International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR)

ISSN: 2347-6567

IJAMSCR |Volume 3 | Issue 4 | Oct – Dec - 2015
www.ijamscr.com

Research Article *Medical Research*

A study on drug utilisation evaluation of HMG -CoA reductase inhibitor (atorvastatin) in a tertiary care teaching hospital

M. Praveen Kumar[1]*, K. Bhanu Prasad[2], Y. Manasa[3], Ayesha Siddiqua[3], Mubeen Ul Hasan[3], Faheem[3]

[1,2]Assistant Professor, Department of Pharmacy Practice, Holy Marry College of Pharmacy, Hyderabad, Telangana, India.

[3]PharmD Interns, Department of Pharmacy Practice, Smt. Sarojini Ramulamma College of Pharmacy, Mahabubnagar, Andhra Pradesh, India – 509001

***Corresponding Author: M. Praveen Kumar**

Email:praveen.pharmd16@gmail.com

ABSTRACT

OBJECTIVES: Our objectives are to determine the safety, efficacy, rationale use of Atorvastatin in patients in a tertiary care teaching hospital and to provide information to health care providers and patients.

METHODOLOGY: It was a prospective observational study which was undertaken in medicine, ICU and casualty departments of 300 bedded multi- speciality tertiary care teaching hospital, SVS hospital, for a period of 6 months. A total of 210 prescriptions were included in the study and were followed for the drug use evaluation to study. This study criterion was the in-patients and out-patients of age greater than 18yrs of either gender who are prescribed with HMG-CoA reductase inhibitor Atorvastatin.

RESULTS: The drug was found to be more safe in males (97.24%) compared to females (93.85%). The drug was found to be more effective in females (98.46%) compared to males (96.55%).The drug was found to be rationally prescribed more in males (95.86%) compared to females (92.31%). In the lipid profile study, all the different parameters like serum cholesterol, High density lipoproteins (HDL), Low density lipoproteins (LDL), Very Low density lipoproteins (VLDL) and triglycerides were found to be in the normal range in about 60-70% of males, where as lipid profile parameters of females were found to be in the normal range in about 20-30% females.

CONCLUSION: We conclude that the drug use was found to be safe, effective and it was rationally prescribed. Interventions for promoting more appropriate use of Atorvastatin should be implemented. Further studies from time to time are required in drug utilization pattern and standard treatment guidelines to be circulated among practicing physicians.

Keywords: Safety, Efficacy, Rationale use, HDL, LDL, VLDL, Triglycerides, Atorvastatin, Interventions.

INTRODUCTION

The World Health Organization (WHO) in 1997 defined drug utilization as the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences[1].

Scope of drug utilization evaluation

Drug use evaluation (DUE) or DU studies is an ongoing, authorized and systematic quality improvement process, which is designed to-

- Review drug use and/or prescribing patterns
- Provide feedback of results to clinicians
- Develop criteria and standards which describe optimal drug use
- Promote appropriate drug use through education and other interventions [2].

They relate the number of cases of adverse effects to the number of patients exposed. Thus Drug use evaluation (DUE) plays a key role in helping the healthcare system to understand, interpret and improve the prescribing, administration and use of medications. The principal aim of DU research is to facilitate rational use of drugs, which implies the prescription of a well -documented drug in an optimal dose on the right indication, with correct information and at an affordable price. It also provides insight into the efficacy of drug use i.e. whether a certain drug therapy provides value for money.

Types of drug use information

- Drug based information
- Problem based information
- Patient information
- Prescriber information

Sources of drug utilization data

- Computerised databases
- Pharmacy Records
- Medical Practioneer Records
- Health Surveys

Instruments for data collection on drug utilization

- Patient files and computer registries
- Home inventories
- Questionnaires

Steps involved in conducting drug use study [2]:

Step 1- Identify drugs or therapeutic areas of practice for inclusion in the program
Step 2- Design of study
Step 3- Define criteria and standards
Step 4- Design the data collection form
Step 5-Data collection
Step 6- Evaluate results
Step 7-Provide feedback of results
Step 8- Develop and implement interventions
Step 9- Re-evaluate to determine if drug use has improved
Step 10- Reassess and revise the DUE program
Step 11- Feedback results

Possible roles for pharmacists in due [3]

- Program development, supervision and coordination
- Education of hospital staff about DUE
- Promotion of goals and objectives of DUE
- Presentation of DUE results at meetings and conferences
- Publication of results in peer-reviewed journals.

