Original Research Article

Assessment of the Compliance of Statin Treatment in HyperlipidemicPatients and its Association with Socioeconomic Status

ABSTRACT

Objectives: To assess the compliance of statin treatment in hyperlipidemicpatients and its association with Socioeconomic StatusNawabshah, Sindh, Pakistan.**Methodology:** This was a retrospectivecross-sectional study using convenient sampling techniqueconductedin collaboration with Department of Cardiology & Medicine People Medical College Hospital (PMCH)Nawabshah, Sindh, Pakistan for the period of 6 months.A total of 100 patients suffering from Hyperlipidemia (diagnosed) were recruited(VOLUNTARY AND WELL INFORMED ABOUT THE RESEARCH PROJECT)fromout patients department (OPD) of Cardiology & Medicine department.The data was collected by administering the questionnaire to Hyperlipidemicpatients after a written consent. All the variables related to socioeconomically class on per designed questionnaire were registered by filling the designed Proforma.**Results:**Out of 100 patients enrolled the mean age of the patients was 49.45± 9.72 years. The mean cholesterol levels were 231.83± 15.9 mg/dl.Statin therapy compliance was compared with socioeconomic status. Statin therapy compliance was achieved in socio-economic status which revealed > 80% proportion of days covered (PDC) response however resultsstatistical significancewas P-value 0.056.**Conclusion:**Hyperlipidemic patients have shown a good compliance to statins. Compliance in both lower and middle class was more than in higher class.

Key words: Compliance, Hyperlipidemia, Nawabshah, Statin.

INTRODUCTION

Patient's adherence with treatment can be strongly predicted through the stability amidrequirements for medication & interests over their usage. The reason of the poor conformity and therapy for asymptomatic long-term condition likedyslipidemia is the demonstration of this opinion of the comparative benefits and risk of treatment. Patients couldconsequently have decreased compliancewith long termmanagement and may not distinguish any benefit of therapy, because there are no clear signs of dyslipidemia [1-5]. Patients treated for primary prevention have lesser acceptance to statin therapy than patients with clear sign of CHD like newACSi-e;

Comment [I1]: GO TO THE METHODOLOGY, INDICATING THE PLACE OF THE RESEARCH

Comment [I2]: SUGGESTION

JOURNAL INDICATIONS:

All manuscripts which deal with the study of human subjects must be accompanied by Institutional Review Board (IRB) or Ethical Committee Approval, or the national or regional equivalent. The name of the Board or Committee giving approval and the study number assigned must accompany the submission. If required, the author should be ready to submit a scanned copy of the IRB or Ethical Committee Approval at any stage of publication (Pre or post publication stage).

For manuscripts involving human experiments, Authors may use the following wording for this section: "All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki."

Comment [I3]: THIS CONCLUSION IS VERY SIMPLE

Comment [I4]: ABBREVIATIONS MUST BE DESCRIBED IN THE FIRST APPEARANCE

acute coronary syndromedue the better awareness of the need for treatment. Aware patients with increased CHD risk like diabetes or hypertension explain greater conformity rates with lipid lowering medication. The consequences of CHDusually occur with increasing age since it is associated with increasing age. Unaware patients of long term management stop taking their medication and may consider themselves cured ontreatment is applied and cholesterol reduced to be suggested level. On other hand, this information may be taken out of context and information sources may not necessarily be precise. Patients' poor info decisions make them non-compliant. As a result, the contribution to the more compliant behavior is due to the more risk awareness of CHD and aids of treatment [6-10].

The aim of this study is to assess the compliance of statin treatment in hyperlipidemicpatients and its associationwith Socioeconomic StatusNawabshah, Sindh, Pakistan?????

GO TO THE METHODOLOGY, INDICATING THE PLACE OF THE RESEARCH

METHODOLOGY

This was a retrospectivecross-sectional study using convenient sampling techniqueconducted in collaboration with Department of Cardiology & Medicine People Medical College Hospital (PMCH)Nawabshah, Sindh, Pakistan for the period of 6 months.A total of 100 patients suffering from Hyperlipidemia (diagnosed) were recruited from out patients department (OPD) of Cardiology & Medicine department.The data was collected by administering the questionnaire to Hyperlipidemicpatients after a written consent. All the variables related to socioeconomically class on per designed questionnaire were registered by filling the designed Proforma.

