Section: Cardiology

Original Research Article

ASSESSMENT OF STATIN INTENSITY AND PRESCRIPTION QUALITY IN PRIMARY AND SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE

Ajay Chaurasia[1], Satish Suryavanshi[2], Ved Prakash Verma[3], S.S Mohanty[4]

[1]*Senior Consultant, Cardio Thoracic & Vascular Surgeon, SMC Heart Institute, VIP Estate, Raipur, India.*
[2-4]*Senior Consultant, Interventional Cardiologist, SMC Heart Institute, VIP Estate, Raipur, India.*

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Corresponding Author:
Dr. S.S Mohanty,
Senior Consultant, Interventional Cardiologist, SMC Heart Institute, VIP Estate, Raipur, India.
Email: drssm2000@yahoo.com

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ABSTRACT

Background: Statins are important drugs for prevention of atherosclerotic cardiovascular disease. In routine Indian practice, the choice of statin and dose may vary due to risk assessment, affordability, fixed-dose combinations and prescriber preference.

Materials and Methods: This prospective observational prescription audit was conducted in a teaching hospital. A total of 384 adult patients were assessed. Patients were classified into primary prevention and secondary prevention groups. Demographic profile, cardiovascular risk factors, lipid profile, indication for statin, prescribed statin, dose intensity, fixed-dose combination use, risk-score documentation, monitoring and short follow-up data were recorded.

Results: Primary prevention group included 134 patients and secondary prevention group included 250 patients. Statin was prescribed in 98 patients (73.1%) in primary prevention and 239 patients (95.6%) in secondary prevention. Atorvastatin was the most commonly used statin in both groups. Fixed-dose combination use was higher in primary prevention (25.5% vs 10.0%). Appropriate statin intensity was documented in 66 patients (67.3%) in primary prevention and 184 patients (77.0%) in secondary prevention. Underdosing was seen in 22.4% and 19.7% respectively. Risk-score documentation in primary prevention was low (23.9%). Follow-up lipid review was advised in 41.8% of primary prevention and 57.7% of secondary prevention prescriptions.

Conclusion: Statin use was high in secondary prevention but dosing gaps were still present. Primary prevention showed lower risk-score documentation and more fixed-dose combination use. Atorvastatin remained the preferred statin. A simple hospital prescription audit may improve statin intensity, lipid monitoring and follow-up advice.

Keywords: Statin; atorvastatin; rosuvastatin; cardiovascular prevention; dyslipidemia.

INTRODUCTION

Cardiovascular disease remains a major cause of death worldwide. Ischemic heart disease and stroke form a large part of this burden.[1] In India, cardiovascular disease has increased over the last few decades due to ageing, diabetes, hypertension, tobacco use, obesity and lifestyle change.[2,3]

Dyslipidemia is one of the important modifiable risk factors for atherosclerotic cardiovascular disease. Indian studies show frequent low HDL cholesterol, high triglycerides and borderline high LDL cholesterol. These lipid abnormalities are seen in both urban and rural populations.[4]

Statins reduce LDL cholesterol and cardiovascular events. They are used for both primary prevention and secondary prevention. The choice of statin

intensity depends on age, baseline risk, diabetes status, LDL cholesterol level and presence of established cardiovascular disease.[5] The Cardiological Society of India and Lipid Association of India have also stressed early and appropriate lipid-lowering treatment in Indian patients because ASCVD occurs at a younger age in Indians.[6,7]

In secondary prevention, high-intensity statin therapy is usually recommended unless contraindicated or not tolerated. In primary prevention, risk estimation and clinician-patient discussion are important before starting therapy.[5,8] In routine practice, these steps may not be documented properly. This can lead to underuse or underdosing of statins.

Indian hospital data on statin utilization are still limited. Existing studies show preference for atorvastatin and rosuvastatin. They also show gaps in risk assessment and dosing, especially in primary prevention and fixed-dose combination prescriptions.[9,10] The uploaded teaching-hospital study also assessed statin type, dose and deviation from ACC/AHA recommendations in primary and secondary prevention groups.[10]

Medium-facility hospitals in India have practical issues. Many patients come from rural or semi-urban areas. Cost, generic availability, fixed-dose combinations and incomplete follow-up affect prescription quality. A prescription audit in such setting can show common gaps and help improve rational statin use.

The present study was planned to assess statin prescribing pattern in primary and secondary cardiovascular prevention in a semi-urban Indian teaching hospital. It also assessed dose intensity, fixed-dose combination use, monitoring and short follow-up lipid review.