ATORVASTATIN

Brand name

Lipitor/Tonact/ Atorvas/ Storvas/Atorlip /Aztor. [4]

Indications

Hypercholesterolemia, Type III familial hyper lipoproteinemia, Elevated serum triglyceride, Homozygous familial hypercholesterolemia

Dosage

ADULTS: PO 10 to 80 mg/day. [4]

Mechanism of action

Reduces production of cholesterol in body by inhibiting enzyme HMG-CoA reductase that catalyzes early rate-limiting step in cholesterol synthesis; increases HDL; reduces LDL, VLDL, and triglycerides. [4]

Adverse drug reactions

Headache; dizziness; asthenia; insomnia; Rash; Sinusitis; pharyngitis; arthralgia; myalgia; rhabdomyolysis.

CONTRAINDICATIONS

Active liver disease or unexplained persistent elevation of serum transaminases, pregnancy, lactation. [4]

OBJECTIVES

PRIMARY OBJECTIVE

- To assess the DUE study of HMG-Co A Reductase inhibitor Atorvastatin.

SECONDARY OBJECTIVES

- To ensure rational use, safety and effectiveness of the drug.
- To assess the prescribing habits and patients compliance through DUE.
- To provide information to the health care providers and patients.
- To evaluate Atorvastatin use with variables like age and gender.

METHODOLOGY

It was a prospective observational study which was undertaken in medicine, ICU and casualty departments of 300 bedded multi- speciality tertiary care teaching hospital, SVS hospital, for a period of 6 months. A total of 210 prescriptions were included in the study and were followed for the drug use evaluation to study. This study criterion was the in-patients and out-patients of age greater than 18yrs of either gender who are prescribed with HMG-CoA reductase inhibitor Atorvastatin. Patient data relevant to the study was obtained from Patient case records, medication charts and lab reports. The study protocol and written informed consent form were approved by the ethical committee at the hospital. All the enrolled patients were monitored from the date of admission until discharge for any change in the drug therapy. Criteria for evaluation include drug safety, efficacy, rational use, comparison of actual use with optimal use and Morisky medication adherence score. A Proforma was designed and pretested to be used for entry of patient's specific information. Data were entered in excel sheet and following indicators were analyzed:

- Subject identity number (I P NO.)
- Age of the patient
- Sex/ gender of patient
- Drug prescribed to patient
- Dose of the prescribed drug
- Frequency of the prescribed drug
- Duration of drug treatment
- Serum cholesterol (before and after drug treatment)
- High density lipoprotein (before and after drug treatment)
- Low density lipoprotein (before and after drug treatment)
- Very low density lipoprotein (before and after drug treatment)
- Triglycerides (before and after drug treatment)
- Is the drug safe?
- Is the drug effective?
- Is the drug rationally prescribed?
- Morisky medication adherence score.

RESULTS

TABLE 1: Gender wise distribution of atorvastatin

	No of Males(n)	% of Males	No of Females(n)	% of Females
Drug use	145	69.05	65	30.95

The above table shows the Gender wise distribution of Atorvastatin.

TABLE 2: Age wise distribution of atorvastatin use according to who in males and females

Age	Number of Males(n)	% of Males	No. of Females(n)	% of Females
20-24	1	00.69	0	00.00
25-29	0	00.00	1	01.54
30-34	8	05.52	0	00.00
35-39	6	04.14	0	00.00
40-44	16	11.03	9	13.85
45-49	18	12.41	2	03.08
50-54	25	17.24	6	09.23
55-59	9	06.21	7	10.77
60-64	26	17.93	13	20.00
65-69	14	09.66	11	16.92
70-74	16	11.03	5	07.69
75-79	2	01.38	4	06.15
80-84	3	02.07	3	04.62
85-90	1	00.69	4	06.15

The above table shows the Age wise distribution of Atorvastatin use according to WHO in Males and Females.

