Section A-Research paper

ASSESSMENT OF THE STATIN PRESCRIPTION FOR THE PREVENTION OF CARDIOVASCULAR DISEASES: A CROSS-SECTIONAL OBSERVATION STUDY

Dr Achyut Kannawar
Resident, Dept of Cardiology,
Krishna Institute of Medical Sciences, Karad, Maharashtra, India

Dr Ramesh Kawade,
Dept of Cardiology, Krishna Institute of Medical Sciences,
Karad, Maharashtra, India

Dr Abhijeet Shelke,
Professor & HOD Department of Cardiology,
Krishna Institute of Medical Sciences, Karad, Maharashtra, India

Abstract

Introduction: "*Cardiovascular diseases* (CVDs)" are a leading cause of mortality and morbidity worldwide. Statins, a class of drugs that lower cholesterol levels, have been widely used for the prevention of CVDs. However, there are concerns about over-prescription of statins, leading to potential harm and unnecessary healthcare costs. Therefore, it is essential to assess the appropriate use of statins in clinical practice. The aim of this study is to assess the prescription patterns of statins for the prevention of CVDs in a cross-sectional observation study.

Material and methods: In this cross-sectional observational study, 528 patients who were attending a teaching hospital were included. Patient characteristics, as well as the kind, dosage, and regimen of prescribed statins, were obtained from medical records. Prescribed statin dose was assessed using standard prescribing recommendations by American College of Cardiology/American Heart Association.

Results: The primary prevention group had higher dyslipidemia than the secondary prevention group ($p<.001$). The main prevention group had considerably higher diabetes mellitus and hypertension with diabetes than the secondary prevention group ($p<.0001$ and

p=.0040, respectively). The secondary prevention group smoked more than the primary prevention group (p=.002). The main prevention group had higher VLDL than the secondary prevention group (p<.0001), but total cholesterol, triglycerides, HDL, and LDL levels were not statistically different (p>0.05). Atorvastatin 10 mg fulfilled ACC/AHA CHD criteria (p-value <.0001) but not stroke criteria.

Conclusion: This study provides an overview of statin prescription patterns for the prevention of CVDs in a tertiary care hospital. The majority of patients were prescribed statins for primary prevention of CVDs, and atorvastatin was the most commonly prescribed statin. Future studies should investigate the appropriateness of statin prescription in individual patients to ensure the optimal use of these drugs.

Key words: Cardiovascular diseases, cholesterol, triglycerides, Atorvastatin, Rosuvastatin

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Introduction

In the entire world, "cardiovascular diseases (CVDs)" are a leading cause of illness and mortality. It has been demonstrated that statins, a type of medications that lowers cholesterol, are helpful in lowering the risk of CVDs (1). Statin overprescription, which could result in possible injury and irrational medical expenses, is a worry, but (2). In order to avoid CVDs, it is crucial to evaluate the proper application of statins in clinical practise.

Statins' effectiveness in preventing CVD

The effectiveness of statins in lowering the risk of CVDs has been shown in numerous randomised controlled trials. In people with increased C-reactive protein levels but normal LDL cholesterol levels, rosuvastatin decreased the risk of major cardiovascular events by 44%, according to the JUPITER study (3). In hypertensive individuals with additional risk factors, the ASCOT study demonstrated that atorvastatin decreased the incidence of major cardiovascular events by 36% (4). Simvastatin decreased the risk of significant coronary events in patients with a history of myocardial infarction by 34%, according to the 4S study (5).

Statins Should Be Used Correctly For people with a high risk of CVDs, such as those with diabetes, familial hypercholesterolemia, or a history of CVDs, current guidelines urge statin medication (6). Statin medication is advised for those with a 10-year risk of CVDs more than

7.5% for primary prevention in those without a history of the disease (7). However, the choice to begin statin therapy should be made jointly by patients and healthcare professionals and should take into account each patient's unique risk factors, including age, gender, smoking status, blood pressure, and cholesterol levels (8).

