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Drug Utilization Pattern and Medication Adherence in Patients Prescribed with Statin: A Prospective Study

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ABSTRACT

Drug utilization evaluation is an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Medication adherence is defined as the degree to which the person's behavior corresponds with the agreed recommendation from a health care provider. Hyperlipidemia is one of the major predisposing factors for heart disease which is controllable. Statin is considered as the primary treatment for hyperlipidemia. The study was undertaken to evaluate the drug utilization pattern and medication adherence of statin. In this prospective study, the study population includes 212 outpatients (146 males and 66 women). The data and other information needed for the study were collected by using individually designed data entry form and MMAS (Morisky medication adherence scale) to determine the adherence. Results of the study indicates two third of the patients is male (69%) in the age group of 60-69(44%). Atorvastatin is the most prescribed statin followed by Rosuvastatin, hypertension is the major associated disease condition. High medication adherence is study population. The major barrier for the nonadherence is the financial hazard.

INTRODUCTION

Hyperlipidaemia is one of the major risk factor which is associated with atherosclerosis and atherosclerosis induced condition such as coronary heart disease, Ischemic cerebrovascular disease and peripheral vascular disease. It is a disorder of lipoprotein metabolism which includes a number of abnormalities such as hypercholesterolemia and hypertriglyceridemia.[1, 2] World Health Organization (WHO) has reported that approximately 60% of Indians will be affected by cardiovascular diseases by 2020. The coronary heart disease (CHD) incidents are correlated with elevated level of Low-Density Lipoprotein (LDL) cholesterol and triacylglycerols and with low level of High-Density Lipoprotein cholesterol.[3]

After therapeutic lifestyle modification, Statin medication is considered as a primary treatment for elevated LDL cholesterol. Statin decreases the coronary event by 23%.[4, 5] These drugs are currently most frequently used and best selling prescription drug worldwide. It works by inhibiting the enzyme called HMG-COA reductase, reduces cardiovascular event and total mortality irrespective of the initial cholesterol concentration.[6]

Drug utilization research is an essential part of pharmacoepidemiology as it describes the nature, determinant and extends of drug exposure. It can be used to compare the observed pattern of drug use for the treatment of a certain disease with current recommendation or guidelines. Medication adherence is defined by the WHO as a degree to which person behavior corresponds with the agreed recommendation from a health care provider. Poor adherence to prescribers regimens can result in serious health consequences. For instances a recent study found that the risk of hospitalization was more than double in patients with diabetes mellitus, hypercholesterolemia, hypertension, congestive heart failure who are poor adherent to prescribed therapies compared with the general population.[7, 8] Although the benefit of statin therapy are modified to a large extent by CHD risk, data are limited on whether adherence rate differ between primary and secondary prevention population. The relationship between high adherence level and improved CHD outcome is documented in several populations.[9, 10]

In this present study, we have evaluated the drug utilization pattern and medication adherence in patients prescribed with Statin. Since there is wide variation in selection and use of these drugs, this study helps to evaluate and analyze drug therapy from time to time.

MATERIALS AND METHODS

Study type: Hospital based prospective study.

Study Site: The study was conducted in two different hospitals – Rajiv Gandhi co-operative hospital and Lakshmi hospital Palakkad, Kerala.

Study Duration: Data collection was conducted over a period of 5 months from November (2019) to March (2020).

Study population: A total of 212 cases were included in this study.

Study criteria

Inclusion criteria: Outpatients of both gender and age 30 years and above with statin therapy, Patients prescribed with statin for more than 45days, Patients with or without co-morbid conditions.

Exclusion Criteria: Patients not willing to give consent for the study.

Study procedure

Signed informed consent was taken from the patient who is willing to participate in the study and pre-designed patient data entry form was used to collect the required information. The details on utilisation pattern of statin in various clinical condition was be recorded in data entry form. Medication adherence is measured by using Morisky 8-item medication adherence scale (MMAS). The barrier for the nonadherence is recorded by using questionnaire.

Ethical Committee approval

The study was approved by Institutional Ethical Committee GCP/IEC/219A/2019**.**

Statistical analysis

It was performed in Graph pad prism version 8.4.1(676) by using descriptive statistics.