MATERIALS AND METHODS

Study design and setting

This was a prospective observational prescription audit conducted in the Department of General Medicine and Cardiology unit of a Indian teaching hospital. The hospital caters to rural and semi-urban patients. Data were collected from OPD prescriptions, admission records and discharge summaries.

Study population

A total of 384 adult patients were included. Patients were aged 30 years and above and had either established atherosclerotic cardiovascular disease or at least one major cardiovascular risk factor.

Patients were divided into two groups.

Primary prevention group: Patients without established ASCVD but with one or more risk factors such as diabetes, hypertension, dyslipidemia, smoking, obesity or family history.

Secondary prevention group: Patients with established coronary artery disease, previous myocardial infarction, post-PCI status, ischemic stroke or peripheral arterial disease.

Inclusion Criteria

Patients with complete prescription record and lipid profile within previous three months were included. Patients already taking statin and newly started on statin were both included.

Exclusion Criteria

Patients with active liver disease, pregnancy, severe drug allergy, incomplete prescription record or refusal for follow-up were excluded.

Data collection

Age, sex, residence, diagnosis, diabetes, hypertension, tobacco use, BMI, lipid profile, statin name, dose, fixed-dose combination use and generic or branded prescription were recorded. Documentation of ASCVD risk score, baseline liver function test, lifestyle advice and follow-up lipid advice was also noted.

Statin intensity assessment

Statin intensity was assessed according to standard cholesterol guideline categories. Atorvastatin 40–80 mg and rosuvastatin 20–40 mg were taken as high-intensity therapy. Atorvastatin 10–20 mg and rosuvastatin 5–10 mg were taken as moderate-intensity therapy.[5,8]

Follow-up assessment

Follow-up at 6 to 8 weeks was recorded when available. Adherence by history, repeat LDL-C testing, dose change, myalgia and liver enzyme elevation were noted.

Statistical Analysis

Data were entered in spreadsheet and analysed using standard statistical software. Continuous variables were expressed as mean ± SD. Categorical variables were expressed as number and percentage. Chi-square test or Fisher exact test was used for categorical variables. Student t-test was used for continuous variables. P value <0.05 was taken as statistically significant.

RESULTS

A total of 384 patients were analysed. Primary prevention group included 134 patients and secondary prevention group included 250 patients.

Table 1: Baseline clinical and lipid profile according to prevention group

Parameter	Primary prevention n=134	Secondary prevention n=250	p value
Age in years	55.8 ± 10.6	62.7 ± 11.4	<0.001
Male sex	76 (56.7%)	172 (68.8%)	0.018
Rural/semi-urban residence	96 (71.6%)	164 (65.6%)	0.230
Hypertension	82 (61.2%)	168 (67.2%)	0.240

Diabetes mellitus	78 (58.2%)	116 (46.4%)	0.027
Current smoking	34 (25.4%)	78 (31.2%)	0.230
Smokeless tobacco use	29 (21.6%)	53 (21.2%)	0.930
BMI ≥23 kg/m²	91 (67.9%)	154 (61.6%)	0.220
LDL-C mg/dL	118.4 ± 34.7	104.2 ± 31.6	<0.001
Triglyceride ≥150 mg/dL	63 (47.0%)	96 (38.4%)	0.100
Low HDL-C	88 (65.7%)	142 (56.8%)	0.090
Lipid profile documented	112 (83.6%)	219 (87.6%)	0.280
Estimated 10-year ASCVD risk ≥7.5%	86 (64.2%)	Not applicable	—

Primary prevention patients were younger than secondary prevention patients. Diabetes was more common in primary prevention group. Male sex was higher in secondary prevention group. LDL-C was higher in primary prevention group. Low HDL-C was frequent in both groups.

Table 2: Statin prescription pattern and monitoring documentation according to prevention group

Prescription variable	Primary prevention n=134	Secondary prevention n=250	p value
Any statin prescribed	98 (73.1%)	239 (95.6%)	<0.001
Atorvastatin single drug	51/98 (52.0%)	154/239 (64.4%)	0.033
Rosuvastatin single drug	22/98 (22.4%)	61/239 (25.5%)	0.550
Atorvastatin fixed-dose combination	21/98 (21.4%)	17/239 (7.1%)	<0.001
Rosuvastatin fixed-dose combination	4/98 (4.1%)	7/239 (2.9%)	0.740
Any fixed-dose combination	25/98 (25.5%)	24/239 (10.0%)	<0.001
Generic prescription	52/98 (53.1%)	151/239 (63.2%)	0.084
Baseline LFT recorded	78/98 (79.6%)	204/239 (85.4%)	0.190
Lifestyle advice recorded	53/98 (54.1%)	152/239 (63.6%)	0.100
Follow-up lipid advice recorded	41/98 (41.8%)	138/239 (57.7%)	0.008

