

A prospective observational study of drug compliance among hypertension patients in a tertiary care hospital

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Abstract

Objectives: 1) To determine the proportion of treatment compliance among hypertensive study participants. 2) To identify social demographic factors that affect treatment compliance among hypertensive study participants.

Methodology: Study was descriptive cross-sectional design, which was conducted in K.I.M.S. Hubli. The study population was hypertensive patients who are on antihypertensives, attended the medicine OPD. A total of 253 patients were included in the study and the study used simple random sampling. Data were analyzed using SPSS software. $P \leq 0.05$ was considered statistical significant.

Results: 160 (63.2%) participants had good compliance and 93 (36.8%) participants had poor compliance to treatment. Patients with formal education level had high good compliance (61.9%) compared to those without education (20.6%). Employed were more compliant (70%) compared with unemployed (28.1%). Participants on 2 antihypertensives were more compliant (58.8%) than participants on single or >2 antihypertensives. Participants without alcohol consumption were more compliant (85%) than who consumes alcohol. Participants who received advice from treating doctor were more compliant (81.9%) than participants without advice.

Conclusions and Recommendation: This study showed low compliance to antihypertensive treatment. It is recommended that hypertensive patients should be counseled regularly to improve the compliance to antihypertensive drugs.

Keywords: drug compliance, rural population, hypertension.

1. Introduction

Hypertension is one of the leading causes of the global burden of disease. Approximately 7.6 million deaths (13–15% of the total) and 92 million disability-adjusted life years worldwide were attributable to high blood pressure in 2001[1]. The prevalence of hypertension increases with advancing age; about 50% of people between the ages of 60 and 69 years old have hypertension, and the prevalence is further increased beyond age 70 [2].

Hypertension defined as any one of the following: systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, taking antihypertensive medications [1]. Elevated arterial pressure causes pathological changes

in the vasculature and hypertrophy of the left ventricle. As a consequence, hypertension is the principal cause of stroke; a major risk factor for coronary artery disease and its attendant complications, MI and sudden cardiac death; and a major contributor to cardiac failure, renal insufficiency, and dissecting aneurysm of the aorta [2].

Risk factors for hypertension are sedentary lifestyle, obesity, smoking and consumption of fatty food [3]. Uncontrolled hypertension is caused by non adherence to the antihypertensive drugs, patients understanding their drug regimens help to improve their adherence, thus will help prevent the complications of hypertension which are debilitating and if not prevented can increase the burden of

a disease that is already on the increase [4]. Non-adherence to prescribed drugs schedule has been and continues to be a major problem the world over. Studies on this subject show that adherence is about 50% for medications in chronic diseases including hypertension and much lower for lifestyle prescriptions [5].

Poor adherence to long-term therapies severely compromises the effectiveness of treatment making this a critical issue in population health both from the perspective of quality of life and of health economics. Interventions aimed at improving adherence would provide a significant positive return on investment through primary prevention (of risk factors) and secondary prevention of adverse health outcomes [6].

1.1 Conceptual definition of terms

Compliance is defined as “the extent to which a person’s behavior (taking medicines, or executing lifestyle changes) coincides with medical or health advice” [7].

Compliance defined as an act of adhering to the regimen of care recommended by the clinician and persisting with it over time [8].

Adherence is defined as "the extent to which a person's behavior - taking medications, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider"[6].

1.2 Objectives

- 1) To determine the proportion of treatment compliance among hypertensive study participants.
- 2) To identify social demographic factors that affect treatment compliance among hypertensive study participants.

2. Methodology

2.1 Study design

The study was descriptive Cross sectional design.

2.2 Study area

Conducted in K.I.M.S. Hubli.

2.3 Study population

The study population were patients with hypertension, who were using antihypertensive treatment and attending at medicine O.P.D

2.4 Sample size

Sample size calculations were made based on the following formula [11]:

$$n = Z^2 p (1-p) / e^2$$

Where by n = the required minimum sample size

e = margin of error (5%)

p = estimated proportion of compliance 9% [12]

z = standard normal deviate corresponding to 95% confidence level=1.96

Considering a margin of error of 5% and a 95% confidence level, then the minimum required sample size will be 139.

2.5 Sampling procedure

Simple random sampling procedure was employed to select the study participants, who met the inclusion criteria, were eligible for inclusion in the sampling list for the study.

2.6 Data collection

In this study data were collected over a period of 2 months. A questionnaire consisting of closed end questions which was asked to all participants to mark their responses. The questionnaire was translated from English to Kannada language that is understood and well spoken by all.