SUGGESTION: **ETHICAL APPROVALSUGGESTION**GO TO METHODOLOGY

This study was approved by ethical review committee of People's University of Medical and Health Sciences for Women Nawabshah, Sindh, Pakistan.

Inclusion criteria:

The following patients were included in this study:

- Both genders.
- Age 30 years and above.
- The diagnosed cases/patients of Hyperlipidemia.

Comment [I5]: GO TO METHODOLOGY

THIS ITEM MUST BE PASSED TO METHODOLOGY, SINCE STUDY WITH HUMANS MUST BE APPROVED BY THE ETHICS COMMITTEE OF THE INSTITUTION.

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- Mild (160-200mg/dl) to moderate (200-290mg/dl) Hyperlipidemic patients were recruited; complicated cases were not taken because complications have developed.

Exclusion criteria:

- Following patients were excluded from the study.
- Sever Hyperlipidemic patents
- Patients with acute Myocardial Infarction.
- Patients below the age of 30 yrs were not included in the study.
- Co morbidities like diabetes, heart failure, hepatic disease, renal impairment.

The patients have to complete seven visits as per schedule given as under in Table 1. The first visit was counted as is baseline on day 1st, the second visit was on day 15th, third visit was scheduled on day 30th, fourth on day 45th,fifth on day 60th, sixth on day 75th day, and last 7th visit of each patient were on day 90th of the study.

Comment [I6]: INFORMATION REPEATED WITH THE TABLE

Table 1: Brief schedule of Patient's visit

Visit	**First Base Line**	**Second**	**Third**	**Fourth**	**Fifth**	**Sixth**	**Seventh**
Day	01st	15th	30th	45th	60th	75th	90th

The portion of the designed Performa was filled on every visit for each patient. Marked empty blisters of tablets were collected back from the patients on every visit also follow Morisky scale to check the compliance [11].

Data analysis

After completion of the study, the data was computed. Finally, data was evaluated by using statistical software SPSS, IBM to check the significance of the results.Compliance to thestatin related to socio economic class was calculated and appropriate test were applied in data analysis.

Comment [I7]: WHICH TEST IS APPROPRIATE??????/

RESULTS

Out of 100 patients enrolled the mean age of the patients was 49.45± 9.72 years. The average among males and females was nearly same. The mean cholesterol levels were 231.83± 15.9 mg/dl (Table 2). Age range of 31 to 50 years was reported in 44 (44%) patients and 51 to 70 years was 56 (56%) (Figure 1).

Table 2: Statistics of demographic variables.

Variables	**Frequency (percentages)**
Gender Male: female	54 (54%) : 46 (46%)
Age in years Mean ±SD	49.45± 9.72
Cholesterol in mg/dl Mean ±SD	231.83± 15.9