Statin prescription was higher in secondary prevention than primary prevention (95.6% vs 73.1%, p<0.001). Atorvastatin single-drug prescription was more common in secondary prevention. Fixed-dose combination use was higher in primary prevention (25.5% vs 10.0%, p<0.001). Follow-up lipid advice was documented more often in secondary prevention (57.7% vs 41.8%, p=0.008).

Table 3: Dose distribution and statin intensity among statin users

Dose pattern	Primary prevention n=98	Secondary prevention n=239
Atorvastatin 10 mg	7 (7.1%)	7 (2.9%)
Atorvastatin 20 mg	22 (22.4%)	31 (13.0%)
Atorvastatin 40 mg	17 (17.3%)	105 (43.9%)
Atorvastatin 80 mg	5 (5.1%)	11 (4.6%)
Rosuvastatin 5 mg	5 (5.1%)	2 (0.8%)
Rosuvastatin 10 mg	10 (10.2%)	14 (5.9%)
Rosuvastatin 20 mg	7 (7.1%)	39 (16.3%)
Rosuvastatin 40 mg	0 (0.0%)	6 (2.5%)
Atorvastatin FDC	21 (21.4%)	17 (7.1%)
Rosuvastatin FDC	4 (4.1%)	7 (2.9%)
Moderate-intensity single statin	44 (44.9%)	54 (22.6%)
High-intensity single statin	29 (29.6%)	161 (67.4%)
Fixed-dose combination	25 (25.5%)	24 (10.0%)

Atorvastatin 40 mg was the commonest prescribed dose in secondary prevention. Moderate-intensity single statin use was higher in primary prevention. High-intensity single statin use was higher in secondary prevention. Fixed-dose combination use was also higher in primary prevention.

Table 4: Guideline concordance and underdosing pattern in statin prescription

Prescribing quality indicator	Primary prevention	Secondary prevention
Statin indicated or strongly considered	107/134 (79.9%)	250/250 (100.0%)
Statin prescribed among indicated patients	91/107 (85.0%)	239/250 (95.6%)
Statin not prescribed despite indication	16/107 (15.0%)	11/250 (4.4%)
Statin prescribed without clear indication documentation	7/98 (7.1%)	Not applicable
Risk score documented in case record	32/134 (23.9%)	Not applicable
Appropriate intensity among statin users	66/98 (67.3%)	184/239 (77.0%)
Underdosing among statin users	22/98 (22.4%)	47/239 (19.7%)
Underdosing without documented reason	15/22 (68.2%)	31/47 (66.0%)
FDC-related underdosing	11/25 (44.0%)	12/24 (50.0%)
Cost or affordability noted as reason	5/22 (22.7%)	9/47 (19.1%)

Dose reduction due to intolerance documented	2/22 (9.1%)	7/47 (14.9%)

Appropriate statin intensity was documented in 67.3% of primary prevention and 77.0% of secondary prevention statin users. Underdosing was seen in 22.4% and 19.7% respectively. Fixed-dose combination related underdosing was seen in 44.0% primary prevention and 50.0% secondary prevention FDC prescriptions.

Table 5: Six-week lipid response and safety follow-up according to prevention group

Follow-up parameter	Primary prevention n=53	Secondary prevention n=125	p value
Follow-up lipid profile available	49 (92.5%)	116 (92.8%)	0.940
Self-reported adherence ≥80%	42 (79.2%)	98 (78.4%)	0.900
Mean LDL-C reduction %	26.4 ± 12.1	38.7 ± 16.8	<0.001
LDL-C <100 mg/dL in primary prevention	31/49 (63.3%)	Not applicable	—
LDL-C <70 mg/dL in secondary prevention	Not applicable	39/116 (33.6%)	—
Dose intensified after review	8 (15.1%)	29 (23.2%)	0.220
Myalgia reported	3 (5.7%)	8 (6.4%)	1.000
ALT rise >3 times upper limit	0 (0.0%)	2 (1.6%)	1.000

Follow-up lipid profile was available in most patients who returned at six weeks. LDL-C reduction was higher in secondary prevention (38.7 ± 16.8% vs 26.4 ± 12.1%, p<0.001). LDL-C <70 mg/dL was achieved in 39/116 (33.6%) secondary prevention patients. Myalgia and significant ALT rise were uncommon.

