

# Asian Journal of Pharmaceutical and Clinical Research ISSN - 0974-2441

Vol 6, Suppl 1, 2013

**Research Article** 

# **SELF - REPORTED MEDICATION ADHERENCE PATTERN OF RURAL INDIAN PATIENTS WITH HYPERTENSION**

# SATHVIK BS<sup>1</sup>, KARIBASAPPA MV<sup>2</sup>, NAGAVI BG<sup>1</sup>

<sup>1</sup> RAK College of Pharmaceutical Sciences, RAK Medical and Health University, Ras Al Khaimah, U.A.E, <sup>2</sup> Department of Pharmacy Practice, JSS College of Pharmacy and JSS Hospital, Mysore India, Email: sathvikbs@rediffmail.com

Received:30 May 2012, Revised and Accepted:21 July 2012

# ABSTRACT

Introduction: Nonadherence to medications is common in hypertensive subjects. Medication adherence pattern of urban hypertensive population has been widely studied. However, little is known about the medication adherence pattern hypertensive subjects residing in rural settings of India. Objective: This study aimed at assessing the self-reported medication adherence pattern of rural hypertensive patients and to evaluate the impact of pharmacist provided education on self reported adherence pattern. Methodology: Study subjects (n=150) were enrolled from three rural areas of Mysore district, Karnataka, India. The study subjects were block randomized to control group (n=75) and intervention group (n=75). Intervention group received the pharmacist education at baseline, 15th, 30th, 45th day and no medication education was provided to control group subjects. Brief Medication Questionnaire (BMQ), a medication adherence measurement questionnaire was administered to the all the study subjects at baseline and 15 days after the last education session. Results: At baseline there was no significant (P > 0.05) difference between the regimen, belief, recall, and access screen scores of control and intervention group patients. Access screen scores of both control ( $0.38 \pm 0.49$ ) and intervention ( $0.57 \pm 0.49$ ) 0.50) group documented lowest scores compared to other three screens of BMQ. While scores of regimen screen documented highest, both in control (1.95 ± 0.74) and in intervention (2.23 ± 0.65) group. There was a significant reduction in the regimen (P = 0.04), belief (P = 0.04), recall (P = 0.01), and access (P = 0.04) screen scores of intervention group patients was observed at 60<sup>th</sup> day of follow-up. But there was no significant (P > 0.04) 0.05) change/reduction in regimen, belief, recall, and access screen scores of control group patients. Belief (P = 0.03) and recall BMQ screen scores (P = 0.05) of intervention and control group patients at final follow-up. But, there was no significant difference in the regimen (P = 0.09) and access screen scores (P = 0.06) of intervention and control group patients at final-follow-up. Conclusion: Study subjects had some belief and recall barriers towards their antihypertensive medications. Pharmacist provided education was found to be helpful in overcoming these barriers.

## **Keywords**:

#### INTRODUCTION

Non-adherence to long-term medications in chronic diseases is a worldwide problem.<sup>1</sup> It has been estimated that 40 to 50% chronic disease patients are nonadherent to their prescribed treatment.<sup>2, 3</sup> Non-adherence to medications is a major concern in the management of chronic disease such as hypertension 4, 5

Vast amount of literature is available on medication adherence pattern of hypertensive subjects.6- 13 Majority of these studies are conducted in clinical / hospital settings and emphasize mainly on urban subjects. Only few studies address the medication adherence pattern of rural hypertensive subjects. 14

The prevalence rate of hypertension in India is estimated to be around 25% - 30% of urban and 10% -15% of rural adults. <sup>15</sup> Little is known about the medication adherence pattern of hypertensive patients residing at rural areas of India and to the best of our knowledge no published literature is available on role effectiveness of pharmacist in the patient education and improving the medication adherence of hypertensive subjects residing at rural settings of India.