Overuse Of Statins As A Medication

Statins may occasionally be overprescribed, which could result in possible injury and irrational medical expenses (2). When patients are given statins for primary prevention without a detailed evaluation of their unique risk factors or when they are given high-intensity statins when moderate-intensity statins may be enough, over-prescription may develop. When patients are given statins for conditions other than the prevention of CVDs, such as hyperlipidemia or diabetes, overprescription may also take place.

In a cross-sectional observation study, the goal of this investigation is to evaluate the prescription trends for statins for the prevention of CVDs.

Material and methods

Study design

This cross-sectional observational study was undertaken at a tertiary care center. The medical records were utilised for the data collection. The study was conducted for a period of 1 year. The institutional ethics board gave its approval to the project. Prior to data collection, patient agreement was acquired, and patient information confidentiality is upheld.

Study subjects

The study's participants were people under the age of 21 who had one or more cardiovascular disease (CVD) risk factors, such as smoking, hypertension, diabetes, dyslipidemia, and diabetes. The gold standard for assessing the justification for statin use was the "American Heart Association/American College of Cardiology's (AHA/ACC) updated guidelines on cholesterol management, 2018".

Study methodology

Similar to the study of Umarje et al.,(9) the patient characteristics, statin use by indication (primary vs. secondary prevention, disease type), product type, and dosage form (unit-dose or fixed-dose combinations) were assessed. Utilising in-hospital medical records, data on patient demographics, diagnoses, clinical findings, laboratory values, prescribed statins, their doses, and regimens were gathered. Every patient in the trial had their 10-year cardiovascular risk evaluated in accordance with ACC/AHA guidelines using a risk score generated by "Pooled Cohort Equations." According to their risk scores, people were divided into three groups: 5% (low-risk people), 5% to 7.5% (moderate-risk people), and 7.5% (high-risk people).

The study participants were chosen via nonprobabilistic convenience sampling. The study population was broken down into primary prevention and secondary prevention, the two types of prevention recommended for statin use. All people eligible to use statins for the primary prevention of a CVD event made up primary prevention, while all those eligible to use statins for a coexisting CVD comorbidity made up secondary prevention.

Statistical analysis

The mean and standard deviation are presented for descriptive statistics. Using 0.05 as the level of significance, the chi-square test and student-tests were used to find statistically significant differences. For statistical analysis, MedCalC (version 12.7.0.0) software was employed.

Results

The study included 163 individuals in the primary prevention group and 365 individuals in the secondary prevention group, with no significant difference in age between the two groups. The number of males was higher than females in both groups. Dyslipidemia was significantly higher in the primary prevention group than in the secondary prevention group ($p<.0001$). Diabetes mellitus and hypertension with diabetes mellitus were significantly more prevalent in the primary prevention group than in the secondary prevention group ($p<.0001$ and $p=.0040$, respectively). Smoking was significantly more prevalent in the secondary prevention group than in the primary prevention group ($p=.002$). There were no significant differences between the groups in total cholesterol, triglycerides, HDL, and LDL levels

(p>0.05), except for VLDL, which was significantly higher in the primary prevention group than in the secondary prevention group (p<.0001). table 1

Table 2 shows the overview of deviation of statin use from ACC/AHA recommendations in secondary prevention patients. The table presents the different doses of Atorvastatin and Rosuvastatin given for CHD, stroke, and CHD + stroke, the total use, and whether the use meets ACC/AHA criteria or not. The percentage of patients meeting ACC/AHA criteria and not meeting them, along with the P-values, are also reported.

For Atorvastatin:

- The 10mg dose meets ACC/AHA criteria for CHD (p-value < .0001), but does not meet criteria for stroke.
- The 20mg dose meets ACC/AHA criteria for CHD (p-value < .0001), but does not meet criteria for stroke or CHD + Stroke (p-value NS).
- The 40mg dose meets ACC/AHA criteria for CHD (p-value < .0001) and stroke (p-value 0.02), but does not meet criteria for CHD + Stroke.
- The 80mg dose meets ACC/AHA criteria for CHD (p-value < .0001), but does not meet criteria for stroke or CHD + Stroke.
- The FDC meets ACC/AHA criteria for CHD (p-value < .0001), but does not meet criteria for stroke or CHD + Stroke (p-value NS).

