Drug Utilization and Evaluation Study of Statins: Tertiary Health Care Centre

Vijay S. Bayaskar[1], V. Hemanth Kumar[2], Jeetendra M Singh[3]

[1]Assistant Professor, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, Maharashtra, India

[2]Associate Professor, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, Maharashtra, India

[3]Professor & Head, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik-422003, Maharashtra, India

Abstract

Background: Drug Utilization Studies (DUS) aim to evaluate factors related to the prescribing, dispensing, administering and its associated events, either beneficial or adverse. Statins are very commonly prescribed drugs for hyperlipidemia and diseases pertaining to cardiovascular system. Hence, statin utility study has been planned. Hyperlipidemia is responsible factor for the atherosclerosis which leads to many diseases including cardiovascular diseases (CVD). Variations among prescriptions in terms of dose and duration is routinely observed. Drug utilization studies are therefore essential for evaluating and analyzing the statin therapy.

Material and Methods: This were a prospective cross sectional observational single centred study. After obtaining approval from ethics committee, study was conducted on patients visiting medicine and cardiovascular clinics. Data was collected on Microsoft excel and appropriate statistics used for analysis.

Results: Analysis of 600 prescriptions was done and results showed that men (56.7%) received more statins than females (44.3%). Among CVDs, hypertensive (49.16%) patients are more commonly prescribed with statins. Among the statins atorvastatin (63.3%) was commonly prescribed than other statins and dose is 10mg. Drugs prescribed by brand name were 80.77% and percentage of fixed drug combinations were 76.67%.

Conclusion: Prescription pattern shows the widespread use of statins in CVDs. Such studies are needed to educate physicians on good prescribing patterns of hypolipidemic agents.

Keywords: Drug utilization study, Dyslipidemia, Cardiovascular diseases, Statins.

Introduction

Drugs play a vital role in health care system. To achieve desired effect of drugs, they should be used rationally. Inappropriate use of drugs can lead to various problems such as cost burden, prolonged hospital stays, development of microbial resistance, adverse effects and mortality[1]. However variations in selection and use of drugs are routinely practiced. Drug utilization studies will be helpful to evaluate and analyse drug therapy from time to time. This in turn can

be useful to practicing physicians in drug prescription[2].

Cardiovascular Diseases (CVD) were responsible for 17.9 million deaths worldwide in 2019. Ischemic heart disease (IHD) contributes 85% deaths out of total deaths that occur due to CVD[3]. The development of atherosclerotic CVD (ASCVD) involves variety of biological processes, behavioural factors, and high plasma cholesterol levels which are thought to play a primary causative role[4].

Dyslipidemia is one of the major risk factors associated with atherosclerosis. Indeed, it is responsible for conditions such as coronary heart disease, ischemic cerebrovascular disease and peripheral vascular diseases. Available treatment options for dyslipidemia involves the use of statins, which are considered highly effective in lowering the cholesterol level. Among all the lipid lowering agents, 3-hydroxy-3-methylglutaryl-coenzymeA (HMG COA) reductase inhibitors (Statins), are a preferred first choice drugs to treat dyslipidemia. They are used due to their high efficacy in reducing LDL-Cholesterol (LDL-C) level. On an average, administration of statins helps to lower LDL-C by 20% to 60%. In addition to lowering cholesterol, statins are shown to decrease risk of coronary events, myocardial infarction and heart failure[5].

Therefore, Drug utilization studies for statins is essential for evaluating and analyzing their therapy. These drug utilization studies are useful to know the prescribing patterns. The present study is aimed to know prescribing pattern of statin, doses of statins in patients treated in Pravara Rural Hospital, Loni.

Materials and methods:

A prospective cross sectional observational single centred study was conducted on patients visiting medicine and cardiovascular clinics of Pravara rual hospital, Loni. The study period is of two years from October 2016- October 2018. Institutional ethics committee permission was obtained prior to conduction of study.

Patients of both gender, who are prescribed with statins were included. Prior informed consent was obtained from patients. Patients with pregnancy and major psychological diseases were excluded.

A total of 600 patients were included in study.

Following data was collected

1) Patient details such as age, gender and disease.

2) Prescription details, such as number of statins, dose, name of individual drugs (brand/ generic name), any fixed drug combinations, average drugs per prescription. All the data was collected on Microsoft excel sheet. Suitable statistic tests were applied.