Thus our study aims at examining the self-reported medication adherence pattern of hypertensive subjects residing in rural areas and also evaluates the impact of pharmacist provided education sessions on self-reported medication adherence pattern. In this study we hypothesized that pharmacist intervention can have a positive impact on self-reported medication adherence pattern of rural hypertensive subjects.

#### METHODOLOGY

This study was conducted in three selected rural areas (rural area is defined as population fewer than 5,000) <sup>16</sup> of Mysore district, Karnataka, India. This was a prospective, open label, block randomized study carried out for a period of nine months. The Institutional Human Ethical Committee of the JSS College of Pharmacy, Mysore, India has approved this study.

Prior to the initiation of the actual study, a survey was conducted by the study pharmacist at the study sites to identify the subjects who are on prescription medications for hypertension. Hypertensive

subjects who are on prescription medications for hypertension, above 18 years of age and who are able to communicate in the local language (Kannada) were included in the study after obtaining the signed informed consent. Study subjects who are taking other forms of medications (Ayurvedic and Homeopathic) and subjects with hearing /cognitive impairment were excluded.

The Study subjects were randomized into intervention and control group in the ratio of 1:1. As the means of two groups were to be compared, with alpha (significance) is set at a two-sided p-value of 5% with the power of the study 95%, the estimated required sample size was minimum of 75 in each group.

Medication adherence of the study subjects was assessed using Brief Medication Questionnaire (BMQ).<sup>17</sup> Intervention patient group received pharmacist education regarding his/her prescribed medications at baseline, 15th, 30th, 45th day. While no education was provided to control group patients during these follow-up visits, but they were just provided with patient information leaflets during the baseline visit. The patients were interviewed and educated by the study pharmacist in patients in-house settings. The education time was limited to 20-25 minutes/ follow-up. Verbal education along with printed materials such as patient information leaflets (PILs) and a medication chart was provided to each patient of the intervention group.

BMQ was administered to all the enrolled patients at baseline and fifteen days after the last follow-up visit (60th day). This was done to evaluate the impact of pharmacist provided medication education on medication knowledge and adherence pattern of the study patients.

All the BMQ screens consisted of a positive and a negative screen. A score of  $\geq 01$  indicates a positive screen denoting patient's reported nonadherence. While a score of zero indicates negative screen, indicating patient adherence to prescribed medications. Higher the BMQ scores, higher the reported rate of non-adherence. 17

Student- paired't' test was performed to find-out the significant difference between BMQ scores of intervention and control groups and to find out the significant change in BMQ scores from baseline to final follow-up. A 'p' value of less than 0.05 is considered as

statistically significant. Statistical analysis was carried out using the statistical package for social sciences (SPSS, Version 10.0).

# RESULTS

A total of 150 hypertensive patients were enrolled into the study. Seventy-nine female and seventy-one male hypertensive patients participated in the study. Majority (n = 57) of the study patients

were in the age group of 51 - 60 years. Greater part of the study patients were illiterate (n = 85) and household duties were the occupation of majority of the study patients. Good number (n = 74) of our study patients had a total family income of less than rupees 30,000/year. In our study, a higher incidence of hypertension was observed in the age group of 51 to 60 years. Demographic details of the study subjects are presented in Table 1.