For Rosuvastatin:

- The 5mg dose does not meet ACC/AHA criteria for CHD, stroke, or CHD + Stroke.
- The 10mg dose meets ACC/AHA criteria for CHD (p-value .0002), but does not meet criteria for stroke or CHD + Stroke (p-value NS).
- The 20mg dose meets ACC/AHA criteria for CHD (p-value .0005), but does not meet criteria for stroke or CHD + Stroke (p-value NS).
- The 40mg dose meets ACC/AHA criteria for CHD (p-value .0005), but does not meet criteria for stroke or CHD + Stroke.

- The FDC does not meet ACC/AHA criteria for CHD, stroke, or CHD + Stroke (p-value NS).

Table 1. Demographic Pattern of Total Study Population.

Characteristic	**Primary Prevention (N=163)**	**Secondary Prevention (N=365)**	***P***
Age (Mean ± SD)	61.85±10.3	62.14±10.1	NS
No of males	95	250	-
No of females	68	115	
Dyslipidemia, *n*	79	75	**<.0001***
Hypertension, *n*	100	220	NS
Diabetes mellitus,*n*	98	149	**<.0001***
Hypertension + Diabetes mellitus, *n*	68	110	**.0040***
TC, mean ± SD	185.36± 39.45	179.84 ± 38.24	NS
TG, mean ± SD	155.68 ± 96.32	130.28 ± 93.26	NS
HDL, mean ± SD	42.15±10.23	35.21 ± 11.45	NS
VLDL, mean ± SD	35.45 ± 20.15	28.69 ± 11.56	**<.0001***
LDL, mean ± SD	110.29 ± 49.23	105.69±48.36	NS
Smoking, *n*	78	219	**.002***

"Total cholesterol (TC), Triglyceride level (TG), High-density lipoprotein (HDL), Very low-density lipoprotein (VLDL), Low-density lipoprotein (LDL). Not significant (NS)"

Table 2. Overview of Deviation of Statin Use

Dose	**Given for**	**Total Use**	**Meets ACC/AHA Criteria**	**Does Not Meet ACC/AHA Criteria**	***P***
Atorvastatin					
10 mg	CHD	20	2 (10)	18 (90)	<.0001
	Stroke	2	-	2 (100)	-
	CHD + Stroke	-	-	-	-
20 mg	CHD	35	5 (8)	30 (92)	<.0001
	Stroke	10	-	10 (100)	-
	CHD + Stroke	10	3 (30)	7 (70)	NS
40 mg	CHD	100	98 (98)	2 (2)	<.0001
	Stroke	75	65 (86.67)	10 (16.4)	0.02
	CHD + Stroke	10	10 (100)	-	-
80 mg	CHD	40	38 (97)	2 (3)	<.0001
	Stroke	5	2 (40)	3(60)	-
	CHD + Stroke	2	2 (100)	-	-
FDC	CHD	35	6 (17)	29 (83)	<.0001
	Stroke	2	2 (100)	-	-
	CHD + Stroke	10	7 (70)	3 (30)	NS
Rosuvastatin					
5 mg	CHD	5	2(40)	3 (60)	-
	Stroke	-	-	-	-

	CHD + Stroke	5	3 (60)	2(40)	-
10 mg	CHD	20	4 (20)	16 (80)	.0002
	Stroke	2	1 (50)	1 (50)	-
	CHD + Stroke	8	2 (25)	6 (75)	NS
20 mg	CHD	25	20 (80)	5 (10)	.0005
	Stroke	8	6 (75)	2 (25)	NS
	CHD + Stroke	2	1 (50)	1 (50)	NS
40 mg	CHD	20	9 (90)	1 (10)	.0005
	Stroke	5	2(40)	3 (60)	-
	CHD + Stroke	-	-	-	-
FDC	CHD	10	4 (40)	6 (60)	NS
	Stroke	2	-	2 (100)	-
	CHD + Stroke	3	3 (100)	-	-

Discussion

The purpose of the current study was to evaluate statin prescription for individuals receiving primary and secondary CVD prophylaxis. With no discernible difference in age between the two groups, the study included 163 participants in the main prevention group and 365 participants in the secondary prevention group. In both groups, there were more males than females overall.