Results

In the current study, a total of 600 prescriptions were audited. Among them 340 (56.7%) patients were male, and 260 (44.3%) patients were female (Figure 1). The ratio of males to female is 1.5. The maximum number of the patients, 250 (41.7%) were in the 56–65-year age group, and least number of patients 15 (2.5%), were in 36-45years age group (Figure 1). The maximum number of patients 295 (49.16 %) were receiving statins for Hypertension, followed by HTN+ DM 170 (28.33%) patients, HTN+IHD 40 (6.66%) patients, MI 35 (5.8%) patients, CCF 35(5.8%) patients, CAD 15(2.5%) patients, IHD 10(1.6%) Patients. (Figure 2).

Statins prescribed in the population under this study included atorvastatin and rosuvastatin of which the drugs were prescribed in 63.33% and 36.66% of the patients respectively. No patients found prescribed with statin other than atorvastatin and rosuvastatin. (Table 1)

In our study population we found that statins prescribed in fixed dose combination were in 460 (76.67%) number of patients while statins that prescribed as only statins were in 140 (23.33%). (Figure 3)

Atorvastatin and Rosuvastatin was prescribed in the hospital under different brand names which included Ecosprin-AV (Atorvastatin) prescribed in - 33.33% (In 200 patients out of 600) followed by Rosutar Gold (Rosuvastatin) -32.5% (195 patients). Atorva (Atorvastatin)19.16%(115patients), MactorASP (atorvastatin)10% (60patients). Rosulip (rosuvastatin)-4.16% (25 patients). Ramitrova (Atorvastatin)-0.83% (5 patients). (Figure 4)

In the study population we found total number of drugs prescribed were 2627 out of that 2122 that is 80.77 % drugs were prescribed by Brand names while 19.22% drugs were prescribed by Generic names. (Table 2)

In the study population we found number of drugs prescribed per prescription minimum 2 and maximum 6. (Table 3)

In this study population atorvastatin mostly prescribed in 10 mg dose followed by 40 mg dose, while Rosuvastatin mostly prescribed in 10 mg dose followed by 40 mg dose. (Table 4)
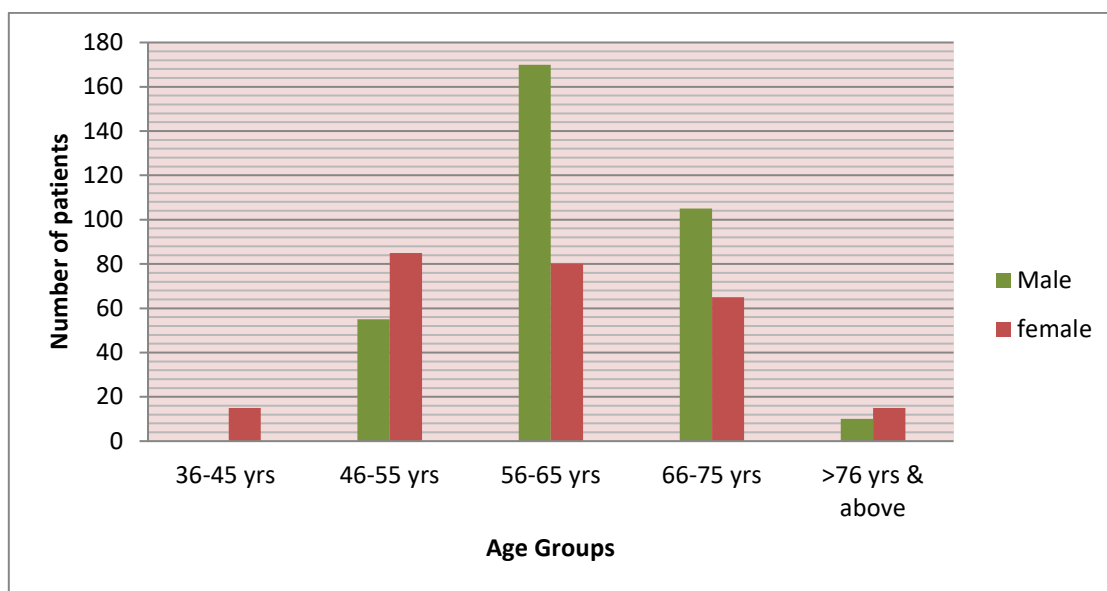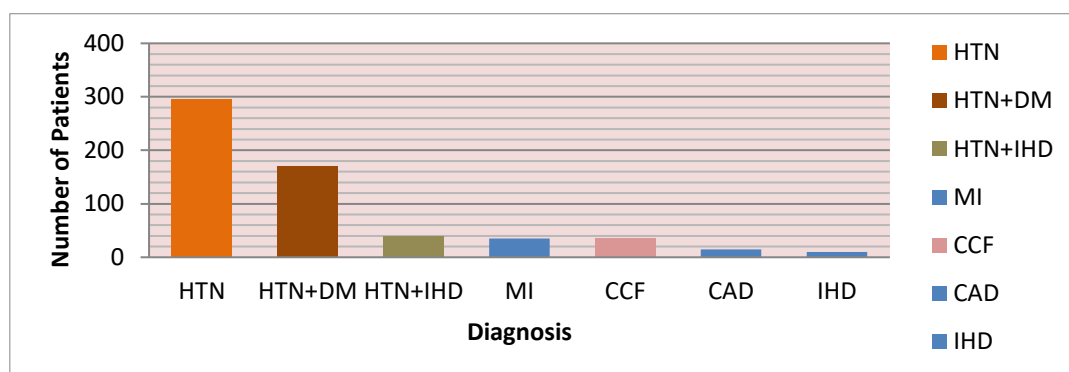

