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Original Research Article

Study on compliance of anti-hypertensive drugs among hypertensive patients in urban health centre of a tertiary care hospital

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ABSTRACT

Background: Hypertension is a chronic condition of concern due to its role in the cardiovascular complications. Poor compliance is assumed to be an important explanation for inadequate blood pressure control, convincing evidence for the same is lacking. This study was undertaken to provide such evidence, so that corrective measures can be recommended to attain better BP control. The aims and objectives of the study were to study compliance pattern and side effects of anti-hypertensive drugs among the known hypertensive patients; to study role of different factors that influence the compliance rate such as age, number of medications, frequency and follow-up visits of antihypertensive medication.
Methods: A total of 207 hypertensive patients were identified from the family folders maintained in the Urban Health Centre, RMMCH and included in the investigation. During first visits, socio-demographic, drug intake history was taken. Follow up was done every two months and thus totally six visits were completed.
Results: Socio demographic factors like age, marital status, literacy, occupation and income have no role on the compliance status. Sex has significant association with the compliance level (86.1%), where males have 93.4% and females 82.7% compliance ($p<0.05$). BMI, exercise, smoking and alcohol, Type of the drug, doses frequency, combination therapy and regularity in refilling the prescription, have no association with compliance status. Frequency of clinical visits has significant association with compliance (visit fortnightly, monthly and occasionally is 94.1%, 85.1% and 75% respectively) $p<0.05$. Significant improvement (73.1%) improvement in compliance in the VI visit is seen among non-compliers from I visit ($p<0.001$).
Conclusions: Simple once a day regimen and visits of the health provider improves the compliance and good blood pressure control.

Keywords: Hypertension, Compliance, Anti-hypertensive drugs, BP control

INTRODUCTION

Hypertension is a major health problem affecting around 40% adults aged 25 and above in the world.[1] It is a chronic condition of concern due to its role in the cardiovascular complications, which are on the increase, including the incidence of stroke, end-stage renal disease and heart failure. It accounts for 57 million DALYs. In India the prevalence varies from 17 to 21 percent in all states with marginal urban-rural differences.[2]

'Compliance' is defined as the extent to which a person's behaviour (in terms of keeping appointments, taking medications, and executing life-style changes) coincides with medical advice. Low patient cooperation erodes many of the proven benefits of antihypertensive therapy. Although poor compliance is always assumed to be an

important explanation for inadequate blood pressure control, convincing evidence for the same is lacking. The present study has been undertaken to provide such evidence, so that corrective measures can be recommended to attain better blood pressure control.

Aims and objectives

- To study the compliance pattern and side effects of anti-hypertensive drugs among the known hypertensive patients identified.
- To study the role of different factors that influence the compliance rate such as age, number of medications, frequency and follow-up visits of antihypertensive medication.

METHODS

Inclusion criteria

Inclusion criteria were known hypertensive patients above 30 years of age, who have been under treatment with medication, for at least six months; patients who were willing to participate in the follow up visits, for the one year study period.

Study setting

The study was conducted in urban Chidambaram town, Cuddalore district, Tamil Nadu, for a period of one year between June 2008 and May 2009. The target study population was selected from 5 catchment wards (Old Bhuvanagiri road, Omakkulam, Sengattan Street, Mandhakarai and Anandheeswarar Koil Street). The total population of the selected ward is 12,525 and the households are 1806, in the catchment area.

Sample size

The sample size was calculated based on the hypothetical frequency of non-compliance in the Indian setup and further taking into consideration of the follow up nature of the study. A total of 188 subjects were calculated as sample size.

Study population

The hypertensive subjects were selected from the family folders maintained in the Urban Health Centre, RMMC&H, Chidambaram. The house visits were made mostly between 5pm and 9pm. A total of 207 hypertensive patients were identified from the family folders and included in the investigation. Of the 207 patients, there were 72 males and 135 females. Only 188 participants, 61 males and 127 females remained in the study till the completion of all 6 visits.

Interview

The interview was conducted by the researcher himself on all the basic and follow up visits. During the first visit, which had been completed in two months, all participants were interviewed with a questionnaire consisting of two sections. For each subject, approximately 45 minutes were spent to measure the parameters and enter the details in the schedule.

Study tools

In section I, details about socio-demographic information including age, sex, marital status, educational attainment, occupation, annual family income and family type were collected. Physical examination included the measures like height, weight, body mass index, waist-hip ratio, pulse and blood pressure. Height was measured in centimetres (cm) using an inch tape and weight in kilograms (Kg) using bathroom weighing machine. The supine waist girth was measured at the level of the umbilicus with the person breathing silently; the standing hip girth was measured at the inter-trochanteric level and BP measurement using mercury sphygmomanometer according to WHO guidelines.