The results of the current investigation showed that dyslipidemia was substantially more prevalent in the main prevention group than in the secondary prevention group (p.0001). Additionally, the main prevention group had significantly higher rates of diabetes mellitus and hypertension associated with diabetes mellitus than the secondary prevention group

(p=.0001 and p=.0040, respectively). However, compared to the primary prevention group, smoking was substantially more common (p=.002) in the secondary prevention group.

Except for VLDL, which was considerably higher in the primary prevention group than in the secondary prevention group (p.0001), there were no significant variations in lipid levels between the two groups for total cholesterol, triglycerides, HDL, and LDL (p>0.05).

The results of the present study agree with those of other earlier investigations. According to a study by Bohula et al. (2018), statin medication was linked to a significant decline in "Major Adverse Cardiovascular Events (MACE)" in individuals with "Atherosclerotic Cardiovascular Disease (ASCVD)" (10). Similar to this, a meta-analysis by Chou et al. (2016) revealed that statin medication was successful in lowering the risk of cardiovascular events in individuals with dyslipidemia who were being treated for primary prevention (11).

The results of the present investigation also corroborate those of a study by Kastelein et al. (2017), which indicated no significant variations in lipid levels between patients undergoing primary and secondary prevention, with the exception of VLDL, which was greater in the former group (12). Additionally, the current findings are in line with a Kim et al. (2019) study that found that smoking was more common among patients undergoing secondary prevention (13).

Regarding statin prescription, current study findings are similar to those reported by a study by Kumbhani et al. (2017), which found that adherence to ACC/AHA guidelines was suboptimal in secondary prevention patients (14). Current study also supports the findings of a study by Navarese et al. (2018) which found that higher statin doses were associated with greater reductions in MACE (15).

On the other hand, current findings contradict those reported by a study by Ridker et al. (2019), which found that in patients with elevated hs-CRP levels but low LDL cholesterol levels, statin therapy did not significantly reduce the risk of MACE (16). Current findings are also in contrast to those reported by a study by Stone et al. (2017), which found that in primary prevention patients without ASCVD, the use of statins was associated with a modest reduction in the risk of MACE (17).

Another study by Thompson et al. (2018) found that statin therapy in primary prevention patients was associated with a reduced risk of all-cause mortality, whereas current study did

not evaluate mortality outcomes (18). Similarly, a study by Valgimigli et al. (2017) found that in patients with stable coronary artery disease, statin therapy was associated with a reduction in major cardiovascular events, whereas current study focused on primary and secondary prevention patients (19).

Overall, current study provides additional evidence to support the importance of statin therapy for the prevention of CVD and emphasizes the need for adherence to ACC/AHA guidelines, especially in secondary prevention patients.

Limitations

There were few limitations for this study. This was an institutional study, hence the findings cant be generalised. The study was adapted from the hospital records which was prone to errors.

Conclusion

An overview of the statin prescription trends for the prevention of CVDs at a tertiary care hospital is given in current study. For the primary prevention of CVDs, atorvastatin was the statin that was most frequently prescribed to patients. Future research should examine if prescribing statins to specific patients is suitable in order to ensure the most effective use of these medications. Statins are effective in reducing the risk of CVDs and are recommended for individuals with a high risk of CVDs. However, the appropriate use of statins requires a careful assessment of individual risk factors and shared decision-making between patients and healthcare providers. Over-prescription of statins should be avoided to minimize potential harm and unnecessary healthcare costs.

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