Demographic, Disease and Treatment Variables	<b>Control Group</b>	Intervention Group
	(n=75) n (%)	(n=75) n (%)
Age (In Years)		
<ul> <li>18-29</li> </ul>	00%	00%
<ul> <li>30-40</li> </ul>	05 (6.7%)	03 (4%)
<ul> <li>41-50</li> </ul>	15 (20%)	13 (17.3%)
■ 51-60	27 (36%)	30 (40%)
<ul> <li>61-70</li> </ul>	19 (25.3%)	14 (18.7%)
■ <u>≥</u> 71	09 (12%)	15 (20%)
Gender		
<ul> <li>Male</li> </ul>	31 (41.3%)	40 (53.3%)
<ul> <li>Female</li> </ul>	44 (58.7%)	35 (46.7%)
Education level		
<ul> <li>Illiterate</li> </ul>	45 (60%)	35 (46.7%)
<ul> <li>Primary school</li> </ul>	10 (13.3%)	18 (24%)
<ul> <li>Secondary school</li> </ul>	10 (13.3%)	14 (18.6%)
<ul> <li>Pre-university</li> </ul>	05 (6.7%)	05 (6.7%)
<ul> <li>Graduation</li> </ul>	05 (6.7%)	03 (4%)
Annual family income		
(In Indian Rupees)		
• < 30,000	42 (56%)	45 (60%)
31,000-60,000	33 (44%)	30 (40%)
■ > 61,000	00 (00%)	00(00%)
Smoking history		
<ul> <li>Past smoker</li> </ul>	07 (9.3%)	05 (6.7%)
<ul> <li>Smoker</li> </ul>	20 (26.7%)	15 (20%)
<ul> <li>Non smoker</li> </ul>	48 (64%)	55 (73.3)
Number of medications		
<ul> <li>Monotherapy</li> </ul>	50 (66.7%)	40 (53.3%)
<ul> <li>Dual therapy</li> </ul>	22 (29.3%)	30 (40%)
<ul> <li>Polytherapy</li> </ul>	03 (4%)	05 (6.7%)

Table 2: Mean + 5D DMQ screen scores of study patients at basen	<b>Fable 2:</b>	: Mean + SD BMO	) screen scores of study	patients at baseling
---	-----------------	-----------------	--------------------------	----------------------

BMQ screens	<b>Control group</b>	Intervention group	P value*
Regimen screen	1.95 ± 0.74	2.23 ± 0.65	0.09
Belief screen	0.98 ± 0.50	0.76 ± 0.42	0.06
Recall screen	$0.71 \pm 0.46$	0.65 ± 0.48	0.33
Access screen	0.38 ± 0.49	0.57 ± 0.50	0.09

\* P value < 0.05 is considered as statistically significant.

Table 3: Mean <u>+</u> SD BMQ screen scores of study patients at final follow-up

BMQ screens	Control group	Intervention group	P value
Regimen screen	1.61 ± 0.58	1.88 ± 0.76	0.09
Belief screen	0.80 ± 0.51	0.53 ± 0.50	0.03*
Recall screen	0.66 ± 0.65	$0.34 \pm 0.48$	0.03*
Access screen	0.57 ± 0.50	$0.34 \pm 0.48$	0.06

\* P value < 0.05 is considered as statistically significant.

### BMQ scores of study patients at baseline

At baseline there was no significant (P > 0.05) difference between the regimen, belief, recall, and access screen scores of control and intervention group patients. Access screen scores of both control (0.38  $\pm$  0.49) and intervention (0.57  $\pm$  0.50) group documented lowest scores compared to other three screens of BMQ. While scores of regimen screen documented highest, both in control (1.95  $\pm$  0.74) and in intervention (2.23  $\pm$  0.65) group (Table 2).

#### BMQ scores of study patients at final follow-up

At final follow-up, there was a significant reduction in the regimen

(P = 0.04), belief (P = 0.04), recall (P = 0.01), and access (P = 0.04) screen scores of intervention group patients was observed (Table 21). But there was no significant (P > 0.05) change/reduction in regimen, belief, recall, and access screen scores of control group patients (Table 3).

There was a significant difference (P < 0.05) in the belief (P = 0.03) and recall BMQ screen scores (P = 0.05) of intervention and control group patients at final follow-up. But, there was no significant difference in the regimen (P = 0.09) and access screen scores (P = 0.06) of intervention and control group patients at final-follow-up (Table 4).