RESULTS

Table No. 1: DISTRIBUTION OF STATIN USE BASED ON GENDER

GENDER	NO OF PATIENTS (n=212)	PERCENTAGE (%)
Male	146	69%
Female	66	31%

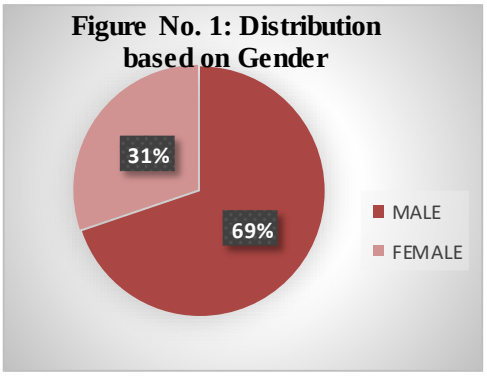


Table No. 2: DISTRIBUTION OF STATIN USE BASED ON AGE

AGE GROUP	NO OF PATIENTS (n=212)	PERCENTAGE (%)
<40	6	3%
40-49	30	14%
50-59	55	26%
60-69	91	44%
70-79	24	11%
≥80	6	3%
Mean (±SD)	60.08(±9.743)	

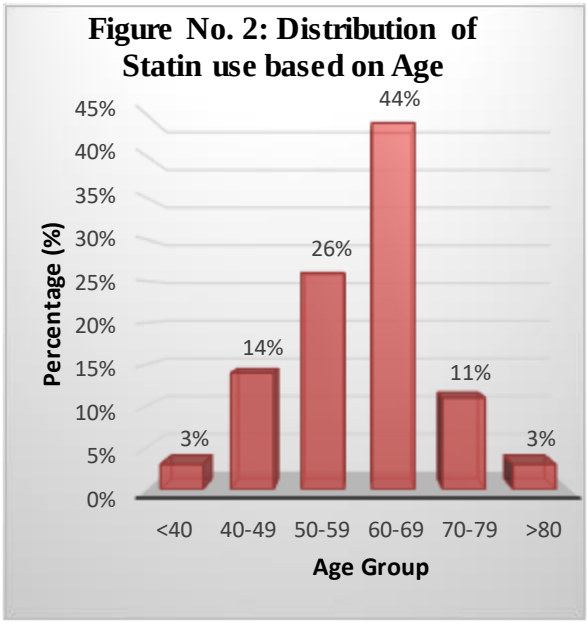


Table No. 3: DISTRIBUTION BASED ON DURATION OF THERAPY

NO OF YEARS	NO OF PATIENTS (n=212)	PERCENTAGE (%)
<1	23	11%
1-4	126	59%
5-9	41	19%
10-14	19	9%
>15	3	1%
Mean(±SD)	3.83(±3.28)	

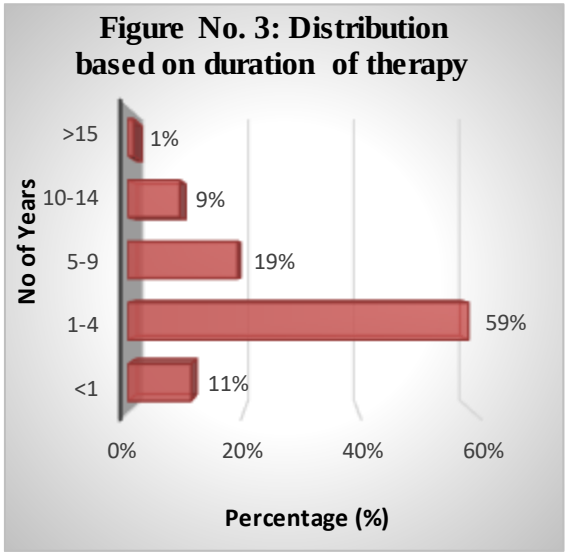


Table No. 4: DISTRIBUTION BASED ON STATIN PRESCRIBED

STATIN PRESCRIBED	NO OF DRUG PRESCRIBED (n=212)	PERCENTAGE (%)
Atorvastatin	133	63%
Rosuvastatin	79	37%

