclerotic coronary artery disease.

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Authors Contribution

Conceptualization: TUR
Methodology: AG, TUR, SS
Formal analysis: JKK
Writing review and editing: MS, AR, AN

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

All the authors declare no conflict of interest.

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