BMQ screens	Study group	Baseline	Final follow-up	P value
Regimen screen	Intervention Group (n=75)	$2.23 \pm 0.65$	$1.88 \pm 0.76$ 1.61 ± 0.58	0.04* 0.06
	control Group (II=75)	P=0.09	P=0.09	
Belief screen	Intervention Group (n=75)	$0.76 \pm 0.42$	0.53 ± 0.50	0.04* 0.14
	Control Group (n=75)	0.98 ± 0.50 P=0.06	0.80 ± 0.51 P=0.03*	
Recall screen	Intervention Group (n=75) Control Group (n=75)	$0.65 \pm 0.48$ $0.71 \pm 0.46$	0.34 ± 0.48 0.66 ± 0.65	0.01*
	Intervention Group (n=75)	P=0.33 0.57 ± 0.50	P=0.03* 0.34 ± 0.48	0.04*
Access screen	Control Group (n=75)	0.38 ± 0.49 P=0.09	0.57 ± 0.50 P=0.06	0.11

Table 4: Mean + SD BMQ screen scores of study patients at baseline and final follow-up

## \* P value < 0.05 is considered as statistically significant

### DISCUSSION

A total of 150 patients have been enrolled into the study. None of the subjects were lost to follow-up in the intervention and control group. This could be due to the reason that follow-up was done at the study subjects in-house settings. Majority of the study subjects belonged to the age group of 51- 60 years with female predominance. Epidemiological studies have reported predominance of hypertension in the age group of 55-74 years, slightly more women having hypertension than men.<sup>18</sup>

Self-reported medication adherence pattern of enrolled patients was assessed using validated questionnaire (BMQ).<sup>17</sup> This questionnaire consists of four screens namely regimen, belief, recall and assess screen. The score range of regimen screen was 0-5, and for the other three screens it was 0 - 2. A score of  $\geq 1$  indicates a positive screen representing regimen non-adherence.<sup>17</sup>

At baseline there was no significant difference between the regimen, belief, recall, and access screen scores of control and intervention group patients. Access screen evaluates the difficulty in buying and refilling their medications. Access screen scores of both control and intervention group documented lowest scores compared to other screens. Antihypertensive medications were easily accessible to the study subjects at free of cost in the rural setting through primary health care centers. This could be the reason for lowest access screen scores in study patients, indicating easy/better accessibility to prescribed medications. However, studies from other developing countries have reported nonadherence due to unaffordable cost of antihypertensive medications.<sup>19, 20</sup> However, in these comparative studies patients had to buy their medications on their own.

Scores of regimen screen documented highest at baseline, both in control and intervention group indicating higher self-reported nonadherence to medications. The regimen screen assesses the patient's knowledge regarding their medications (name, dose, indications). Highest scores in regimen screen could be due to lack of knowledge of rural hypertensive patients regarding the name, dose, indication and efficacy of their medications and missed doses. Lack of knowledge and inadequate understanding of prescribed medication has been related to poor medication adherence.<sup>21, 22</sup>

At final follow-up, there was a considerable drop in the regimen, belief, recall and access BMQ screen scores of intervention group patients than control group patients. This reduction in the BMQ screen scores indicates improvement in the self-reported adherence pattern of intervention group patients after pharmacist provided education sessions to intervention group. Although there was a significant (P<0.05) reduction in the BMQ regimen screen scores of intervention group patients at final follow-up, the regimen screen scores were greater than one. Score of greater than one in regimen screen a final follow-up indicates a positive screen representing self-reported nonadherence. This could be due to the lower literacy rate of majority of our study patients (n=85), which might have contributed to poor recall / comprehension of name, dose, indication and efficacy of their medications.<sup>13, 23</sup>

The belief screen of BMQ consisted of two questions inquiring the patients (a) How well your medications work for you? (b) Whether they had difficulty with any of the medications or if the medications bothered them in any way. Considerable drop in the belief screen scores of intervention group patients was observed at the end of the study period. This indicates improved belief of the intervention group patients towards the effectiveness of antihypertensive medications after pharmacist-provided education intervention.

Past research has shown that patients are more likely to be nonadherent when they have lack of belief towards the beneficial effects of their medications. Such belief of individuals can be related to theory of Health Belief Model (HBM). According to this theory, individuals will be more likely to adhere to medical regimen if they believe that the benefits (perceived benefits) of the behaviors considered are immense, and such behavior is both possible and useful.<sup>24</sup> Hence while educating our study patients, we took care that patient understand the beneficial effects of their medications along with consequences of being nonadherent to their medications.

