

**INTERNATIONAL JOURNAL OF ADVANCES IN PHARMACY,
BIOLOGY AND CHEMISTRY****Research Article****Assessment of Medication Adherence and Quality of
Life in Hyperlipidemia patients****R. Hari Babu^{1*}, R. Nagaraju², KVSRG. Prasad² and Sureshwar Reddy³**¹Chebrolu Hanumaiah Institute of Pharmaceutical Sciences, Guntur Andhra Pradesh, India.²Institute of Pharmaceutical Technology, Sri Padmavathi Mahila Visvavidyalayam, Tirupathi, Andhra Pradesh, India.³Department of General Medicine, Rajiv Gandhi Institute of Medical Sciences, Kadapa, Andhra Pradesh, India.**ABSTRACT**

In this study, we aimed to evaluate medication adherence and quality of life (QOL) in patients with hyperlipidemia. A Prospective, Randomized study was carried out in the department of general medicine for a period of 24 months in Rajiv Gandhi Institute of Medical Sciences after taking the Ethical Clearance. The patient data was collected by using a well designed questionnaire after taking their consent. The questionnaires were used to assess medication adherence via interviews, and pill and QOL was by patient report. A total of 600 patients were screened, out of which 516 patients were included in referral center group and 337 patients included in the paid clinic group. 80.4% of the total studied patients were considered to be adherence with their hypolipidemic therapies. The rates of adherence were similar between the referral center and paid clinics (78.6% vs 83.1% p=0.1). Patients who were adherence with their hypolipidemic medications also had a better health status in terms of social activities than non-adherence patients (98.1% vs 97.0%, p=0.03). This study concludes that non-adherence to medication is prevalent in the study groups but on lower side of the range, adherent patients had fewer limitations in their quality of life compared to non-adherent.

Keywords: Adherence, Hyperlipidemia, Quality of life.**INTRODUCTION**

Coronary heart disease (CHD) is one among the major causes of mortality in developed countries and is rapidly becoming so in developing countries^{1,2}. It has been predicted that cardiovascular diseases will be the most important cause of mortality in India by the year 2015³. Hyperlipidemia, characterized by elevated serum Total Cholesterol, LDL-C and triacylglycerol concentrations as well as reduced HDL-C concentrations are identified risk factors for coronary artery disease, and is a major concern in both developed as well as developing countries. Absolute risk of coronary heart disease increases with age in both men and women as a result of progressive accumulation of coronary atherosclerosis with aging⁴. Hypertension, smoking, diabetes, obesity, physical inactivity, and

atherogenic diets have all been identified as modifiable risk factors for heart disease. Age, male gender, and a family history of premature coronary heart disease (CHD) have been identified as nonmodifiable risk factors⁵. The word of QoL *Quality of life* is defined as a multidimensional construct that reflects the quality of the physical, emotional, social, and role- or function-associated life situation of an individual. QoL is directly associated with patients' subjective health status, daily living functions and severity of disease⁶. The degree of consensus between the desired and the actual life situation is part of quality of life. According to a World Health Organization definition, quality of life consists of the physical, emotional, and social well-being of an individual^{7,8,9}. The assessment of quality of life is increasingly being used as a measurement tool in the evaluation of health care outcomes and lifestyle

status¹⁰. There are several systems for evaluating quality of life. These range from the general (Medical Outcomes Study 36-Item Short-Form Health Survey²⁴) to the disease-specific¹¹. We included Dartmouth COOP functional health assessment charts for quality of life assessment¹², because it is generalizable, simple to administer, reproducible, and validated. The COOP/WONCA has been specifically designed to be practical and to be of clinical value when used in a busy clinical setting and it covers a core set of functional aspects including physical fitness, feelings, daily and social activities, changes in health, and overall health. Patients were asked to rate against a 5-point scale for each aspect. The purpose of present study was to assess the medication adherence and QOL in hyperlipidemia study population.