Figure No: 1 Age verses gender distribution

HTN-Hypertension, **CAD**-Coronary Disease, **CCF**-Congestive Cardiac Failure, **IHD**-Ischemic Heart Disease, **MI**-Myocardial Infarction, **DM**-Diabetes Mellitus
Figure 2: Disease wise distribution

Table 1: Distribution of statins in study subjects

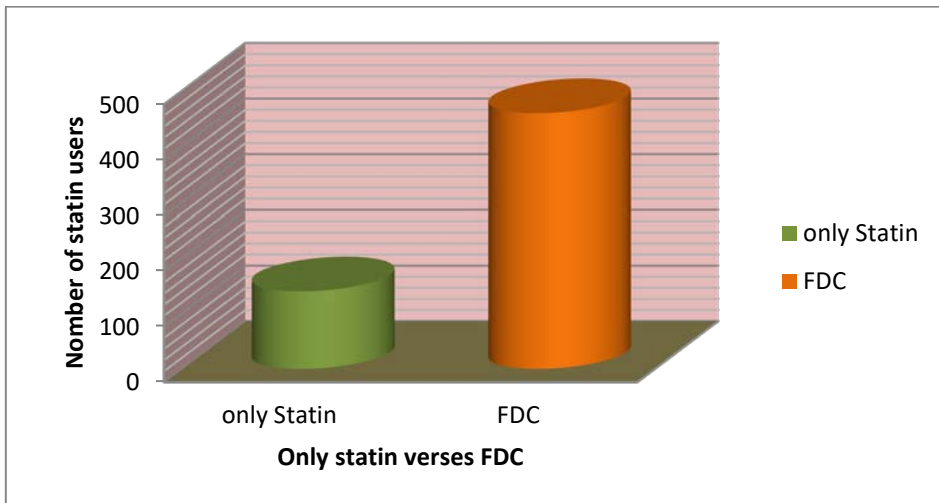| Name of the Statins	Number of patients	Percentage %
Atorvastatin	380	63.33
Rosuvastatin	220	36.66
Total	**600**	**100**

Figure 3: Fixed Dose Combination Verses only statins
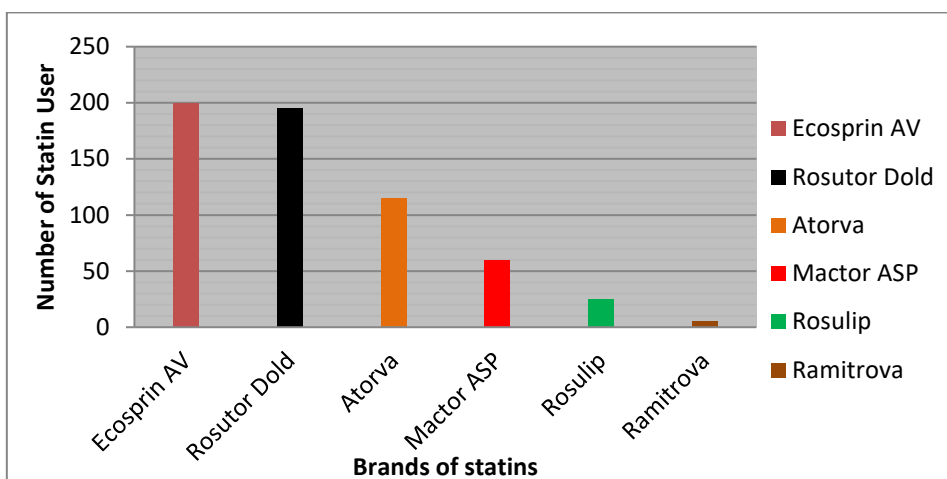