When we asked our patients regarding any of their medications bother them. Nonetheless, no single patient mentioned that any of his or her medication is troublesome. Although few patients did experience side effects to their antihypertensive medications in the past, still they mentioned that medications are not bothering them. In contrast to our findings, studies from the past have reported noncompliance to antihypertensive medications due to side effects of the medications.<sup>25-27</sup>

The two-item recall screen assessed the difficulty they experienced in remembering the exact dosage regimen of their medications. The drop in the recall screen scores of intervention group patients could be due to the frequent medication education provided by the pharmacist.

A drop in the regimen, belief and recall screen scores of control group patients was observed at final follow-up, which was not statistically significant (P<0.05). But this drop in these three BMQ screen scores of control group patients could be due to the influence of written education material (patient information leaflets) provided to control group patients by the study pharmacist. Provision of patient information leaflets might have improved the comprehension of literate patients towards their medications resulting in decrease in the BMQ screen scores of control group patients. In addition, control group patients might have learnt the answers to these questions during the course of the study.

These findings suggest that educating patients about their disease and its management helps improve adherence seen in the intervention group patients suggest that improved adherence leads to improved treatment out comes. This finding is supported by several studies, which documented the role of pharmacist in improving the patient medication knowledge, adherence and improved therapeutic outcome. <sup>1,5,6</sup>

There are a quite a few limitations with this study. Medication adherence was measured using self-reported behavioral measure. Adherence to medications is overestimated by this method. Secondly, we did not use an objective method such as pill count, to confirm the accuracy of self-reported medication adherence. It is possible that improvement in the medication adherence has been overestimated in our study as the same pharmacist who educated the patients assessed the medication adherence of the intervention and control group, contributing some possible bias towards intervention group. The impact of improved medication adherence on blood pressure of the patient was not determined and the short duration of follow up of the study patients is another limitation.

#### CONCLUSION

Pharmacist provided education was found to be effective in improving the medication adherence pattern of rural hypertensive patients towards their antihypertensive medication(s). The study emphasizes the potential role of the pharmacist in educating rural patients with chronic diseases.

#### ACKNOWLEDGEMENTS

We are grateful to Bonnie L. Svarstad for permitting us to use BMQ for our study. We thank all the Physicians and Staff of Primary Health Centers of Hadinaaru, Mahadevapur, and Sutturu for all the timely help during the course of our study. We are also grateful to the Head, Department of Pharmacy Practice and Principal, JSS College of Pharmacy, JSS University, Mysore, for all the support.