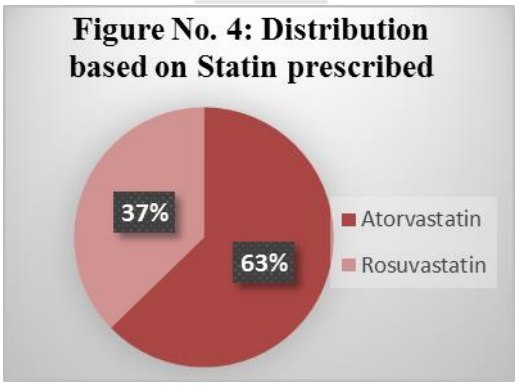
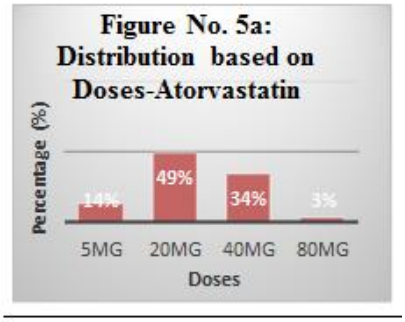


Table No. 4a: DISTRIBUTION BASED ON PRESCRIBING PATTEN OF STATIN

CATEGORY	STATIN MONOTHERAPY (n=145)	PERCENTAGE (%)
Atorvastatin	98	68%
Rosuvastatin	47	32%
FIXED DOSE COMBINATIONS (ATORVASTATIN) (n-35)		
Atorvastatin + Aspirin	3	9%
Atorvastatin + Clopidogrel	17	49%
Atorvastatin + Aspirin + Clopidogrel	15	43%
FIXED DOSE COMBINATIONS (ROSUVASTATIN) (n-32)		
Rosuvastatin + Aspirin	5	16%
Rosuvastatin + Clopidogrel	4	12%
Rosuvastatin + Aspirin + Clopidogrel	22	69%
Rosuvastatin + Fenofibrate	1	3%

TABLE 5: DISTRIBUTION BASED ON DOSE OF STATIN PRESCRIBED.

DOSES	ATORVASTATIN (n=133)	PERCENTAGE (%)
5mg	19	14%
20mg	65	49%
40mg	45	34%
80mg	4	3%
DOSES	**ROSUVASTATIN (n=79)**	**PERCENTAGE (%)**
10mg	15	19%
20mg	38	48%
40mg	26	33%



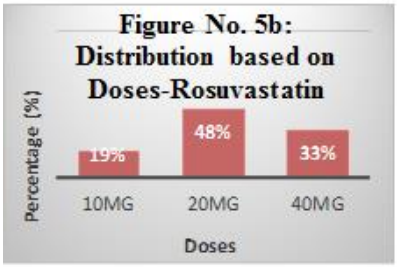


Table No. 6: DISTRIBUTION BASED ON INDICATION OF STATIN

CLINICAL CONDITION	NO OF PATIENTS (n=212)	PERCENTAGE (%)
Dyslipidemia	99	47%
Diabetics Mellitus	83	39%
Hypertension	87	41%
Ischemic Heart Disease	141	67%

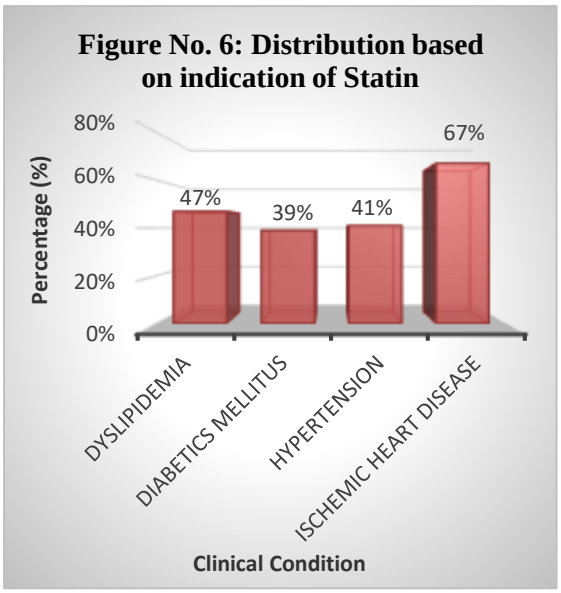


Table No. 7: DISTRIBUTION BASED ON NON-STATIN DRUGS PRESCRIBED

CATEGORY OF DRUG	NO OF DRUG PRESCRIBED (n=212)	PERCENTAGE (%)
Anti-Hypertensive	144	68%
Proton Pump Inhibitor	134	63%
Anti-Platelet	109	51%
Anti-Diabetic	78	37%