Figure 4: Brand Wise Distribution of statins in study Subjects

Table 2: Distribution of Drugs by Brand and Generic names

Total no of Drugs Prescribed	Drugs prescribed by brand names	Drugs prescribed by generic names
2627	2122	505
Percentage %	**80.77**	**19.22**

Table 3: Drug prescribed per Prescription

Total no of Drugs Prescribed	Minimum	Maximum	Mean	SD
Per Prescription	2	6	4.41	±924

Table 4: Dose Wise Distribution of statins in study subjects

Doses of Statins In mg	Statin			
	Atorvastatin		Rosuvastatin	
	N	%	N	%
10	255	67.10	195	88.63
20	10	2.63	05	2.27
40	90	23.68	20	9.09
80	25*	6.37	--	0
Total	**380**	**100**	**220**	**100**

Note: * indicates Atorvastatin was prescribed more often in higher doses as compared to Rosuvastatin (p<0.001)

Discussion:

During past few years numerous drug utility studies have been conducted worldwide to make drugs safer and more effective. Such types of drug utilization studies are helpful to determine the pattern of prescription and rationality of drug use. The present study was conducted to find out prescribing pattern of drugs used in cardiovascular clinic in tertiary care hospital. Drug related records of 600 patients were audited over period of 2 years to know the utilization of HMG-COA reductase inhibitors in a tertiary care hospital (PRH). Analysis of our data revealed that the male to female ratio is 1.5 in present study and is almost similar to the reports by Helali A *et al[6]*, Sreedevi *et al.[7],* Gupta S *et al.[2],* Molnar *et al.[8].*

We found that statins have been prescribed for patients with age range of 39-80 years. Similar results were found in the study done by Praveen K.G, *et al.[9],* Shiva, et *al.*[1] Estari M. *et al.[10].*

In our study subjects most of the males i.e. 170(50.0%) come under the age group of 56-65 years, while maximum number of females i.e. 85(32.7%) come under the age group of 46-55years. Similar results were reported by Gupta S. *et al.[2]*, Pilai PG *et al.[11],* Muhit MA *et al.[12].*

Atorvastatin was prescribed statin in 63.34% of total patients and rosuvastatin in 36.66 % patients. This finding correlates with the study results of Muhit M A *et al.[12]* (where they found atotvastatin and rosuvastatin and simvastatin were the only statins used, among them atorvastatin was used mostly in 75.4% rosuvastatin in19.62% and simvastatin used in 4.97%) Prasad A *et al.[13].*

The statins in the form of various fixed dose combinations were prescribed in 460 (76.67%) patients while atorvastatin or rosuvastatin alone to 140 (23.33%). Among patients prescribed FDC the atorvastatin was prescribed in 265 patients and atorvastatin alone in 115 patients. Rosuvastatin in the form of FDC was prescribed in 195 patients and rosuvastatin alone in 25 patients. Our study results do not correlate with study results of Gupta S *et al[2]* where maximum patients (65%) were prescribed with statins alone and remaining were prescribed in the form of FDCs.

This study shows that atorvastatin either alone or in combination is the most preferred agent in PRH, Loni. Among the various atorvastatin combinations, the FDC of atorvastatin 10 mg + aspirin 75 mg was prescribed in 260 patients and FDC containing atorvastatin 10 mg+ aspirin 75 + ramipril 5 mg was prescribed only in 5 patients. The brand name Ecosprin AV was prescribed to 33.33% of total patients receiving atorvastatin and rosuvastatin, while 52.63% of patients receiving atorvastatin. Thus, Ecosprin AV turned out to be most preferred FDC of atorvastatin in

PRH Loni. Rosuva statin was prescribed by brand name Rosutor Gold to 32.5% of total patients receiving statins, while 88.63% of patients receiving rosuvastatin. Our study results differ from the study results of the Praveen KG *et al.[9]* where they found Atorva was the major brand of atorvastatin and Rosuvas of Rosuvastatin.

