Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 04, 2021

A PROSPECTIVE OBSERVATIONAL STUDY ON THE ASSESSMENT OF MEDICATION ADHERENCE AND COMPLIANCE IN PATIENTS WITH HYPERTENSION IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Long-term use of pharmacotherapy is quite common in the treatment of chronic illnesses. Although the medications used in pharmacotherapy are effective in combating disease, however, approximately half of the patients do not follow the prescriptions properly. Poor medication adherence is caused by a variety of factors, such as low health literacy, prescription of complex drug regimens, communication gap, suppression of adverse effects, and treatment with more than one physician.Health-care machinery related such as incompatible timings, limited window of visits and lack of infrastructure. Due to the complexity and variety of medication adherence barriers, identifying patient issues and developing solutions to improve adherence must be multifaceted.The present prospective observational study focuses on estimation of medication adherence and compliance in hypertensive patients using Modified Hill Bone High Blood Pressure Compliance Scale.Cognitive behaviour, food habits, carelessness, missing scheduled appointments, using OTC medications were found to be the major factors that affectedpatient's medication adherence and compliance.

Keywords:

Medication Adherence, Compliance, Hill Bone's High Blood Pressure Compliance Scale.

INTRODUCTION:

Medicationsare routinely prescribed to cardiovascular patients to address hypertensive, congestive, anginal and arrhythmic issuesin addition to those caused by common co-morbidities. Adherence to such medications, however, may be suboptimal.[1]Medication non-adherence is common in patients with cardiovascular diseases thereby predisposing the patients to the risk of stroke and complications. A proper analysis of factors that influence medication adherence is detrimental in providing comprehensive attention to patients suffering from cardiovascular disease.[2]

Low household income and poor socio-economic status may influence medication adherence, as well as a lack of basic awareness about hypertension and its management. Other factorssuch as side effects associated with prescribed medications; the cost of medicines; co-consumption of herbal formulations; lack of clinical signs and symptoms; infrequent visits to a physician; and lack of confidence on the health infrastructureand physicians also contribute to medication non-adherence. Gender based in association with medication adherence is poorly explored[3].

The Hill-Bone Compliance to High Pressure Level Therapy Scale assesses patient behaviour in three key areas 1) less consumption of sodium, 2) keepingappointment, and 3) intake of medication. This scale is made up of 14 items divided into three subscales. Each item is rated on a four-point scale.In these settings, estimating compliance to hypertension treatment must rely on the interview of the patient or, patient declarations[4,5]. Self-administered medication users typically do not complete their daily prescribed doses. Guiding patients with medication adherence may improve the benefits associated with prescribed medication.[6]Various research findings suggest a therapeutic benefit for sticking to a prescribed medication regimen.Therefore, frequent non-compliance results in morbidity and

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 04, 2021

increased health-care costs.[7] The present study was aimed at measurement of medication adherence in hypertensive patients.

The purpose of this study was to determine the psychometric parcels of a questionnaire measure of cases adhering to specific to evoke cases. Drug use in a variety of clinical samples is reported. In hypertension cases, the trustworthiness and validity were evaluated. Other patient groups were subjected to new analyses[8]. The Hill-Bone Compliance Scale is designed specifically for hypertensive patients[9]. Patients who refuse all therapy frequently do not volunteer to participate in research, which is a common difficulty with adherence studies based on informed consent. This is a significant constraint that cannot be alleviated due to ethical considerations [10,11].