TABLE 3: Gender wise distribution of the safety of the drug

Safety of the drug	No of patients in whom the drug is safe(n)	% of patients in whom the drug is safe	No of patients in whom the drug is not safe(n)	% of patients in whom the drug is not safe
MALE (145)	141	97.24	4	2.76
FEMALE (65)	61	93.85	4	6.15

The above table shows the gender wise distribution of the safety of the drug

TABLE 4: Age wise distribution of the safety of the drug

Age	No of patients in whom the drug is safe(n)	% of patients in whom the drug is safe	No of patients in whom the drug is not safe(n)	% of patients in whom the drug is not safe
20-24	1	00.48	0	0.00
25-29	1	00.48	0	0.00
30-34	8	03.81	0	0.00
35-39	6	02.86	0	0.00
40-44	25	11.90	0	0.00
45-49	19	09.05	1	0.48
50-54	27	12.86	4	1.90
55-59	16	07.62	0	0.00
60-64	38	18.10	1	0.48
65-69	25	11.90	0	0.00
70-74	20	09.52	1	0.48
75-79	5	02.38	1	0.48
80-84	6	02.86	0	0.00
85-90	5	02.38	0	0.00

The above table shows the age wise distribution of the safety of drug

TABLE 5: Gender wise distribution of the efficacy of the drug

Efficacy	No of patients in whom the drug is effective(n)	% of patients in whom the drug is effective	No of patients in whom the drug is not effective(n)	% of patients in whom the drug is not effective
MALE (145)	140	96.55	5	3.45
FEMALE (65)	64	98.46	1	1.54

The above table shows the gender wise distribution of the efficacy of the drug

TABLE 6: Age wise distribution of the efficacy of the drug

Age	No of patients in whom the drug is Effective(n)	% of patients in whom the drug is Effective	No of patients in whom the drug is Not Effective(n)	% of patients in whom the drug is Not Effective
20-24	1	0.48	0	0.00
25-29	1	0.48	0	0.00
30-34	8	3.81	0	0.00
35-39	6	2.86	0	0.00
40-44	25	11.90	0	0.00
45-49	19	9.05	1	0.48
50-54	30	14.29	1	0.48
55-59	16	7.62	0	0.00
60-64	38	18.10	1	0.48
65-69	25	11.90	0	0.00
70-74	20	9.52	1	0.48
75-79	5	2.38	1	0.48
80-84	6	2.86	0	0.00
85-90	5	2.38	0	0.00

The above table shows the age wise distribution of the efficacy of the drug

TABLE 7: Gender wise distribution of the rational use of the drug

Rational use	No. of Patients with Rational use of drug(n)	% of Patients with Rational use of drug	No. of Patients Without Rational use of drug(n)	% of Patients Without Rational use of drug
Male (n=145)	139	95.86	6	4.14
Female(n=65)	60	92.31	5	7.69

The above table shows the gender wise distribution of the rational use of the drug

TABLE 8: Age wise distribution of the rational use of the drug

Age	No. of Patients with rational use of drug(n)	% of Patients with rational use of drug	% of Patients with rational use of drug	% of Patients with rational use of drug
20-24	1	0.48	0	0.00
25-29	0	0.00	1	0.48
30-34	8	3.81	0	0.00

35-39	5	2.38	1	0.48
40-44	24	11.43	1	0.48
45-49	19	9.05	1	0.48
50-54	31	14.76	0	0.00
55-59	16	7.62	0	0.00
60-64	36	17.14	3	1.43
65-69	24	11.43	1	0.48
70-74	20	9.52	1	0.48
75-79	5	2.38	1	0.48
80-84	5	2.38	1	0.48
85-90	5	2.38	0	0.00

The above table shows the age wise distribution of the rational use of the drug

TABLE 9: Gender wise distribution of lipid profile

Variables	**Total**	**No. of Males**	**% of Males**	**No. of Females**	**% of Females**
Sr. Cholesterol <200mg/dl	190	131	68.9	59	31.1
HDL>35mg/dl	139	94	67.6	45	32.4
LDL<100mg/dl	153	105	68.6	48	31.4
VLDL5-40mg/dl	182	132	72.5	50	27.5
Triglycerides<150mg/dl	167	117	70.1	50	29.9