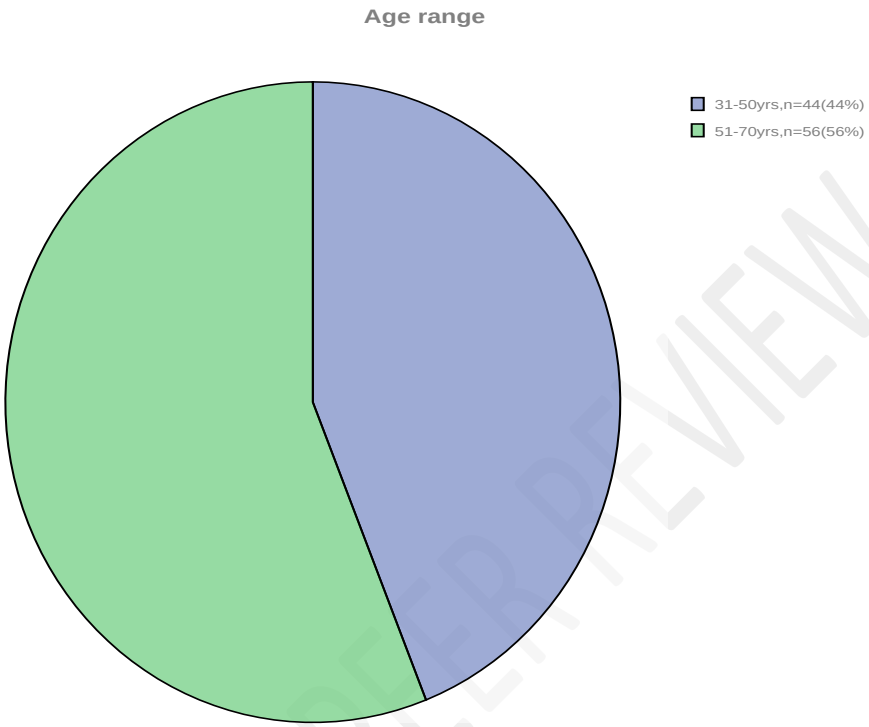

Fig. 1. Frequency of Age groups.

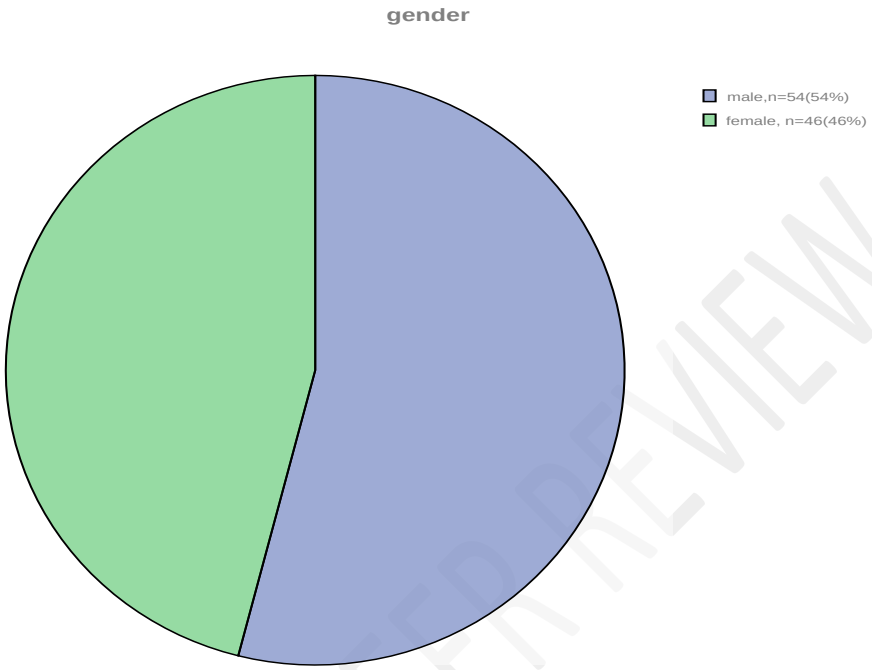

Fig. 2. Frequency of both genders

The cholesterol levels of mild to moderate levels were divided into three ranges one from 201-220mg/dl affecting n=25(25%) individuals, other 221-240mg/dl in n= 61(61%), 241-260mg/dl in n= 14(14%) (Figure 3). The range between 221-240mg/dl was higher compared to levels from 201-220mg/dl and much lower levels from 241-260mg/dl.