The purpose of this study was to investigate medication adherence in patients and the relationships between basic health information, cognition, and knowledge.Hence, through our prospective study we made an attempt to identify risk factors for medication non-adherence in a population of cardiovascular disease patients

Methodology

A prospective observationalstudy was carried out in Manipal Hospital from Nov 10 for a period of 6 months among 354 patients suffering with hypertension and cardiac problems.Patients were interviewed withModified HillBone High Blood Pressure Compliancescale withreference to Indian population that consistsof 26questions related to patients'medication adherence and compliance towards therapy andassigned score accordingly.Subjects were chosen based on the exclusion and inclusion criteria. After including the subjects into the study, the data was collected in the questionnaire form.In-Patients and Out-Patient data was collected in the various departments (Cardiology, Endocrinology, Oncology, Nephrology etc.) during the study period and all the necessary information from the patient's case sheet was collected. The data collected includes patients' demographic details, Past medical history, Social and family history, Final Diagnosis, Present Medication and Interview responses for Modified Hill Bone High Blood Pressure Compliance Scale as shown in Figure 1.The data collected from the patient includes name, age, gender, in/out patient number, diagnosis, Present Medication.Then the patient is interviewed for the medication adherence and Compliance by using Modified Hill Bone High Blood Pressure Compliance Scale questionnaire and scoring was given accordingly.

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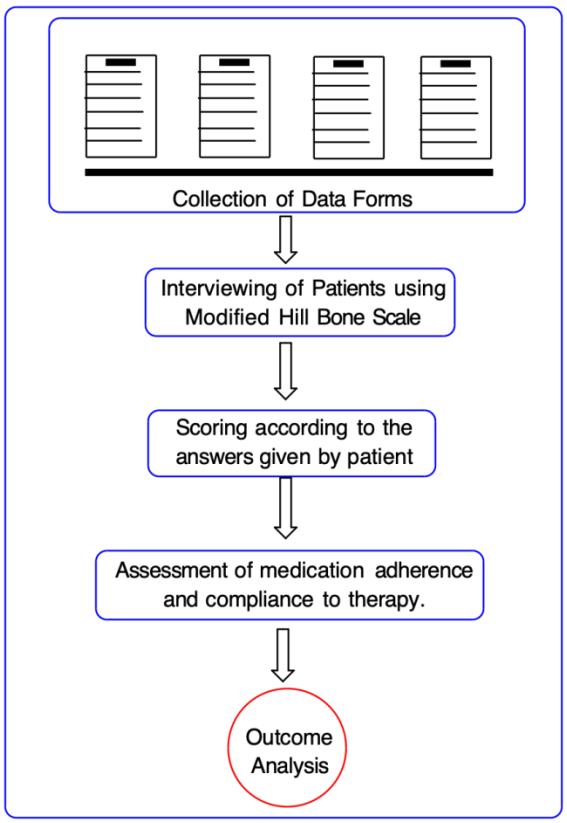

Figure 1. Categories of Males and Females according to their Mode of Compliance and Adherence

Before initiating the study, we explained the purpose of our study to the patient and a consent form was obtained from the patient who is willing to participate in our study. Principle Component Analysis and Chi Square Analysis were performed on the data obtained to assess the relation between various variables and their significance.

The Modified Hill Bone High Blood Pressure Compliance Scale: (With reference to Indian population) is mentioned below.

1. How often do you forget to take your HBP medicine?
2. How often do you decide not to take your HBP medicine?
3. How often do you eat salty food?
4. How often do you shake salt, fonder, or aromate on your food before you eat it?
5. How often do you eat fast food? (KFC, McDonalds, fat cook, fish and chips).
6. How often do you get the next appointment before you leave the clinic?
7. How often do you often miss scheduled appointment?
8. How often do you leave the dispensary without obtaining your prescribed pills? (Due to long line, closure of the clinic, forgot).
9. How often do you run out of HBP pills?
10. How often do you skip your HBP pills 1-3 days before you go to the clinic?
11. How often do you miss taking your HBP pills when you feel better?
12. How often do you miss taking your HBP pills when you feel sick?
13. How often do you take someone else's HBP pills?
14. How often do you miss taking your HBP pills when you care less?
15. How often/regularly do neglect to get your BP check-up?
16. Do you observe or felt any change in signs/symptoms while you take medicine, such as, Palpitations, Excessive sweating and you stopped taking medications?
17. Whether you take any of these OTC drugs:

- NSAIDS

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- Caffeine (Dart, Saridon).
- Cold medications(decongestants)

18. Apart from prescribed medication, whether you take any of the medications from other systems of medicine as given below:

- Homeopathy
- Herbal supplements
- Ayurvedic medicine
- Unani system

19. Whether you take MSG (monosodium glutamate) as a food additive?

20. How often do you eat?

- Pickles with salt preservatives
- Dry/salt fish, dry prawns, dry meat etc.
- Dried chillies with high salt content.