2.7 Inclusion criteria

- 1) Patients of age 18 years and above,
- 2) Participants with a diagnosis of hypertension for at least one month with or without other co-existing medical conditions.
- 3) Participants who have been taking antihypertensive treatment for at least past one month ago.
- 4) Patients who agreed and consented to participate in the study.

2.8 Exclusion criteria

- 1) Patients who had not started antihypertensive
- 2) Patients less than 18 years of age
- 3) Patients on antihypertensive medication who could not consent to participate in the study.

2.9 Data management

2.9.1 Variables and measurement

The outcome variable was medication regimen compliance. Medication regimen compliance was composed of 8 items, asking how often you forget to take your medicine. The responses were measured on a 4-point Likert scale: (1) Every day (2) frequently, (3) rarely or (4) never. Data analysis was performed using SPSS software programme. Information was summarized using frequency tables and cross tabulations. Frequency distributions were done then bivariate analysis using chi-square. Multiple linear regressions were done with treatment compliance as the outcome variable. A P-value of equal or less than 0.05 was considered a statistically significant.

2.9.2 Dependent variable

Treatment compliance to antihypertensive drugs.

2.9.3 Independent variables

Social demographic characteristics are age, sex, marital status, level of education and occupation.

2.10 Ethical consideration

Ethical clearance has been taken. Written informed consent was obtained. Confidentiality was guaranteed.

3. Results

This study was conducted for 2months; a total number of 253 hypertensive patients who were attending General Medicine O.P.D. K.I.M.S, Hubballi, from the age 18 years and above were selected. From these, 253 patients who agreed to participate were included in the study, and however four participants refused to participate.

The socio-demographic characteristics of the respondents are shown in **Table 1**.

Table 1: Socio-demographic details of the study participants (N=253)

Sl. No.	Characteristics	Frequency	Percentage
1	Age category in years		
	30-44	39	15.4
	45-59	113	44.7
	≥60	101	39.9
2	Sex		
	Male	160	63.2
	Female	93	36.8
3	Marital status		
	Single	7	2.8
	Married	246	97.2
4	Education		
	Illiterate	59	23.3
	Primary school	82	32.4
	Secondary school	77	30.4
	Post-secondary	24	9.5
	Degree	11	4.3
5	Occupation		
	Government employee	14	5.5
	Non- government employee	44	17.4
	Self – employed	108	42.7
	Student	12	4.7
	Unemployed	75	29.6

There were 160 (63.2%) males and 93 (36.8%) females. There were 39 (15.4%) aged 30-44 years, 113 (44.7%) aged 45-59 years and 101(39.9%) aged ≥ 60 years. 246 (97.2%) of participants were married while 7 (2.8%) were unmarried. Among 59 (23.3%) participants were illiterate, 82 (32.4%) had primary school level of education, 77 (30.4%) had secondary school level of education, 24 (9.5%) had post-secondary school level of education and 11(4.3%) were completed degree. While 14 (5.5%) participants were government employee, 44 (17.4%) participants were non- government employee, 108 (42.7%) participants were self- employee, 12 (4.7%) participants were students and 75 (29.6%) participants were an unemployed.

Clinical profile of study participants was explored and was shown in Table 2.

Table 2: Clinical profile of study participants (N=253)

Sl. No.	Characteristics	Frequency	Percentage
1	Duration of hypertension		
	≤ 1 year	66	26.1
	2-4 years	123	48.6
	> 4 years	64	25.3
2	Co-morbid conditions		
	Heart problem	23	9.1
	Paralysis of limb	14	5.5
	Visual impairment	44	17.4
	Kidney problem	25	9.9
	Multiple	14	5.5
	None	133	52.6
3	Number of anti-hypertensive taken		
	1	79	31.2
	2	154	60.9
	>2	20	7.9
4	Smoking tobacco		
	Yes	45	17.8
	No	208	82.2
5	Alcohol consumption		
	Yes	49	19.4
	No	204	80.6
6	Lack of advice from treating doctor		
	Yes	61	24.1
	No	192	75.9

There were 66 (26.1%) participants had hypertension ≤ 1year of duration, 123 (48.6%) participants had hypertension since 2-4 years of duration, 64 (25.3%) participants had hypertension > 4 years of duration. Hypertension may associated with other co-morbid conditions such as hypertension with heart problem in 23 (9.1%) participants, hypertension with paralysis of limb in 14 (5.5%) participants, hypertension with visual impairment in 44 (17.4%) participants, hypertension with kidney problem in 25 (9.9%) participants, hypertension with multiple problems in 14 (5.5%) participants, isolated hypertension in 133 (52.6%) participants. 79 (31.2%) participants were on one type of antihypertensive agents, 154 (60.9%) were on two types of antihypertensive agents, 20 (7.9%) participants were on >2 type of antihypertensive agents. There were 45 (17.8%) smokers and 208 (82.2%) were non-smokers.