Blood pressure measurement

BP was measured using "The Gold standard" mercury sphygmomanometer on the right arm of each individual, as per the JNC VII and WHO guidelines, after resting the patient in sitting posture for five minutes.

Follow ups

From then on follow up of each participant in the study was done every two months and thus totally six visits were completed. Approximately 20 minutes were spent with each individual for collecting the details in the follow up visits.

Statistical Analysis

Data were initially entered and managed in SYSTAT 7 software. The data file was imported into SPSS 13.0 for the analysis. Most of the significance tests were two tailed and statistical significance was defined at 0.05 or 0.001 alpha level.

RESULTS

A total of 188 patients participated in the study out of which 61 were males and 127 were females.

As shown in Table 1, majority of the study population were in the age group of 50-69 (54.3%). 23% of study population were in the age group of 40-49. >70 were around 20%.

Drug compliance reported in the first visit is good in a majority (86.2%) of the respondents. Among females, (82.6%) of them are taking drugs regularly, where as in males the drug compliance is relatively higher (93.4%) (Table 2).

Table 1: Age and sex wise distribution of respondents.

Age (In years)	Sex		Total (%)
	Male (%)	Female (%)	
30 – 39	1 (1.6)	4 (3.1)	5 (2.7)
40 – 49	9 (14.8)	34 (26.8)	43 (22.9)
50 – 59	18 (29.5)	31 (24.4)	49 (26.1)
60 – 69	18 (29.5)	35 (27.6)	53 (28.2)
70 &>70	15 (24.6)	23 (18.1)	38 (20.2)
Total	61 (100.0)	127 (100.0)	188 (100.0)

Table 2: Compliance pattern based on sex in the first visit.

Regular drug intake	Male (%)	Female (%)	Total (%)
91- 100% of days	57 (93.4)	105 (82.6)	162 (86.2)
≤90% of days	4 (6.6)	22 (17.3)	26 (13.9)
Total	61 (100.0)	127 (100.0)	188 (100.0)

From Table 3, the reasons for non-compliance is presented across two levels viz., 50-90% and <50% and sex of the respondents. The commonest reason among males is absence of symptoms and forgot to replenish the drugs. Among females the reasons are forgetfulness, forgot to replenish, lack of funds to buy drugs because of high cost and absence of symptoms.

From Table 4, we can infer that around 53.7% of the respondents are found to have knowledge of their blood pressure control.

Out of 85 subjects, who visit their physician every fortnight, 94.1% were compliant and the other groups also have 85.1% and 75% compliance status, who visit their doctor, once in a month or occasionally respectively (Table 5).

This two way Table 6, shows that there is a significant association ($p<0.05$) between number of clinic visits and compliance level.

Table 3: Distribution of reported reason for non-compliance.

Reason for Non-compliance	50 – 90% Non-Compliance		<50% Non-Compliance		Response (%)
	Male	Female	Male	Female	
Absence of symptoms	2 (1.1)	4 (2.1)	0 (0)	0 (0)	6 (14.6)
Lack of funds to buy drugs	0 (0)	5 (2.7)	0 (0)	1 (0.5)	6 (14.6)
Side effects of the drugs	0 (0)	1 (0.5)	0 (0)	0 (0)	1 (2.4)
Forget to replenish	2 (1.1)	8 (4.3)	0 (0)	0 (0)	10 (24.4)
Normal BP during the last visit	0 (0)	1 (0.5)	0 (0)	0 (0)	1 (2.4)
Forgetfulness	1 (0.5)	8 (4.3)	0 (0)	0 (0)	9 (22.0)
Busy Schedule	0 (0)	3 (1.6)	0 (0)	0 (0)	3 (7.3)
Others	1 (0.5)	2 (1.1)	0 (0)	2 (1.0)	5 (12.2)
Total	6	32	0	3	41 (100.0)

Table 4: Distribution of respondents by knowledge about BP control and BP status.

Normal BP		Frequency	Percentage (%)
Knowledge	Known	101	53.7
	Not Known	87	46.3
Systolic BP	Right response 120-140	90	47.9
	Wrong response <120 &>140	98	52.1
Diastolic BP	Right response 70-90	81	43.1
	Wrong response <70 &>90	107	56.9

Table 5: Association of compliance and frequency of visits.