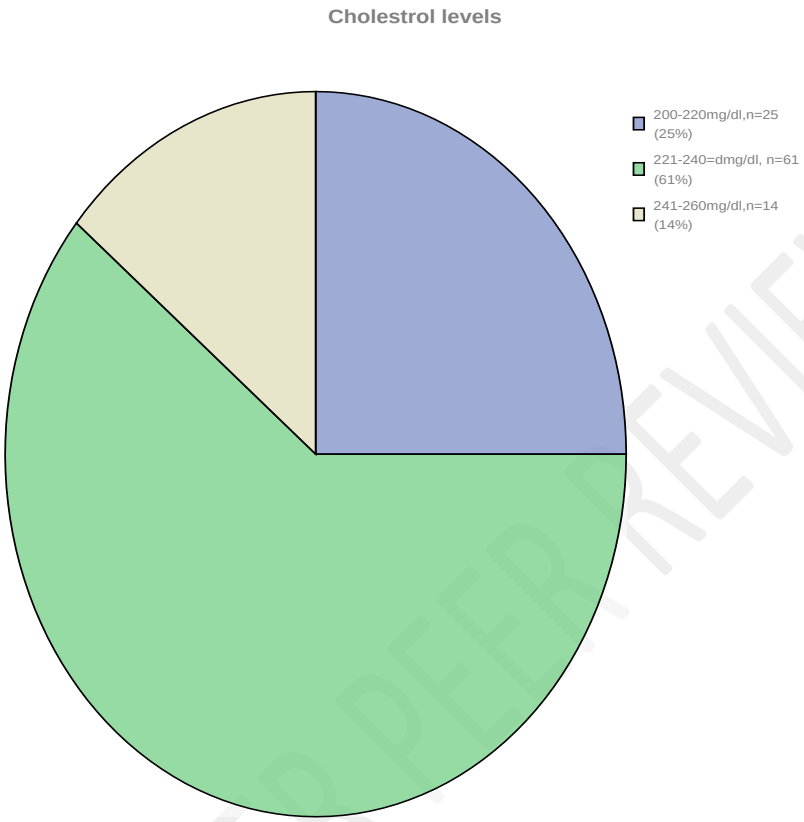

Fig. 3. Frequency of serum Cholesterol levels

The socioeconomic group was divided into three on the basis of monthly income i-e; lower class with monthly income of less than 10,000 rupees, middle class with monthly income between range of 10,000 to 50,000 rupees and higher class is considered those having above 50,000.

The lower class affected was n= 40(40%), middle class in n= 43(43%), and higher class in n= 17(17%). (Figure 4).

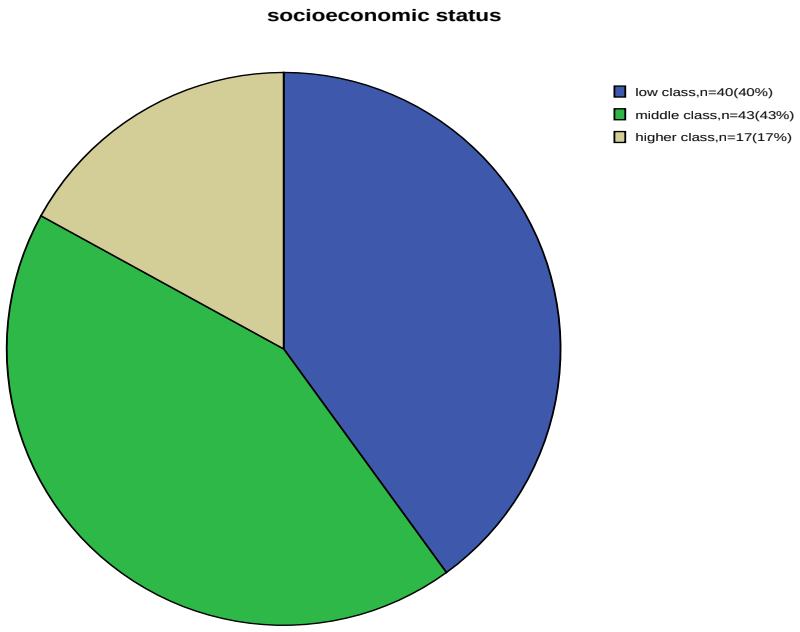

Fig. 4. Frequency of socioeconomic status

Both the groups the statin therapy compliance was compared with socioeconomic status. Statin therapy compliance was achieved in both age groups revealing no statistical significance after comparison of socioeconomic status with statin therapy, however all groups lower, middle and higher class have shown PDC> 80%??????with slightly lower compliance seen in lower class probably due to non-affordability. (p value-0.056) (Table 3).