There were 49 (19.4%) alcoholics and 204 (80.6%) doesn't drink alcohol. There were lack of advice from treating doctors in 61 (24.1%) participants and advice given in 192 (75.9%) participants.

The association between socio-demographic factors and treatment compliance was explored. **Table 3**

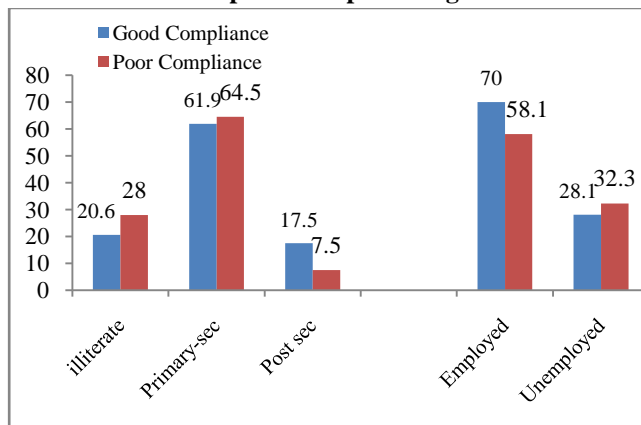
Table 3: Distribution of participant's demographic factors by treatment compliance

Sl. No.	Characteristics	Compliance to treatment		X ² value, df	P value
		Good n (%)	Poor n (%)		
1	Age				
	30-44	25 (15.6)	14 (15.1)		
	45-59	79 (49.4)	34 (36.6)	4.81, 2	0.09
	≥60	56 (35)	45 (48.4)		
2	Sex				
	Male	101 (63.1)	59 (63.4)		
	Female	59 (36.9)	34 (36.6)	0.003, 1	0.96
3	Education				
	Illiterate	33 (20.6)	26 (28)		
	Primary-secondary	99 (61.9)	60 (64.5)	5.65, 3	0.05*
	Post-secondary and above	28 (17.5)	7 (7.5)		
4	Occupation				
	Employed	112 (70)	54 (58.1)		
	Unemployed	45 (28.1)	30 (32.3)	9.16, 2	0.01*
	Student	3 (1.9)	9 (9.7)		
5	Marital status				
	Married	155 (96.9)	91 (97.8)		
	Single	5 (3.1)	2 (2.2)	0.208, 1	0.64

Figure 1: Age, gender with treatment compliance in percentage



Figure 2: Education, occupation and treatment compliance in percentage



(Figure 1 and Figure 2) shows that the age between 30-44 years, good compliance to treatment was 25 (15.6%) and poor compliance to treatment was 14 (15.1%), the age between 45-59 years, good compliance to treatment was more that is of 79 (49.4%) and poor compliance to treatment was 34 (36.6%) and the aged ≥ 60 years, good compliance to treatment was 56 (35%) and poor compliance to treatment was 45 (48.4%). X² value of 4.81 and difference was 2. P = 0.09 was not statistically significant. 101 (63.1%) of males had good compliance than females 59 (36.9%). X² value of 0.003 and difference was 1. P = 0.96 was not statistically significant. Primary and secondary school level of education participants had more good compliance 99 (61.9%) than illiterate 33(20.6%) and post secondary and degree education participants 28 (17.5%). X² value of 5.65 and difference was 3. P = 0.05 was statistically significant.

Participants who were employed 112 (70%) had high proportion of good treatment compliance compared to those who were not employed that is 30 (32.3%). X² value of 9.16 and difference was 2. P = 0.01 was statistically significant. Married participants 155 (96.9%) had high proportion of treatment compliance than those who did not have partners that is 5 (3.1%). X² value of 0.208 and difference was 1. P = 0.64 was not statistically significant.