METHODOLOGY

The study was an open prospective, randomized study of 516 ambulatory patients attending Department of General Medicine & Cardiology, Rajiv Gandhi Institute of Medical Sciences, a tertiary care health facility in Kadapa, South India. After obtaining an ethical approval from the ethical Committee, this study was conducted for 24 months between 2nd Nov 2008 and 31st Oct, 2010. Patient were randomized into referral center and paid clinic group based on their consultation with physician. Patients attending the referral center during free of service consultation were enrolled into referral center group and visiting during pay service are enrolled into paid clinic group. The objectives of the study were explained to patients in both the groups, consent were obtained and were interviewed face to face collecting their sociodemographic details, medication adherence, and quality of life and entered in the questionnaire. Adherence scores range from 0 to 100%; <80% of medications taken was used as the cutoff for nonadherence in this study. Pill counts of all medication prescribed to each patient were conducted. Patients reported number of pills remaining in bottles and other containers (Tablet strips) for each medication. Adherence to medication was calculated as percentage of doses removed/doses prescribed $\times 100$. The COOP/WONCA chart covered a core set of functional that evaluates QOL across four areas: physical, emotional, social, and health. Items are reverse scored and transformed to a 0–100 scale, with higher scores representing better QOL. Descriptive statistical analysis has been carried out in the present study. Non-parametric continuous data that could not be successfully transformed into normally distributed data were analyzed by Mann-Whitney test, McNemar's test whereas categorical data, such as gender were analyzed by Chi - Square (χ^2) test.

RESULTS

Out of six hundred patients were identified in the study. 84 patients were excluded due to administration of drugs by care givers (n=58), refusal to enter the study (n=22), presence of functional impairment (n=3), and patient death (n=1). As a result, 516 patients included in the referral center group. Three hundred and fifty patients were identified and recruited during the same study period in paid clinic group. Among them, 13 patients were excluded due to drug administration by care givers (n =10), and refusal to enter the study (n=3), As a result, 337 patients included in the Paid clinic group. Table.1 gives the sociodemographic details of hyperlipidemia patients. Out of total 853 patients enrolled in the study, 490 patients were female patient. 363 were male patients. Maximum number of patients' were from 40 to 60 years of age followed by above 60 years, and 20 to 40 years respectively. 169 illiterate patients were present in referral center group, 544 were educated and 51 patients were highly educated. Majority of hyperlipidemia patients (>40%) in the study were from retired group followed by house wives and least are (0.3%) students. 49 patients in referral center were smokers as compared to 25 patients in paid clinic, and all these patients were males. 43 male patients were having a habit of alcohol drinking in referral center and 20 in paid clinic. 80.4% of the total studied patients were considered to be adherence with their hypolipidemic therapies. The rates of adherence were similar between the referral center and paid clinics (78.6% vs 83.1% p=0.1) shown in Table.2. The adherence rate decreased with increasing number of hypolipidemic drugs. Eighty-four percent (430 out of 512 patients) of the patients taking one hypolipidemic drug were considered to be adherence. This percentage dropped to 75% (252 out of 336 patients) in patients taking two or three hypolipidemic drugs and further decreased to 40% (2 out of 5 patients) in patients taking two or three hypolipidemic drugs and other chronic drug use. Among the non-adherence patients (n=167), thirteen percent had persistence problem (i.e. taking <80% or >120% of the prescribed amount) (15% in Referral center vs 12% in Paid clinic, p=0.21). Besides, fourteen percent had incorrect knowledge of prescribed drug dosage, 28.1% had incorrect knowledge of dosing frequency, and 20.4% had incorrect knowledge of both the drug dosage and dosing frequency, Nineteen percent had tried to modify the dosing regimen by themselves. Another 18% had knowledge problem of the regimen and modified therapeutic regimen. Table.3 presents the results on each aspect of Qol in the two study groups. Using percentage of patients with scores ranging from moderate to very good as an indicator, patients attending paid clinic had a better health status in

most aspects including physical fitness, feelings, daily activities, social activities, and overall health than patients attending the referral center. Patients who were adherence with their hypolipidemic medications also had a better health status in terms of social activities than non-adherence patients (98.1% vs 97.0%, $p=0.03$).

DISCUSSION

Non-adherence to medication is a major obstacle with chronic therapies that have been reported in many overseas studies^{13,14}. Base line characters of hyperlipidemia patients were analyzed between the study groups and 74 to 75% of patients were in the age group of 40 to 60 years. There was no significant difference in age distribution indicating that subject sample in both groups is homogenous. Females were more often affected than males as there were 42 to 57% in the study groups. This is similar to the hospital based studies of¹⁵, in which majority of patients were females (36%). Socioeconomic status is an important risk factor, indirectly reflecting the medication adherence of the hyperlipidemia patients. Socioeconomic status was determined by Kuppuswamy classification based on three variables in urban community namely education, occupation and income¹⁶. In the present study hyperlipidemia was commonly encountered in middle socioeconomic class (56 to 59%) followed by lower class (34 to 38%). Hyperlipidemia patients with high socioeconomic status were least in number (7%). There was no significant difference found in socioeconomic status in study groups. A population based cohort study to examine whether socioeconomic status is associated with hyperlipidemia concluded that, middle socioeconomic status is a strong risk factor for hyperlipidemia¹⁷. The prevalence of non-adherence in our study was about 20% (overall 19.6%, 21.4% in referral center group, 16.9% in paid clinic group, $p=0.10$). Our finding is on the lower side of the range reported in other studies¹⁸. This may be related to the fact that non-adherence was especially prevalent amongst the newly diagnosed hyperlipidemia patient e.g. within the first year of diagnosis who were not included in our survey. Beside, those patients with higher motivation in drug taking might be more likely to participate in the survey.