21. How often do you consume alcohol?

22. Whether you are an acute or chronic smoker?

23. Whether you frequently drink carbonated beverages containing caffeine?

E.g.: Thumps up, Sting, Coca Cola.

24. Whether you encounter excessive stress at your work place frequently?

25. Whether you forget to take medicine and food while you are busy at work?

26.Whether you areunaffordable to buy the medicinesthat were prescribed to your disease condition?

➢ Scale has totally **26** items included in itwith a four-point response format:

✓ **1** None of the time

✓ **2** Some of the time

✓ **3** Most of the time

✓ **4** All the time

➢ Items are assumed to be additive, andwhen summed up, the score ranges from:

26 (Maximum)-104 **(**Minimum).

Based on score the patient was assessedas whether he/she is having good or poor medication adherence andcompliance with antihypertensive medications prescribed to them

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(see Table 1).

Table-1. Representation of Scores to Scale Assessment.

Srl.No	Score	Result
1	26-52	Good compliance and adherence
2	53-78	Intermediate compliance and adherence
3	79-104	Poor compliance and adherence

Results and Discussion:

Our study was carried out at Manipal Hospitals for about a period of 6 months from December 2020 to April 2020. Within the study duration 354 patients were included in our study and they were evaluated and analysed for the Medication adherence and compliance by using Hill Bone High Blood Pressure Compliance Scale and scoring was given accordingly. Among these 354 patients 135 were males and 219 were females.The demographic details of the same is shown in Table 2. Based on categories of adherence the high adherence and compliance was found in 289 patients (81.6%), medium adherence was found in about 65 (19.4%) patients & low adherence was found in 0(0%) patients. Gender distribution among decreased medication adherence and compliance people was males 21 (32.3%) & females 44 (67.7%).

Table 2. Demographic characteristics of enrolled patients

Characteristics		Data
1. No. of patients	Male	135 (38.1%)
	Female	219 (61.9%)
2. Age in years	30-40yrs	26 (7.30%)
	41-50yrs	49 (14%)
	51-60yrs	111 (31%
	61-70yrs	108 (31%)
	71->80yrs	60 (16.90%)

The above table shows that among 354 patients the total number of male patients enrolled in this study were 135(38.1%) and the females were of 219(61.9%). In the enrolled majority of the patients were under the age group of 51-60yrs (111-31%) followed by 61-70yrs (108-31%) and 71->80yrs (60-16.9%), then 41-50yrs (49-14%) and the least number of patients were found in the age group of 30-40yrs (26-7.30%).Table 3 shows the Category of Questionnaire and the responses of male and female participants.

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Table 3. Category of Questionnaires

Category of Questionnaires	No. of patients Males	PERCENTAGE	No. of patients In female.	PERCENTAGE.
How often do you forget to take your HBP medicine?	2	9.5%	2	4.5%
How often do you decide not to take your HBP medicine	0	0	4	9.09%
How often do you eat salty food?	5	23.8%	8	18.18%
How often do you shake salt, fonder, or aromat on your food before you eat it?	6	28.5%	7	15.9%
How often do you eat fast food? (KFC, McDonalds, fat cook, fish and chips).	3	14.2%	7	15.9%
How often do you get the next appointment before you leave the clinic?	5	23.8%	21	47.7%
How often do you often miss scheduled appointment?	2	9.5%	4	9.09%
How often do you leave the dispensary without obtaining your prescribed pills? (Due to long line, closure of the clinic, forgot).	2	9.5%	9	20.45%
How often do you run out of HBP pills?	1	4.7%	5	11.3%
How often do you skip your HBP pills 1-3 days before you go to the clinic?	0	0	10	22.7%
How often do you miss taking your HBP pills when you feel better?	2	9.5%	8	18.18%
How often do you miss taking your HBP pills when you feel sick?	1	4.7%	6	13.6%
How often do you take someone else's HBP pills?	4	19%	10	22.7%
How often do you miss taking your HBP pills when you care less?	7	33.3%	19	43.18%
How often/regularly do neglect to get your BP checkup?	5	23.8%	9	20.45%
Do you observe or felt any change in signs/symptoms while you take medicine, such as, Palpitations,	2	9.5%	10	22.7%