The association between Clinical profile of study participants and treatment compliance was explored. **Table 4** (Figure 3 and Figure 4) shows that the participants with duration of hypertension ≤ 1 year, good compliance to treatment was 46 (28.8%) and poor compliance to treatment was 20 (21.5%). 2 -4 years duration of hypertension, good compliance to treatment was 71(44.4%) and poor compliance to treatment was 52 (55.9%). Duration of hypertension >4 years, good compliance to treatment was 43 (26.9%) and poor compliance to treatment was 21 (22.6%). X² value of 3.22 and difference was 1. P = 0.20 was not statistically significant.

Table 4: Clinical profile of study participants and treatment compliance

Sl. No	Characteristics	Compliance to treatment		X ² value, df	p value
		Good n (%)	Poor n (%)		
1	Duration of hypertension				
	≤ 1 year	46 (28.8)	20 (21.5)		
	2-4 years	71 (44.4)	52 (55.9)	3.22, 1	0.20
	> 4 years	43 (26.9)	21 (22.6)		
2	No. of drugs taken				
	1	58 (36.3)	21 (22.6)		
	2	94 (58.8)	60 (64.5)	8.48, 2	0.01*
	>2	8 (5)	12 (12.9)		
3	Co-morbidity				
	Present	70 (43.8)	50 (53.8)	2.36, 1	0.12
	Absent	90 (56.3)	43 (46.2)		
4	Smoking tobacco				
	Yes	25 (15.6)	20 (21.5)		
	No	135 (84.4)	73 (78.5)	1.39, 1	0.23
5	Alcohol consumption				
	Yes	24 (15)	25 (26.9)		
	No	136 (85)	68 (73.1)	5.31, 1	0.02*
6	Lack of advice from treating doctor				
	Yes	29 (18.1)	32 (34.4)		
	No	131 (81.9)	61 (65.6)	8.52, 1	0.006*

Participants on single antihypertensive agents, 58 (36.3%) were good compliance and 21 (22.6%) were poor compliance. Participants on 2 types of antihypertensive agents, 94 (58.8%) were good compliance and 60 (64.5%) were poor compliance. Participants on >2 types of antihypertensive agents, 8 (5%) were good compliance and 12 (12.9%) were poor compliance to treatment. X² value of 8.48 and difference was 2. P = 0.01 was statistically significant. Hypertension with co-morbidity, good compliance to treatment was 70 (43.8%) and poor compliance was 50 (53.8%). Hypertension with co-morbidity, good compliance to treatment was 70 (43.8%) and poor compliance was 50 (53.8%).

Hypertension without co-morbidity, good compliance to treatment was 90 (56.3%) and poor

compliance was 43 (46.2%). X² value of 2.36 and difference was 1. P = 0.12 was not statistically significant. Hypertension with tobacco smoking, good compliance to treatment was found to be 25(15.6%) and poor compliance was found to be 20 (21.5%). hypertension without tobacco smoking, good compliance to treatment was 135 (84.4%) and poor compliance was 73 (78.5%). X² value of 1.39 and difference was 1. P = 0.23 was not statistically significant. Hypertension with alcohol consumption the good compliance to treatment was 24(15%) and poor compliance was 25 (26.9%). Hypertension without alcohol consumption, the good compliance to treatment was 136 (85%) and poor compliance was 68 (73.1%). X² value of 5.31 and difference was 1. P = 0.02 was statistically significant. Hypertension with lack of advice from treating doctor, the good compliance to treatment was seen in 29(18.1%) and poor compliance was seen in 32 (34.4%). Hypertension participants taken advice from treating doctor, the good compliance to treatment was seen in 131(81.9%) and poor compliance was seen in 61 (65.6%). X² value of 8.52 and difference was 1. P = 0.006 was statistically significant.

Figure 3: Duration of hypertension, number of drugs taken and co-morbidity status with treatment compliance in percentage