In the present study adherence rate decreased with increasing number of hypolipidemic drugs. 84% of the patients taking one hypolipidemic drug were

considered to be more adherent compared to 75% taking two or three hypolipidemic drugs and 40% taking two or three hypolipidemic drugs and other chronic drug use. This is similar to studies on large patient population in clinical practice¹⁹, showing increase in number of drugs decreases adherence to drugs. Although the prevalence of non-adherence in patients attending the two different settings was similar, patients attending referral center had a more complex pattern of non-adherence. 26% of patients from the referral center had attempted to modify their regimens in addition to having poor knowledge about them. This is in contrast to only 2% of patients from the paid clinic with the same problem ($p=0.001$). This could be explained by a number of factors. Patients in the referral center group were older; more debilitated and received more medications than the paid clinic group patients. It requires a higher level of skills to schedule the more complicated dosing regimen properly. Besides, the inadequate communication between physician and patients in referral center group might also explain patients' poor knowledge. This miscommunication occurred most frequently when physician modified treatment regimen. As a result, patient might still follow the wrong regimen from the previous visit. Among the six aspects in the functional status assessment, the ratings for social activities was found to be marginally better in adherent than non-adherent patients (percentage with moderate to very good ratings 98% vs 89%, $p=0.3$). This finding suggests that adherent patients had fewer limitations in their social activities with family, friends, neighbors, or groups. They might also reflect a better family and/or social support in the adherent patients. In this regard, social factors have been identified to positively affect patient medication adherence in different studies²⁰.

CONCLUSION

This study conclude that nonadherence to medication is prevalent in the study groups but on lower side of the range compared to other studies. Adherence rates decreases with increase in number of drugs. Communication between physician and patients should be encouraged to enhance adherence and adherent patients had fewer limitations in their quality of life.

ACKNOWLEDGEMENT

The authors thanks to Rajiv Gandhi Institute of Medical Sciences, Kadapa to carry out this work.

Table.1: Sociodemographic details of the study groups

Sociodemographic variables	Total study population (n=853)	Referral center group (n=516)	Paid clinic group (n=337)	P –value
20-40	48(5.6%)	24(4.65%)	17(5.04%)	0.15
40-60	611(71.6%)	386(74.81%)	256(75.97%)	0.17
>60	194(22.7%)	106(20.55%)	64(18.99%)	0.15
Male	363(42.5%)	225(43.6%)	138(40.9%)	0.44
Female	490(57.4%)	291(56.4%)	199(59.0%)	0.15
Nil	258(30.2%)	169(32.7%)	89(26.4%)	0.49
Intermediate	544(66.8%)	314(60.9%)	230(68.1%)	0.17
Graduation	51(5.97%)	33(6.4%)	18(5.3%)	0.53
Employed	217(25.43%)	94(18.2%)	123(36.5%)	<0.001
Unemployed	16(1.9%)	11(2.1%)	5(1.5%)	0.53
Retired	338(39.6%)	238(46.1%)	100(29.7%)	<0.001
House wife	258(30.2%)	156(30.2%)	102(30.3%)	0.99
Student	3(0.3%)	3(0.6%)	0(0%)	0.28
Smoking	74(8.7%)	49(9.5%)	25(7.4%)	0.29
Alcohol drinking	43(5.0%)	23(4.4%)	20(5.9%)	0.34