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Excessive sweating and you stopped taking medications?				
Whether you take any of these OTC drugs: NSAIDS, Caffeine (Dart, Sadiron). Cold medications (decongestants)	9	42.8%	17	38.6%
Apart from prescribed medication, whether you take any of the medications from other systems of medicine as given below: Homeopathy, Herbal supplements, Ayurvedic medicine, Unani system	1	4.7%	6	13.6%
Whether you take MSG (monosodium glutamate) as a food additive?	2	9.5%	0	0
How often do you eat? • Pickles with salt preservatives • Dry/salt fish, dry prawns, dry meat etc. Dried chilies with high salt content	5	23.8%	16	36.36%
How often do you consume alcohol?	2	9.5%	0	0
Whether you are an acute or chronic smoker?	6	28.5%	0	0
Whether you frequently drink carbonated beverages containing caffeine? E.g.: Thumps up, Sting, Coca Cola.	6	28.5%	8	18.18%
Whether you encounter excessive stress at your work place frequently?	6	28.5%	19	43.18%
Whether you forget to take medicine and food while you are busy at work?	3	14.2%	11	25%
Whether you areunaffordable to buy the medicinesthat were prescribed to your disease condition?	6	28.5%	15	34%

The results shown above that 9.5% of male patients and 4.5% of female patients often forget to take high blood pressure medications, 23.8 percent of male patients and 18.1 8% of female patients often eat salty food, 28.5% male patients and 15.9 percent of female patients often take food in addition to additional salts, 14.2 percent and 15.9 percent of male and female patients respectively eat fast food on a regular basis, 23.8 percent males and 47.7 % females often get an appointment after visit to a clinic, 9.5 % of males and 9.09% of females often missed the schedule appointment made with the doctor, 9.5% males and 20.45% females of an leave the dispensary without obtaining proper prescribed pills, 4.7% males and 11.3% females often run out of high blood pressure medications before the scheduled visit to the doctor, 9.5 % males and 18.18% females often mistaken high blood pressure medications when they feel better, 4.7% males and 13.6% of females often may fail to take high blood pressure pills when they feel sick, 19% meals and 20 2.7% females often take high blood pressure medications recommended to some other patient on a recommended basis, 33.3% of males and 43.1 8% of females often miss taking high blood pressure medications and are more careless, 23.8 percent males and 20.4 5% females of an regularly missed the blood pressure check-up, 9.5 % males and 22.7 percent females felt change in signs and symptoms while on medication and immediately stop medications, 42.8% meals and that 8.6% females take over the counter drugs such as nonsteroidal anti-inflammatory drugs caffeine cold medication suggest nasal decongestants along with high blood pressure medications on a regular basis, 4.7% of males and 13.6% of females also follow other systems of

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medications such as homeopathy and herbal therapy along with allopathic medication, 9.5% of males often take monosodium glutamate as a food additives, 23.8 percent of males and 36.3 6% of females of an eight pickles with salt preservatives or consume drive or Salt fish apart from dried chilies with high salt content, 9.5 % of males often consume alcohol along with high blood pressure medications, 28.5 percent of males are accurate as well as chronic smokers, 28.5% of males and 18.1 8% of females of an take carbonated beverages containing caffeine, 28.5 percent of males and 43.1 8% of females often encounter excessive stress at their workplace ,14.2% of males and 25% of females often forget to take high blood pressure medications along with food while busy at work and 28.5% of males and 34% of females cannot afford high blood pressure medications prescribed to them.