## REFERENCES

- 1. Poor adherence to long-term treatment of chronic diseases is a worldwide problem. Pan Am J Public Health 2003; 14: 218-21
- Dunbar-Jacob J, Erlen JA, Schlenk EA, Ryan CM, Sereika SM, Doswell WM. Adherence in chronic disease. Annu Rev Nurs Res 2000;18:48-90
- Adherence to long term therapies: evidence for action.hhttp://www.who.int/chp/knowledge/publications/adh erence\_full\_report.pdf. (Accessed on 12/8/2006)
- Juan J Gascon, Montserrat Sanchez-Ortuno, Bartolome Llor, David Skidmore, Pedro J Saturno. Why hypertensive patients do not comply with the treatment. Family Practice 2004; 21 (2): 125-130.
- Lagi A, Rossi A, Passaleva MT, Cartei A, Cencetti S. Compliance with therapy in hypertensive patients. Internal and Emergency Medicine 2006; 1(3): 204-208.
- Lehane E, McCarthy G.An examination of the intentional and unintentional aspects of medication non-adherence in patients diagnosed with hypertension. J Clin Nurs 2007 Apr;16(4):698-706.
- Harmon G, Lefante J, Wood-Krousel M. Overcoming barriers: Role of providers in improving patient adherence to antihypertensive medications. Curr Opin Cardiol 2006;21:310– 315
- Staffan S, Kjellgren KI, Ahlner J, Saljo R. Reasons for adherence with antihypertensive medications. *Int J Cardiol.* 2000;76:157– 163
- 9. Girvin BG, Johnston GD. Comparison of the effects of a 7-day period of noncomplianceon blood pressure control using three different antihypertensive agents. J Hypertens. 2004; 22:1409-1414.
- Qureshi NN, Hatcher J, Chaturvedi N, Jafar TH. Effect of general practitioner education on adherence to antihypertensive drugs: cluster randomised controlled trial. BMJ 2007; 335:1030.
- 11. Elzubier AG, Husain AA, Suleiman IA, Hamid ZA. Drug compliance among hypertensive patients in Kassala, Eastern Sudan. *East Mediterr Health J* 2000; 6: 100–105.
- 12. Kopec G, Kloch M, czarnecka D. Factors affecting the cooperation of hypertensive patients in the process of treatment. Przegl Lek 2004; 61:902–5.
- 13. Ponnusanker S, Surulivelrajan M, Anandamoorthy N and Suresh B. Assessment of impact of medication counseling on patients medication knowledge and compliance in an outpatient clinic in South India. Patient Education Counseling 2004; 54: 55-60.
- 14. McLane CG, Zyzanski SJ, Flocke SA. Factors associated with medication noncompliance in rural elderly hypertensive patients. Am J Hypertens 1995;8(2):206-9

- 15. Gupta R. Trends in hypertension epidemiology in India. J Hum Hypertens 2004; 18(2):73-8.
- 16. Kurian V. New `rural area' definition to benefit life insurance companies.

http://www.thehindubusinessline.com/2002/10/29/stories/2 002102901831000.htm. (Accessed on 10/01/2006).

- Svarstad BL, Chewning BA, Sleath BL, Claesson C. The brief medication questionnaire: Atool for screening patient adherence and barriers to adherence. Patient Educ Couns 1999; 37: 113-24
- Gupta R, Gupta VP. Hypertension epidemiology in India: lessons from Jaipur Heart Watch. Current Science 2009; 97(3): 349-355.
- 19. Ohene Buabeng K, Matowe L, Plange-Rhule J. Unaffordable drug prices: the major cause of non-compliance with hypertension medication in Ghana. J Pharm Sci 2004;7:350–352.
- Elzubier G, Husain AA, Suleim. IA, Hamid ZA. Drug compliance among hypertensive patients in Kassala, Eastern Sudan. Eastern Mediterranean Health Journal 2000;6(1):100-105
- 21. Makaryus AN, Friedman EA. Patients<sup>4</sup>understanding of their treatment plans and diagnosis at discharge. Mayo Clin Croc 2005;80: 991-4.
- 22. Rosner F. Patient noncompliance: Causes and solutions. Mount Sinai J Med 2006; 73: 553-9.
- Boonstra E, Lindbaek M, Ngome E, Tshukudu K and Fugelli P. Libeling and patient knowledge of dispensed drugs as quality indicators in primary care in Botswana, Qual. Saf. Health Care. 2003; 12:168-75.
- 24. Janz NK, Becker MH. The health belief model: a decade later. Health Educ Q 1984; 11:1-47.
- Shaw E, Anderson JG, Maloney M, Jay SJ, Fagan D. Factors associated with noncompliance of patients taking antihypertensive medications. Hosp Pharm 1995; 30: 201-203, 206-207.
- Grégoire JP, Moisan J, Guibert R, Ciampi A, Milot A, Gaudet M, Cote I. Determinants of discontinuation of new courses of antihypertensive medications. *J Clin Epidemiol* 2002; 55:728–35.
- 27. Düsing R, Weisser B, Mengden T, Vetter H. Changes in antihypertensive therapy-the role of adverse effects and compliance. Blood Press 1998;7(5-6):313-5