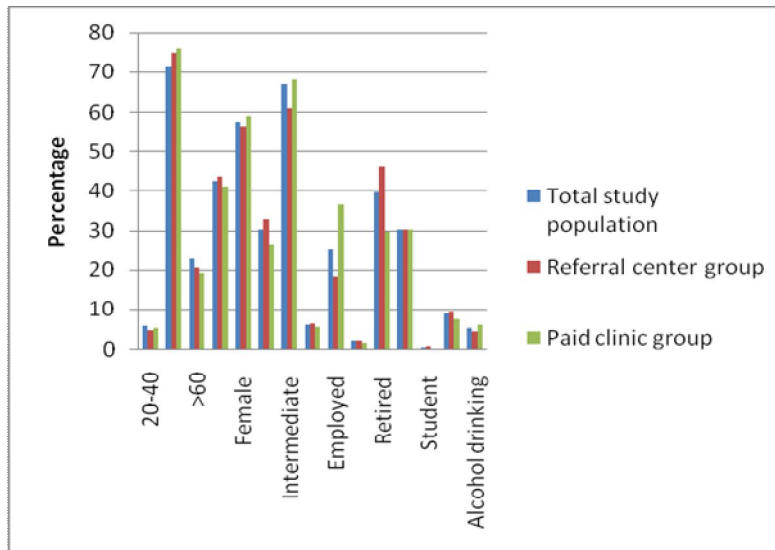


Table 2: Pattern of patient medication non-adherence between study groups

	Total study population (n=167)	Referral center group (n=110)	Paid clinic group (n=57)	p-value *
Incorrect knowledge of regimen				
Incorrect drug dosage	24(14.4%)	21(19.1%)	3(5.3%)	0.02
Incorrect dosing frequency	47(28.14%)	18(16.4%)	29(50.9%)	<0.001
Incorrect drug dosage and dosing frequency	34(20.4%)	23(20.9%)	11(19.3%)	0.81
Attempt to self-modify regimen				
Self-modify dosage regimen	32(19.2%)	19(17.3%)	13(22.8%)	0.39
Incorrect regimen knowledge and attempt to modify dosage regimen				
Self-modify regimen and knowledge problem on dosage and/or frequency	30(18.0%)	29(26.4%)	1(1.8%)	0.001

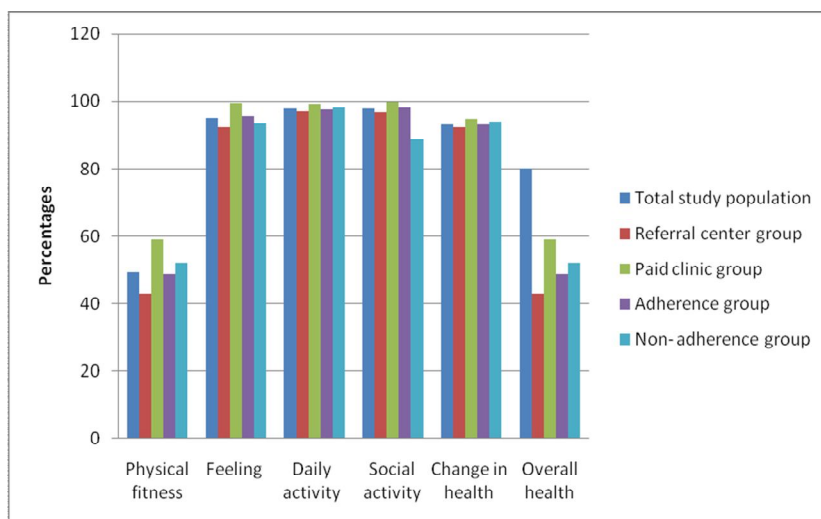
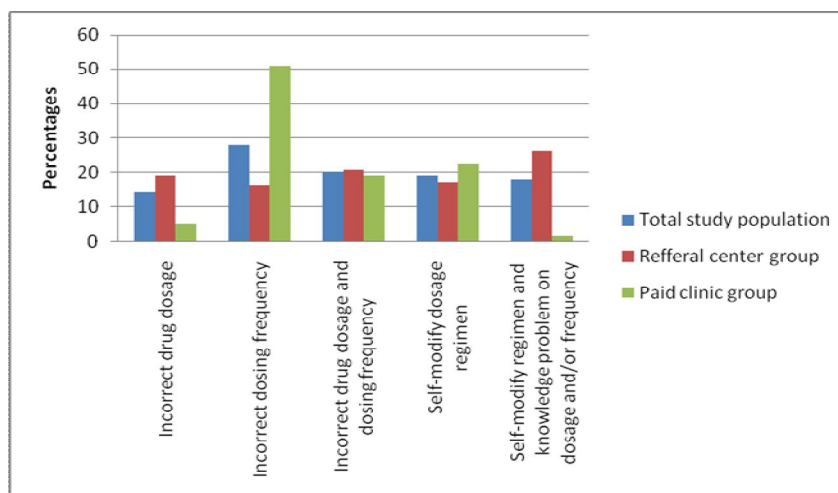
*Chi- square test

Table 3: Patients showing moderate to very good health status in the study groups