Table 4 shows the Compliance and adherence data in various Age group and Sex. In the age group of 30-40, 7 male and 10 female patients demonstrated good compliance and adherence 2 male and 7 female patients demonstrated modest compliance and adherence respectively.

Table 4. Categories of Males and Females according to their Mode of Compliance and Adherence with differentiation individually

AGE	**GOOD MEDICATION ADHERENCE AND COMPLIANCE**		**MODERATE MEDICATION ADHERENCE AND COMPLIANCE**		**POOR MEDICATION ADHERENCE AND COMPLIANCE**	
	MALE	**FEMALE**	**MALE**	**FEMALE**	**MALE**	**FEMALE**
30-40	7(6%)	10(6%)	2(19.5%)	7(15%)	0	0
41-50	21(18%)	24(13%)	2(19.5%)	2(5%)	0	0
51-60	37(32%)	55(31%)	6(29%)	13(30%)	0	0
61-70	34(30%)	56(52%)	5(23%)	13(30%)	0	0
71->80	15(13%)	30(17%)	6(29%)	9(20%)	0	0
TOTAL	114(100%)	175(100%)	21(100%)	44(100%)	0	0

In the age group of 41 to 50, 21 male patients and 24 female patients demonstrated good compliance and adherence, two male patients and two female patients demonstrated moderate compliance and adherence respectively. In the age group of 51-60, 37 male and 55 female patients demonstrated good compliance and adherence, 6 male and 13 female patients demonstrated moderate compliance and adherence respectively. In the age group of 61 to 70, 34 male and 56 female patients demonstrated good compliance and adherence, 5 male and 13 female patients demonstrated moderate compliance and adherence respectively. In the age group of 71 to 80, 15 male and 30 female patients demonstrated good compliance and adherence 6 male and 9 female patients demonstrated moderate compliance and adherence respectively.Table 5 shows the categories of males and females in accordance with the mode of compliance and adherence respectively.

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Table 5. Categories of Males and Females according to their Mode of Compliance and Adherence

SEX	GOOD COMPLIANCE AND ADHERENCE	MODERATE COMPLIANCE AND ADHERENCE	POOR COMPLIANCE AND ADHERENCE
MALES	175	44	0
FEMALES	114	21	0
TOTAL	289	65	0

A total of 175 males and 114 females accounted for the 289 patients that demonstrated good compliance and adherence followed by 44 males and 21 females that accounted for 65 moderate compliance and adherence patients. No poor compliance and adherence were observed in all the patients.

Principal Component Analysis as shown in Fig.2, shows that the first eight questions were important for deciding the overall outcome of analysis. Question 1 had an eigen value of 6.490, Question number 2 had an eigenvalue of 3.91, question number 3 had an eigenvalue of 2.79, question number 4 had an eigenvalue of 2.12, question number 5 had an eigenvalue of 1.86, question number 6 head and eyes and value of 1.40, question number 7 had an eigenvalue of 1.25 and question number 8 had an eigenvalue of 1.18. Higher the eigen value higher the contribution to the over outcome of analysis. Question 1- 8 had an overall contribution of 23.2, 14.0, 10.0, 7.6, 6.6, 5.0, 4.5 and 4.2% respectively.