Table 3: Association of statin compliance with socioeconomic status

Variables	Statin compliance		P value
	PDC*>80%????	**PDC*<80%????**	
Socioeconomic levels			
Low	29	11	0.543
Middle	31	12	
Higher	10	7	

*proportion of days covered

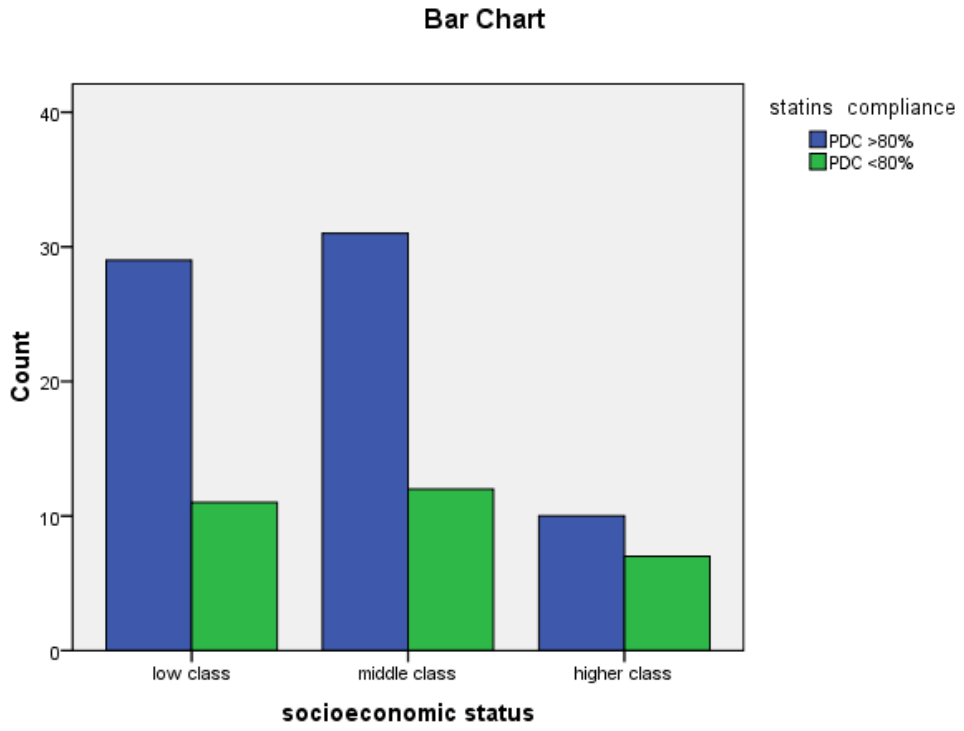

Fig. 5. Graphical presentation of Stain compliance association with socioeconomic status

DISCUSSION

The mortality is declining in patients with coronary heart diseases due to strategies involving risk reduction which has been achieved by statin use. The mortality benefits from Myocardial Infarction seen after statin therapy has also been reduced from 21% to 7%. Despite this usefulness, non-compliance is a significant risk that poses the individual to suffer from preventable cause. Compliance has been shown to be reduced in Chinese and Asians[12].

A study carried out by Qamaral-Haq, showed increased incidence among higher socioeconomic people of younger age are more affected.Also found increased compliance in patients with

comorbidities like hypertension and dyslipidemia. He in his research conducted that 150 patients responded to diet and regular exercise and that restriction of diet reduced **significantlylipids**in hyperlipidemic patients [13].

In our study comparison between two groups like the patients with hyperlipidemia with socioeconomic status showed that no statistical significance was revealed after socioeconomic status with hyperlipidemia however little higher incidence was seen in middle aged individuals.

In our study both the groupsi-e; the statin therapy compliance was compared with socioeconomic status. Statin therapy compliance no statistical significance was revealed after socioeconomic status with statin therapy, however all groups lower, middle and higher class have shown PDC>?????80% with slightly lower compliance seen in lower class probably due to non-affordability.

Therefor it is necessary that patients whether symptomatic or having asymptomatic hyperlipidemias should have strict dietary control as well as strict compliance and adherence of antihyperlipidemic medications. Not only this but also the control of comorbidities like strict glycemic control in diabetes mellitus, hypertension, and all other modifiable factors like quit smoking or alcohol abuse, control of obesity by modifying lifestyles is important in order to achieve desired goal and help decrease morbidity and mortality due to complications of hyperlipidemia.