*By Chi-test comparing referral center and paid clinic group

Ratings	Total study population (n=853)	Referral center group (n=516)	Paid clinic group (n=337)	p-value*	Adherence group (n=686)	Non-adherence group (n=167)	p-value**
Physical fitness	421(49.3%)	222(43.02)	199(59.05)	<0.001	334(48.68)	87(52.09)	0.43
Feeling	811(95.0%)	476(92.24)	335(99.40)	<0.001	655(95.48)	156(93.41)	0.27
Daily activity	834(97.8%)	500(96.89)	334(99.10)	0.03	670(97.66)	164(98.20)	0.19
Social activity	835(97.9%)	499(96.70)	336(99.70)	0.003	673(98.10)	148(88.62)	0.51
Change in health	795(93.2%)	476(92.24)	319(94.65)	0.17	638(93.00)	157(94.01)	0.74
Overall health	683(80.1%)	222(43.02)	199(59.05)	<0.001	334(48.68)	87(52.09)	0.43

**By Chi-square test comparing adherence and non adherence group



REFERENCES

1. Bhatnagar D. The metabolic basis of increased coronary risk attributed to people from the Indian sub-continent. 1998;74:1087-1094.
2. Singh RB, Rastogi V, Niaz MA, Ghosh S, Sy RG and Janus ED. Serum cholesterol and coronary artery disease in populations with low cholesterol levels: The Indian paradox. *Int J Cardiol*, 1998;65:81–90.
3. Reddy KS. Cardiovascular diseases in India. *World Health Stat Q*. 1993;46:101–107.
4. Vanisha Nambiar and Parul Guin. Prevalence of hyperglycemia and hyperlipidemia among the middle aged and elderly population in a University setup. *Indian Journal of Gerontology*, 2007;21(1):30-43.
5. NCEP III. Executive summary of the third report of the national cholesterol education program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). *JAMA*. 2001;285:2486-2497.
6. Spilker B and Revicki DA: Taxonomy of Quality of Life. In: Spilker B ed. *Quality of Life and Pharmacoeconomics in Clinical Trials*. 2nd ed. Philadelphia, Lippincott-Raven Publishers: 1996;25-31.
7. Relman AS. Assessment and accountability: the third revolution in medical care. *N Engl J Med*. 1988;319:1220-1222.
8. Brook RH, Davies-Avery A and Greenfield S. Assessing the quality of care using outcome methods: an overview of the method. *Med Care*. 1977; 15: 5-15.
9. Bullinger M and Hasford J. Evaluating quality-of-life measures for clinical trials in Germany. *Control Clin Trials*. 1991;12:91S-105S.
10. Schipper H, Clinch JJ and Olweny CHLM. Quality of life studies: definition and conceptual issues. In: Spilker B, ed. *Quality of Life and Pharmacoeconomics in Clinical Trials*. Philadelphia, Pa: Lippincott-Raven Publishers; 1996:11-24.
11. El Achhab Y, Nejjari C, Chikri M and Lyoussi B. Disease-specific health-related quality of life instruments among adults diabetic: A systematic review. *Diabetes Res Clin Pract*. 2008;80(2):171-84.
12. Scholten JHG and Weel C van. Functional status assessment in family practice. *Disability and Rehabilitation*, 1993;15(2):96-101.
13. Brooke Aggarwal and Lori Mosca. Lifestyle and psychosocial risk factors predict non-adherence to medication. *Ann Behav Me*. 2010;40(2):228–233.
14. Monica Ramirez Basco and Jessica Smith. Faulty Decision-Making: Impact on Treatment Adherence in Bipolar Disorder *Primary Psychiatry*. 2009;16(8):53-58
15. Cocchi R, Viglino G, Cancarini G, Catizone L, Favazza A, Tommasi A, Salomone M, Segoloni GP, Torpia R and Giangrande A. Prevalence of hyperlipidemia in a cohort of CAPD patients. Italian Cooperative Peritoneal Dialysis Study Group (ICPDSG). *Miner Electrolyte Metab*. 1996;22(1-3):22-5.
16. Mishra D and Singh HP. Kuppuswami's socio-economic status scale – A revision. *Indian J Pediatr*. 2003;70:273-274.
17. Vijayakumar G, Arun R and Kutty VR. High prevalence of type 2 diabetes mellitus and other metabolic disorders in rural central Kerala. *J Assoc Physicians India*. 2009; 57:563-7.
18. Nelson LA, Graham MR, Lindsey CC and Rasur. Adherence to antihyperlipidemic medication and lipid control in diabetic veterans affairs patients with psychotic disorders. *Psychosomatics*. 2011;52(4):310-8.
19. Weng TC, Yang YH, Lin SJ and Tai SH. A systematic review and meta-analysis on the therapeutic equivalence of statins. *J Clin Pharm Ther*. 2012;35(2):139-151.
20. Elliott RA, Shinogle JA and Peele P. Understanding medication compliance and persistence from an economics perspective. *Value Health*. 2008;11(4):600-610.