The most commonly prescribed dose of atorvastatin was found to be 10 mg/day, comprising of 67 % followed by 40 mg/day to 23.68%. The dose of rosuvastatin most commonly prescribed was also 10 mg/day which comprised of 88.63%. Our study results are similar to the results of the study done by Nikhil Raj PV[14] and like Praveen K.G *et al.[9].* It is therefore concluded that the most commonly prescribed dose of either atorvastatin or rosuvastatin is 10 mg/day.

Our study shows that average number of drugs prescribed per patient was 4.41. Average number drug prescribed differs from 6.1 reported by Gupta S *et al.[2].*

Conclusion:

Current study mainly focuses on prescription pattern of hypolipidemic drugs, few points can be highlighted. Hypertensive patients are more commonly prescribed with hypolipidemic drugs. Among the hypolipidemic, statins more specifically atorvastatin which is either prescribed monotherapy or fixed dose combinations. These drug utilization and evaluation studies are required to assess the rational use of drugs. Hence such periodic studies will be helpful in revision of guidelines accordingly. Furthermore, studies on drug compliance and adverse drug reactions of statins will be more helpful to assess the long-term effects of statins on quality of life of patients.

Reference:

1. Siva S, John SM, Roshan M. Drug Utilization Evaluation of HMG-COA Reductase Inhibitors in a Tertiary Care Teaching Hospital. Indian Journal of Pharmacy Practice. 2017;10(4).
2. Gupta S, Kumar R, Kumar D, Bhat S, Kumar D, Bhat NK, Mahajan S. Study of prescribing patterns of hypolipidemic agents in a tertiary care teaching hospital in North India. National Journal of Physiology, Pharmacy and Pharmacology. 2017;7(2):198.
3. World Health Organization Fact Sheet: https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds).
4. Davies JT, Delfino SF, Feinberg CE, Johnson MF, Nappi VL, Olinger JT, Schwab AP, Swanson HI. Current and emerging uses of statins in clinical therapeutics: a review. Lipid insights. 2016 Jan;9: LPI-S37450.
5. Hsieh HC, Hsu JC, Lu CY. 10-year trends in statin utilization in Taiwan: a retrospective study using Taiwan's National Health Insurance Research Database. BMJ open. 2017 May 1;7(5):e014150.
6. Helali AM, McLay J, Mohamed IN. Prescribing trends of statins in Scotland: A drug utilization study. Bangladesh J Pharmacol. 2013 Jan 1; 8:401-09.
7. Sreedevi K, Rao JV, Fareedullah MD, Vijayakumar S. A study on prescription pattern of statins in cardiovascular disease. Der Pharmacia Lettre. 2011;3(3):393-6.
8. Molnar AO, Coca SG, Devereaux PJ, Jain AK, Kitchlu A, Luo J, Parikh CR, Paterson JM, Siddiqui N, Wald R, Walsh M. Statin use associates with a lower incidence of acute kidney injury after major elective surgery. Journal of the American Society of Nephrology. 2011 Apr 14: ASN-2010050442.
9. Praveen KG, Arun K. Drug utilization and evaluation of HMG-co Areductase inhibitors in tertiary care teaching hospital. Indian journal of pharmacy practice. 2013;6(4).

10. Estari M, Reddy AS, Bikshapathi T, Satyanarayana J, Venkanna L, Reddy MK. The investigation of serum lipids and prevalence of dyslipidemia in urban adult population of Warangal district, Andhra Pradesh, India. Biol Med. 2009;1(2):61-5.

11. Pillai PG, Suresh P, Aggarwal G, Doshi G, Bhatia V. Studies on the prescriptions of cardiovascular units. Journal of Applied Pharmaceutical Science. 2011 May 1;1(3):128.

12. Muhit MA, Rahman MO, Raihan SZ, Asaduzzaman M, Akbar MA, Sharmin N, Faroque AB. Cardiovascular disease prevalence and prescription patterns at a tertiary level hospital in Bangladesh. Journal of Applied Pharmaceutical Science. 2012 Mar 1;2(3):8.

13. Prasad A, Datta PP, Mohanty M, Swain T, Panda P. Prospective, Pharmacoepidemiologic Study of Prescribing Patterns for Lipid Lowering Drugs at a Tertiary Care Teaching Hospital in East India. Natl J of Med Res. 2012;2(4):400-3.

14. Nikhil Raj P.V, Utilization Pattern of Statins In An Indian, Population, Dissertation Submitted, APRIL 2012.