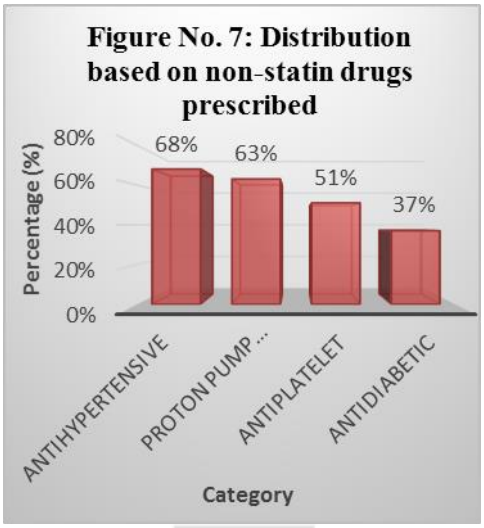


Table No. 8: PATIENTS DISTRIBUTION ACCORDING TO MORISKY- 8ITEM MEDICATION ADHERENCE SCALE (MMAS)

CATEGORY	NO OF PATIENTS (n=212)	PERCENTAGE (%)
Patients with high adherence	174 (Male-121 Female-53)	83%
Patients with medium adherence	11 (Male-7 Female-4)	5%
Patients with low adherence	27 (Male-18 Female-9)	13%

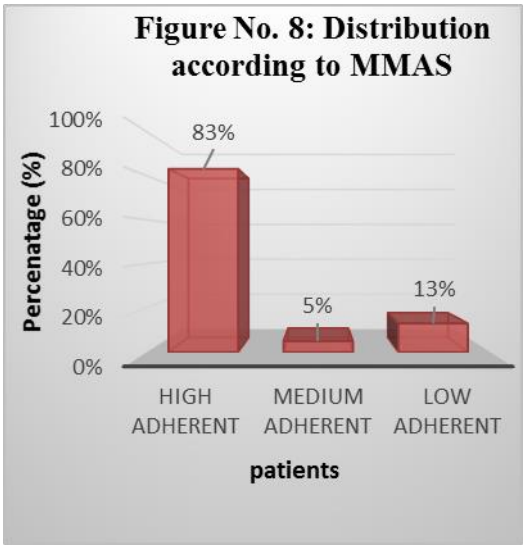
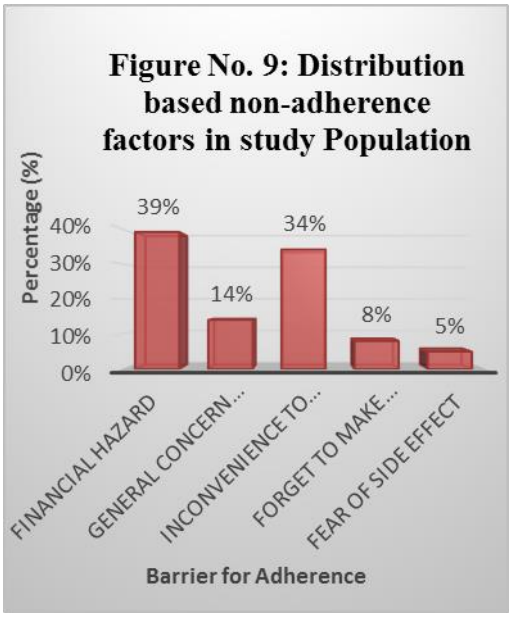


Table No. 9: DISTRIBUTION BASED ON NON-ADHERENT FACTORS IN STUDY POPULATION

BARRIER FOR ADHERENCE	NO OF PATIENTS (n=38)	PERCENTAGE (%)
Financial hazard	15	39%
Inconvenience to stick into medication plan	13	34%
General concern about medication	5	14%
Forget to take medication	3	8%
Fear of side effect	2	5%



DISCUSSION

Many studies have been carried out on the drug utilisation pattern of statin in developed and developing countries. Similarly, studies show that many patients have suboptimal adherence to statin medication which leads to serious health consequences.