CONCLUSION

Hyperlipidemic patients have shown a good compliance to statins. Compliance in both lower and middle class was more than in higher class.

ETHICAL APPROVALSUGGESTIONGO TO METHODOLOGY

This study was approved by ethical review committee of People's University of Medical and Health Sciences for Women Nawabshah, Sindh, Pakistan.

COMPETING INTERESTS DISCLAIMER:

Comment [I8]: DOES NOT DISCUSS ITS DATA WITH THE CONSULTED LITERATURE WHICH IS LITTLE

Comment [I9]: WHAT DOES PDC MEAN??? DESCRIPTION OF ABBREVIATIONS

Comment [I10]: RECOMMENDATION?? ??

Comment [I11]: THIS CONCLUSION IS VERY SIMPLE: ENLARGE

Comment [I12]: GO TO METHODOLOGY

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Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

REFERENCES

1. Joshi C, Jayasinghe UW, Parker S, Del Mar C, Russell G, Lloyd J, Mazza D, Denney-Wilson E, van Driel M, Taylor R, Harris MF; Preventive Evidence into Practice (PEP) Partnership Group. Does health literacy affect patients' receipt of preventative primary care? A multilevel analysis. BMC FamPract. 2014. 25;15(1):171.

2. Marie T. Brown, and Jennifer K. Bussell. Medication Adherence: WHO Cares? Mayo Clin Proc. 2011. 86(4): 304–314.

3. Maningat P, Gordon BR, Breslow JL. How do we improve patient compliance andadherence to long-term statin therapy? CurrAtheroscler Rep. 2013 Jan;15(1):291.

4. Benner JS, Glynn RJ, Mogun H, Neumann PJ, Weinstein MC, Avorn J. Long-term persistence in use of statin therapy in elderly patients. JAMA. 2002 Jul 24-31;288(4):455-61.

5. Wei MY, Ito MK, Cohen JD, Brinton EA, Jacobson TA. Predictors of statin adherence, switching, and discontinuation in the USAGE survey: understanding the use of statins in America and gaps in patient education. J ClinLipidol. 2013. 7(5):472-83.

6. Cutrona SL, Choudhry NK, Fischer MA, et al. Targeting cardiovascular medication adherence interventions. J Am Pharm Assoc2012. 52(3):381–397.

7. Miller M, Stone NJ, Ballantyne C, Bittner V, Criqui MH, Ginsberg HN, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. Circulation. 2011 May 24. 123(20):2292-333.

8. Pilia G, Chen WM, Scuteri A, Orrú M, Albai G, Dei M, et al. Heritability of cardiovascular and personality traits in 6,148 Sardinians. *PLoS Genet*. 2006 Aug 25. 2(8):e132.

9. Bansal S, Buring JE, Rifai N, Mora S, Sacks FM, Ridker PM. Fasting compared with nonfasting triglycerides and risk of cardiovascular events in women. *JAMA*. 2007 Jul 18. 298(3):309-16.

10. US Food and Drug Administration. Safety: Zocor (simvastatin): label change - new restrictions, contraindications, and dose limitations. Posted: June 8, 2011. Available at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedical Products/ucm258384.htm. Accessed: November 1, 2013.

11. MoriskyDE(1), Ang A, Krousel-Wood M, Ward HJ.Predictive validity of a medication adherence measure in an outpatient setting.JClinHypertens (Greenwich). 2008 May;10(5):348-54.

12. Muhammad SaleemBarech, Syed Mohammad Sadiq, Abdul Kareem Zarkoon, Gulan Dam, KaleemUllah. Risk factors for ischemic stroke in patients attending a tertiary hospital in Quetta. Pak J Neurological Sci Jan - Mar 2010;5(1):1-5.

13. QamarulHaq. Lipid Profile. Professional Med J Jan - Mar 2009;16(1):82-6.

Comment [I13]: NAME DOES NOT AGREE WITH THE NAME REFERRED TO IN THE ARTICLE
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