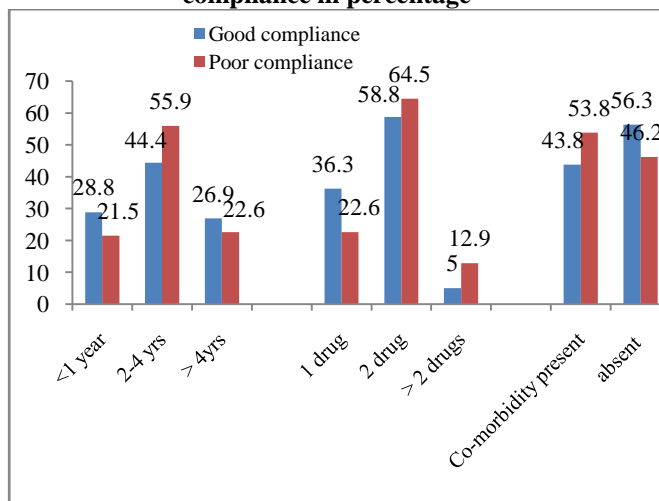
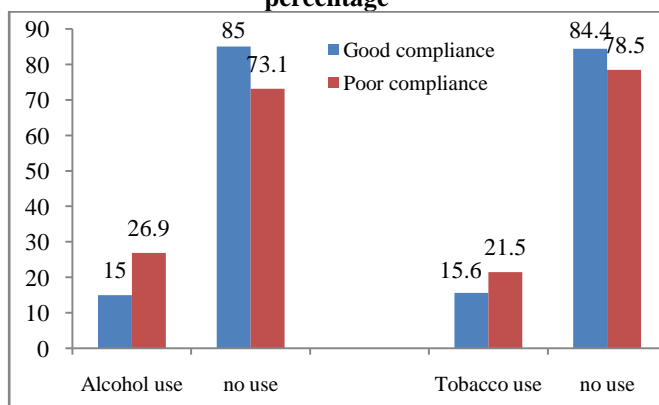


Figure 4: Substance abuse and treatment compliance in percentage



Total there were 160 (63.2%) participants had good compliance to treatment and 93 (36.8%) participants had poor compliance to treatment shown in table 5.

Table 5: Treatment compliance of the study subjects (N=253)

Compliance to treatment	Frequency	Percentage
Good	160	63.2
Poor	93	36.8

4. Discussion

This study explored factors affecting treatment compliance among hypertensive patients attended General Medicine O.P.D. K.I.M.S. Hubballi. The current study shows that, participants who were 45-59 years of age had higher level of good compliance to treatment (49.4%) compared to those 30-44 and ≥ 60 years of age. The possible explanation of these results might be the truth that, the young people have higher income since they are able to work and thus can afford to buy medication compared to older people. Another possible reason is that older people might have more than one disease due to aging reason, which might have led them using many drugs which make them tired, hence, stop taking drugs. Cognitive and functional impairment in elderly patients increases their risk of poor drug compliance, so they need a family to remind, support and assist them in taking drugs.

In this study male were more compliant (63.1%) compared with female (36.9%). The possible explanation of these results might be income and thus can afford to buy medication.

The finding showed that patients with formal education level had high good compliance to treatment (61.9%) compared to those without education level (20.6%). The possible explanation of these results might be, understanding the advice from the treating doctors. It was statistically significant.

In this study employed participants were more compliant (70%) compared with unemployed participants (28.1%). The possible explanation of these results might be income since they are employed thus can afford to buy medication. It was statistically significant. The relationship between marital status and treatment compliance was observed. Married participants were more compliant with treatment (96.9%) than non-married participants (3.1%). Marital status might influence compliance with medication positively. The help and support from a spouse could be the reason.

In this study participants with duration of hypertension between 2-4 years were more compliant (44.4%) compared with ≤ 1 years and 4years. The possible explanation of these results might be ≤ 1 forget to take drug as they were newly diagnosed and > 4 years may be fear of addiction.

The finding showed that participants on 2 antihypertensive agents were more compliant (58.8%) than participants on single or >2 antihypertensive agents. It was statistically significant.

Hypertension patients without co-morbidity were more compliant (56.3%) than with co-morbidity.

Non-smoker participants were more compliant (84.4%) than smokers.

Participants without alcohol consumption were more compliant (85%) than who consumes alcohol. It was statistically significant.

Participants who received advice from treating doctor were more compliant (81.9%) than participants without advice. It was statistically significant.

5. Limitation of the study

This study was conducted in K.I.M.S. Hubballi only and did not include patients who attended private Hospitals. Therefore results cannot be generalized to all hypertension patients in Hubballi. However, the results have important insights for some hospitals within the same characteristics.

Self reporting of treatment compliance could introduce recall bias by either over reporting or under reporting depending on patient's behavior on the recent past.

6. Conclusion and Recommendation

The study showed that good compliance to antihypertensive treatment was more compared to poor compliance to treatment among study participants. Patients need advice, support and information from health professionals in order to be able to understand the importance of using drugs as prescribed. It is recommended that hypertensive patients should be counseled every time whenever they visit to physician to improve the compliance to antihypertensive drugs, salt restriction and to do exercise daily, so that they should have better control of hypertension.

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