In this study having population of 212 patients, two third of the study population is male i.e. 146(71%) and 66(31%) are female as the risk factor of ischemic heart disease are higher in males than females (Table 1). The result is similar for the study conducted by S**eema Gupta** et al, in 2016.[2] Majority of males and females were in the age group of 60-69 years with the mean(±SD) of 60.08(±9.743) (Table 2), about 91(44%) patient, as the frequency and incidence of cardiovascular events increases sharply with increase in age and associated risk factor are considerably higher in older individuals.[11] Distribution based on duration of therapy shows that the majority of the patients are taking statin for the period of 1-4 years with the mean(±SD) of 3.835(±3.28), which is 126 (59%) patients followed by 5 to 9 years which is 41(19%) patients of the total study population (Table 3).

On analysis of Statin prescribed, Atorvastatin and Rosuvastatin is the only prescribed statins. Were Atorvastatin was prescribed for 131(63%) patients and Rosuvastatin was prescribed for 79(37%) patients out of the total study population (Table 4). The prescribing pattern of Statin shows that statins was prescribed in monotherapy and fixed dose combinations, similar to the result depicted in study conducted by **Sangeetha Raja** *et al* in 2014. In monotherapy, Atorvastatin is prescribed for 98(68%) patients and Rosuvastatin 47(32%) patients. In fixed dose combination Atorvastatin is prescribed for 35 patients and Rosuvastatin in 32 patients (Table 4 a). Distribution based on doses prescribed reveals that 20mg of Atorvastatin and Rosuvastatin was highly prescribed followed by 40 mg (Fig 5.a & 5.b).

Morbidity pattern demonstrated that majority of the patients were having Ischemic Heart Disease (67%) followed by Dyslipidemia (47%), Hypertension (41%), Diabetes mellitus (39%). This suggests that patient may present with more than one disease and statin is prescribed for both primary and secondary prevention of diseases (Fig 6). Apart from statins, patients were prescribed with concomitant drugs such as Anti-Hypertensive's (68%), Proton Pump Inhibitor (63%), Anti-Platelet (51%), and Anti-Diabetic (37%) (Fig. 7).

Patient's adherence to statin therapy was checked by using Morisky 8 Questionnaire. A study conducted by shows **Nikil Raj P.V** in 2012, 67.4% patients on statin therapy is highly adherent to statin therapy. Similarly in our study majority of the study population i.e. 174(83%) patients were highly adherent to treatment plan, 11(5%) patients showed medium adherence and 27(13%) patients showed low adherences to treatment plan (table 8, fig 8). The reported nonadherent factors on study population was financial hazards (39%), general concern about medications (14%), inconvenience to stick into medication plans (34%), forget to take medications (8%), fear of side effects (5%) (Table & Fig. 9).

CONCLUSION

The study was mainly focused on the drug utilisation pattern and medication adherence of statin. Atorvastatin is the mostly prescribed statin in the age group of 60-69. Statin was both prescribed for primary and secondary prevention of the diseases and concomitant drugs are prescribed for Hypertension, Diabetes. It is prescribed both in monotherapy and combination therapy. 83% of the patient is highly adherent to the treatment plan and the major non-adherent factor among the study population is financial hazard.

The study depicts the over-all utilisation habit in the study set-up is appropriate and rational to a large extent. Only set-back is lesser number of drugs are prescribed by generic name. Prescribing in generic name can make better availability of the drug at affordable price and the influence of pharmaceutical companies can be minimised since the major non-adherent factor is financial hazard. While universal adherence for all patients is the desirable goal, some efforts should focus on improving adherence among high risk population who are the most likely benefit from statin use.

ACKNOWLEDGMENT

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