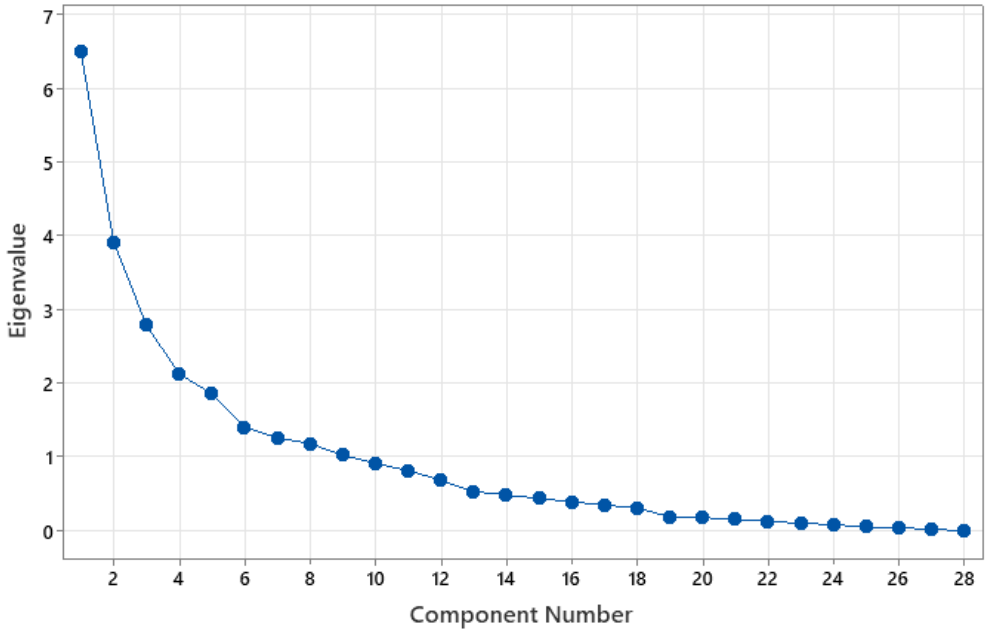

Figure 2. Principal Component Analysis of Data obtained from questionnaire.

We also performed the Chi-square analysis to study the association of sex of the individual and compliance but did not find any significant correlation with respect to sex of the individual and medication adherence and compliance.

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The results for the same are shown below.

P value and statistical significance

Test	**Chi-square**	
Chi-square, df	**1.146, 1**	
Z	1.071	
P value	0.2843	
P value summary	**ns**	
One- or two-sided	Two-sided	
Statistically significant (P < 0.05)?	No	
Effect size	Value	95% CI
Odds ratio	1.365	0.7781 to 2.371
Reciprocal of odds ratio	0.7327	0.4217 to 1.285
Methods used to compute CIs		
Odds ratio	Baptista-Pike	

Data analysed	**Good Compliance**	**Moderate Compliance**	**Total**
Male	**114**	**21**	**135**
Female	**175**	**44**	**219**
Total	**289**	**65**	**354**

Percentage of row total	Good Compliance	Moderate Compliance
Male	84.44%	15.56%
Female	79.91%	20.09%

Percentage of column total	Good Compliance	Moderate Compliance
Male	39.45%	32.31%
Female	60.55%	67.69%

Percentage of grand total	Good Compliance	Moderate Compliance
Male	32.20%	5.93%

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Female	49.44%	12.43%

We also performed the Chi-square analysis to study the association of age of an individual and medical adherence and compliance but did not find any significant correlation with respect to age of the individual and medication adherence and compliance.

The results for the same are shown below.

P value and statistical significance

Test	Chi-square
Chi-square, df	**2.131, 2**
P value	**0.3445**
P value summary	**Ns**
One- or two-sided	NA
Statistically significant (P < 0.05)?	No
Data analysed	
Number of rows	3
Number of columns	2

Conclusion

Cognitive behaviour, food habits, carelessness, missing scheduled appointments, using OTC medications are the major factors that affect patient's medication adherence and compliance. Lowering medication adherence is also caused to some extent in males by smoking and alcohol consumption. Furthermore, we found no association between Age and Medication Adherence or Sex and Medication Adherence, effectively ruling out the role of the above two factors in Medication Adherence.

Medication adherence is extremely complex and suffers from inter-individual variationsrequiring multipronged approaches to tackle the problem. Adherence is a critical factor regulating pharmacotherapy, and plays a vital role for medications prescribed for chronic conditions. Measuring medication adherence is difficult because it varies from person to person. Adherence is a complex integration of patient, drug, and physician, but lack of drug related awareness and willingness to alter behaviourare the key limitations for improving adherence.

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