The above table shows the gender wise distribution of lipid profile

TABLE 10: Serum cholesterol levels after treatment in different age groups

AGE	**Serum cholesterol levels after treatment <200mg/dl No. of Patients with serum cholesterol levels in normal range (n=190)**	**(%) of Patients with serum cholesterol levels in normal range**
20-24	1	00.53
25-29	1	00.53
30-34	8	04.21
35-39	5	02.63
40-44	24	12.63
45-49	18	09.47
50-54	26	13.68
55-59	14	07.37
60-64	34	17.89
65-69	25	13.16
70-74	19	10.00
75-79	4	02.11
80-84	6	03.16
85-90	5	02.63

The above table shows the Serum Cholesterol levels after treatment in different age groups

TABLE 11: HDL levels after treatment in different age groups

AGE	HDL levels after treatment>35mg/dl No. of Patients with HDL levels in normal range (n=139)	(%) of Patients with HDL levels in normal range
20-24	1	0.72
25-29	0	0.00
30-34	5	3.60
35-39	5	3.60
40-44	19	13.67
45-49	11	7.91
50-54	19	13.67
55-59	11	7.91
60-64	27	19.42
65-69	15	10.79
70-74	14	10.07
75-79	2	1.44
80-84	5	3.60
85-90	5	3.60

The above table shows the HDL levels after treatment in different age groups

TABLE 12: LDL Levels after treatment in different age groups

AGE	LDL levels after treatment<100mg/dl No of Patients with LDL levels in normal range(n=152)	(%) of Patients with LDL levels in normal range
20-24	0	0.00
25-29	1	0.66
30-34	7	4.61
35-39	3	1.97
40-44	16	10.53
45-49	13	8.55
50-54	22	14.47
55-59	13	8.55
60-64	31	20.39
65-69	21	13.82
70-74	14	9.21
75-79	3	1.97
80-84	5	3.29
85-90	3	1.97

The above table shows the LDL levels after treatment in different age groups

TABLE 13: VLDL Levels after treatment in different age groups

AGE	VLDL levels after treatment 5-40mg/dl No. of Patients with VLDL levels in normal range(n=182)	(%) of Patients with VLDL levels in normal range
20-24	1	0.55
25-29	0	0.00
30-34	8	4.40
35-39	5	2.75
40-44	23	12.64
45-49	19	10.44
50-54	27	14.84
55-59	13	7.14
60-64	33	18.13
65-69	21	11.54
70-74	18	9.89
75-79	6	3.30
80-84	4	2.20
85-90	4	2.20

The above table shows the VLDL levels after treatment in different age groups

TABLE 14: Triglyceride levels after treatment in different age groups

AGE	Triglyceride levels after treatment<150mg/dl No. of Patients with Triglycerides levels in normal range (n= 167)	(%) of Patients with Triglycerides levels in normal range
20-24	0	0.0
25-29	1	0.6
30-34	8	4.8
35-39	4	2.4
40-44	23	13.8
45-49	17	10.2
50-54	26	15.6
55-59	11	6.6
60-64	29	17.4
65-69	17	10.2
70-74	18	10.8
75-79	4	2.4
80-84	5	3.0
85-90	4	2.4

The above table shows the Triglyceride levels after treatment in different age groups

TABLE 15: Gender wise distribution of diagnosis

Diagnosis	Total	No. of Males	% of Males	No. of Females	% of Females
Cerebro Vascular accident	123	82	66.7%	41	33.3%
Coronary artery disease	50	36	72.0%	14	28%
Other disorders	37	27	73.0%	10	27%

The above table shows the gender wise distribution of diagnosis

TABLE 16: Age wise distribution of diagnosis IN (%)

AGE	Cerebro-Vascular Accident (100%)	Coronary Artery Disease (100%)	Other Disorders (100%)
20-24	0.0	0	2.7
25-29	0.0	2	0.0
30-34	5.7	0	2.7
35-39	1.6	4	5.4
40-44	9.8	16	13.5
45-49	7.3	14	10.8
50-54	14.6	16	13.5
55-59	8.1	6	8.1
60-64	20.3	18	13.5
65-69	13.0	12	10.8
70-74	11.4	6	8.1
75-79	3.3	4	0.0
80-84	2.4	2	5.4
85-90	2.4	0	5.4