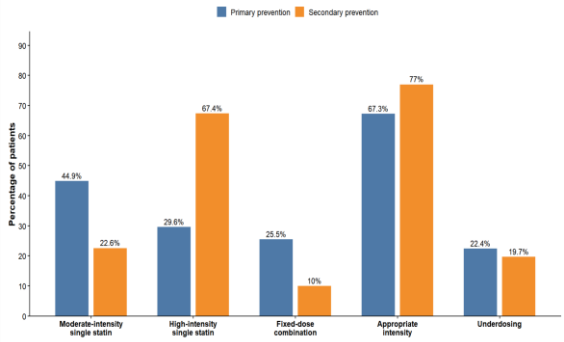

Figure 1: Statin intensity pattern in primary and secondary prevention

DISCUSSION

The present study showed high statin use in secondary prevention but lower use in primary prevention. This is expected because established ASCVD gives a clear indication for statin therapy. Still, 4.4% of secondary prevention patients were not prescribed statin. This is a correctable prescription gap. The uploaded teaching-hospital study also found better dosing agreement in secondary prevention than primary prevention, but underdosing was still seen in routine practice.[10]

Atorvastatin was the preferred statin in both groups. This is similar to an Indian physician survey where atorvastatin and rosuvastatin were the commonly preferred statins in lipid management.[11] Wider availability, lower cost and physician familiarity may explain this pattern in Indian hospitals. A previous Indian statin utilization study also reported that statin use increased over time, but per capita prescription remained lower than high-income countries.[12]

Fixed-dose combination use was higher in primary prevention. This may reflect prescriber preference for combined treatment in patients with hypertension, diabetes or dyslipidemia. But FDC use also contributed to underdosing. A review of dyslipidemia management in India has also noted heterogeneity in lipid management practice and gaps in application of guideline-based treatment.[13]

Secondary prevention patients received high-intensity single statin more often. Atorvastatin 40 mg was the commonest dose in this group. This is in agreement with current ACS guidance where intensive lipid lowering is recommended after acute coronary syndrome.[14] Chronic coronary disease guidance also supports evidence-based lipid-lowering therapy for patients with established coronary disease.[15]

Primary prevention showed lower risk-score documentation. Only 23.9% patients had documented risk assessment. This is important because primary prevention statin decision depends on diabetes status, LDL-C level, baseline ASCVD risk and risk-enhancing factors. The recent Lipid Association of India statement also stresses Indian-specific risk assessment and early lipid management because ASCVD risk is high in Indian patients.[7]

Follow-up lipid advice was not universal. It was documented in 41.8% of primary prevention and 57.7% of secondary prevention prescriptions. This is a practical problem because statin treatment should not end with the first prescription. LDL-C response, adherence and dose intensification should be reviewed. The REMAINS study in Indian adults with first acute coronary event showed that residual lipid abnormalities may persist despite statin or lipid-lowering therapy.[17]

In the present study, LDL-C reduction was higher in secondary prevention. However, LDL-C <70 mg/dL was achieved only in one-third of secondary prevention patients who had follow-up lipid profile.

This suggests that high-intensity statin alone may not be enough in all patients. Dose review, adherence check and addition of non-statin therapy may be required in selected high-risk patients.

Adverse effects were uncommon. Myalgia was reported in few patients and significant ALT rise was rare. An Indian post-PCI study comparing high-dose atorvastatin and rosuvastatin also found that high-dose statins were effective, safe and generally tolerated.[18] Fear of adverse effects should not lead to routine low-dose prescribing without proper reason.

The study highlights simple practice gaps in a medium-facility Indian hospital. The main gaps were low risk-score documentation, FDC-related underdosing and incomplete follow-up lipid advice. A simple statin prescription checklist can improve rational use. It should include indication, statin intensity, baseline lipid profile, LFT record, lifestyle advice and date for repeat lipid testing.

CONCLUSION

Statin use was high in secondary prevention but dosing gaps were still present. Primary prevention had lower statin use, poor risk-score documentation and more fixed-dose combination use. Atorvastatin was the most commonly prescribed statin. Underdosing was mostly seen without documented reason. Routine prescription audit, risk assessment and follow-up lipid advice can improve rational statin use in Indian medium-facility hospitals.

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