The above table shows the age wise distribution of diagnosis

DISCUSSION

Prescriptions of 210 consecutive admissions were audited over a 6-month period to study drug utilization use of Atorvastatin in a tertiary care teaching hospital. The data was collected from the medicine, Casualty, and ICU departments of the hospital. In our study male population was more, (69.05%) and (39.05%) of patients were found to be females. In a similar study carried out by Jyothi.K, Jagadish Babu. D drug utilization evaluation of cephalosporins in general medicine units of rural tertiary care hospital of Karnataka the male population was found to be more in (50.50%) than the female (49.50%).This findings is similar to a study conducted by Shankar et al that showed a male predominance (61.6%) compared to females (38.8%). A study conducted in surgery departments at a tertiary care centre also showed that a greater proportion of study population was males (52%) than females (48%). In the age wise distribution of Atorvastatin in males and females, patients between the age group 60-64 were found to be more (17.93% and 20%) respectively. In a study carried out at a rural tertiary care hospital majority of the patients belonged to age group of 51-60 followed by the 21-30 years. In the gender wise distribution of safety of drug, the drug was found to be more safe in males (97.24%) compared to females (93.85%). In the age wise distribution of safety of drug, the drug was found to be safer in patients between the age group 60-64 (18.10%). Some patients complained of adverse effects. The adverse effects reported were Rhabdomyolysis (Muscle pain), Xerostomia, and Thrombocytopenia. In the gender wise distribution of

efficacy of drug, the drug was found to be more effective in females (98.46%) when compared to males (96.55%). In a study carried out by Nattakarn Suwansuksree MD*,Visanu Thamlikitkul MD*, Preyanuj Yamwong MD* on Drug Use Evaluation of Statins at Siriraj Hospital, Bangkok, Thailand the drug, Atorvastatin was not found to be effective in about 8% of patients. In the age wise distribution of efficacy of drug, the drug was found to be more effective in patients between the age group 60-64 (18.10%). In our audit the drug was found to be rationally prescribed more in males (95.86%) compared to females (92.31%).In the age wise distribution of rational use of drugs, the drug was found to be rationally prescribed more in patients between the age group 60-64 (17.14%). We found that few patients were not given the right dose though they were prescribed the right dose. It may be due to the negligence of nurses and attenders of the hospital in not giving the right dose. Mostly we observed that patients were given lesser dose than the actual dose. This was overcome by us by counselling the patients and providing information of the drug to the patients and their attenders. In the lipid profile study, all the different parameters like serum cholesterol, HDL, LDL, VLDL and triglycerides were found to be in the normal range in about 60-70% of males, where as lipid profile parameters of females were found to be in the normal range in about 20-30% females. After treatment with Atorvastatin, serum cholesterol levels were found to reach the therapeutic goals (<200mg/dl), mostly in patients between the age group 60-64 (17.89%). In a similar study carried out by Nattakarn Suwansuksree MD, Visanu Thamlikitkul MD, Preyanuj Yamwong MD at Siriraj Hospital Bangkok, Thailand cholesterol levels could not be controlled in some patients despite of them receiving higher doses. After treatment with atorvastatin, HDL, LDL and VLDL levels were found to reach the therapeutic goals mostly in patients between the age group 60-64 (19.42%), (20.39%) and (18.13%) respectively. The triglyceride levels were found to be normal (<150mg/dl), mostly in patients between the age group 60-64 (17.40%). In the gender wise distribution of duration of stay, males were found to stay more days in hospital when compared to females. A similar study statistics conducted in a rural tertiary hospital of Karnataka showed that the average length of hospital stay of study patients was found to be 7 days ranging from 3 to 25 days. This was similar to the study conducted in a teaching hospital in Nepal where the median length of stay was 9 days. Of all the 210 patients admitted in the hospital we found that most of the males (73%) were diagnosed with other disorders-? like epistaxis, Type 2 diabetes mellitus with cellulitis of neck, Hypertension, Myocardial infarction, Altered sensorium, Dilated cardiomyopathy, refractory heart failure and most of the females (33%) were diagnosed with Cerebro-vascular accident. In age wise distribution of diagnosis we found that patients diagnosed with Cerebro-vascular accident were mostly of the age group of 60-64 (20.3%),where as patients diagnosed with coronary artery disease were also belonged to the age group of 60-64(18%). Patients with other disorders were mostly seen in the age group of 40-44, 50-54 and 60-64 i.e (13.5%).The results also highlight several areas that need improvements. Most importantly, there is a need to promote rational use of the drug which may in turn improve the effectiveness of the drug.

CONCLUSION

In the present study the drug use evaluation of Atorvastatin in a tertiary care teaching hospital with special reference to the use of the drug in Medicine, Causality, and ICU departments was observed. The data of 210 patients was evaluated. The rational use, safety and effectiveness of the drug were ensured. Patient compliance to the drug was also assessed by preparing questionnaires. Brochures for the proper and effective use of the drug were also provided to the prescribers and patients. Further interventions like extension of the study duration, comparative study of drug utilization of the different class of drugs can be more useful. The comparison of drug utilization with the income would also act as a beneficiary tool.

REFERENCES

[1]. WHO Expert Committee. The Selection of Essential Drugs, Technical Report Series no. 615. Geneva: World Health Organization, 1977.

[2]. Einarson T. Pharmcoepidemiology. In: Parthasarathi G, Hansen KN, Nahata MC, editors. A Text book of Clinical Pharmacy Practice essential concepts and skills. 1st ed., Hyderabad: Universities Press (India) Limited; 2008. P. 405-23.

[3]. Sathvik B. Drug use evaluation. In: Parthasarathi G, Hansen KN, Nahata MC, editors. A Text book of Clinical Pharmacy Practice essential concepts and skills. 2nd ed., Hyderabad: Universities Press (India) Limited; 2012. P.460.

[4]. A-Z Drug facts David S. Tatro, PharmD ; 2003.

[5]. Folke S, Donald B. Drug utilization .Introduction to drug utilization research. WHO office of publications .2003; 76-84.

[6]. Heinonen TM, Stein E, Weiss SR, et al. The lipid-lowering effects of atorvastatin, a new HMG-CoA reductase inhibitor: Results of a randomized, double-masked study. ClinTher.1996; 18: 853–863.

[7]. Nawrocki JW, Weiss SR, Davidson MH, et al. Reduction of LDL cholesterol by 25% to 60% in patients with primary hyper cholesterolemia by atorvastatin, a new HMG-CoA reductase inhibitor. Arterioscler Thromb VascBiol. 1995; 15: 678 682.

[8]. Jones P, Kafonek S, Laurora I, Hunninghake D. Comparative dose efficacy study of atorvastatin versus simvastatin, pravastatin, lovastatin, and fluvastatin in patients with hypercholesterolemia (the CURVES study) [published correction appears in Am J Cardiol. 1998;82:128]. Am J Cardiol.1998; 81: 582–587.

[9]. Guerin M, Egger P, Soudant C, et al. Dose-dependent action of atorvastatin in type IIB hyperlipidemia: Preferential and progressive reduction of atherogenic apo Bcontaining lipoprotein subclasses (VLDL-2,IDL,LDL) and stimulation of cellular cholesterol efflux. Atherosclerosis.2002; 163:287–296.

[10]. Black DM, Bakker-Arkema RG, Nawrocki JW. An overview of the clinical safety profile of atorvastatin (Lipitor), a new HMG-CoA reductase inhibitor. Arch Intern Med. 1998; 158: 577–584.

How to cite this article: M. Praveen Kumar, K. Bhanu Prasad, Y. Manasa, Ayesha Siddiqua, Mubeen Ul Hasan, Faheem, A Study On Drug Utilisation Evaluation Of Hmg -Coa Reductase Inhibitor (Atorvastatin) In A Tertiary Care Teaching Hospital. Int J of Allied Med Sci and Clin Res 2015;3(4):510-520
Source of Support: Nil. **Conflict of Interest:** None declared.