Clinic visit	Compliance status		Total (%)
	>90% of days	**≤90% of days**	
Fortnightly	80 (94.1)*	5 (5.9)	85 (45.2)**
Monthly	40 (85.1)	7 (14.9)	47 (25.0)
Occasionally	42 (75.0)	14 (25.0)	56 (29.8)
Total	162 (86.2)	26 (13.8)	188 (100.0)

$\chi^2 = 10.41$

Table 6: Compliance status between first and sixth visits.

Compliance I Visit	Compliance VI Visit		Total
	>90% of Days	≤90% of Days	
>90% of days	162 (100.0)*	0 (0)	162 (86.2)**
≤90% of days	19 (73.1)	7 (26.9)	26 (13.8)
Total	181 (96.3)	7 (3.7)	188 (100.0)

Table 7: Controlled BP status by sex in the first & sixth visits.

BP Control	VI Visit –Male		VI Visit – Female	
I Visit	Controlled BP	Uncontrolled BP	Controlled BP	Uncontrolled BP
Controlled BP	19 (100.0)	0 (0)	40 (95.2)	2 (4.8)
Uncontrolled BP	31 (73.8)	11 (26.2)	55 (64.7)	30 (35.3)

Table 8: The trend of mean systolic and diastolic blood pressure in all six visits.

Visit	Systolic BP mmHg		Diastolic BP mmHg	
	Mean	SD	Mean	SD
I	148.15	20.08	94.34	13.03
II	144.15	18.00	90.79	11.56
III	141.44	17.38	87.98	10.35
IV	139.36	16.08	85.69	9.32
V	137.18	13.88	84.62	8.36
VI	137.07	14.08	84.36	8.28
One way ANOVA with repeated measurement.	F = 67.84; p<0.001		F = 68.19; p<0.001	

Table 9: Multiple comparison test result for the BP trend in all 6 visits.

Level	Systolic BP		Diastolic BP	
	F	P value	F	P value
II Vs I	36.60	0.001	40.25	0.001
III Vs II	58.28	0.001	60.73	0.001
IV Vs III	60.46	0.001	72.28	0.001
V Vs IV	100.42	0.001	76.36	0.001
VI Vs V	75.54	0.001	82.36	0.001

Table 10: Compliance status by number of drugs consumed per day.

No. of Drugs	Compliance Status		Total (%)
	>90% of days (%)	≤90% of days (%)	
1 Drug	118 (89.4)*	14 (10.6)	132 (70.2)**
2 Drugs	42 (79.2)	11 (20.8)	53 (28.2)
3 Drugs	2 (66.7)	1 (33.3)	3 (1.6)
Total	162 (86.2)	26 (13.8)	188 (100.0)

The patients in the compliance level, remained at the same level of compliance in the VI visit compared to I visit. There is improvement in the compliance level among the non-compliant subjects: 73% migrated to the compliant group and the total compliance level has improved from 86.2% to 96.3%.

From Table 7, In the VI visit, there is a 100% improvement in BP control in males and 95.2% in females compared to the first visit. And also there is improvement towards compliance status in the subjects with uncontrolled group, 73.8% in males and 64.7% in females. The Mc Nemar's chi-square test shows a significant association (p<0.001) between I and VI visit BP status. Shift from uncontrolled group to control group between I and VI visit is significant.

As shown in Table 8, the average systolic blood pressure and diastolic blood pressure at the first visit is 148 mmHg & 94 mmHg respectively. Gradually the mean systolic

blood pressure and diastolic blood pressure reduced in each visit. "One Way ANOVA test with one variable repeated measure" is applied to find out any significant variation in the mean BP at each visit. The significant 'P' value confirms that there is a reduction in the mean systolic blood pressure and diastolic blood pressure levels.

When multiple comparison tests with "difference contrast" was applied in each and every visit, roughly 3 mmHg and 2 mmHg reduction occurred in systolic blood pressure and diastolic blood pressure, respectively. The above results shown in Table 9, confirm that repeated visits by the health care provider will improve the compliance among patients and hence good blood pressure control.

In 132 patients with mono-therapy, 89.4% were compliant with treatment and in 52 patients with 2 drug regimen, 79.2% were compliant. Non-compliance was more with 3 drug treatment 33.3% (Table 10).

Table 11: Distribution for overall reported side effects of drug therapy.

Side effect	Frequency	Percentage (%)
Yes	89	47.3
No	99	52.7

The chi-square test ($p>0.05$) shows that, there is no significant association between number of drugs consumed per day and compliance status, perhaps because of small number in the different groups (i.e. 2 drugs / 3 drugs).

The association between BP control and number of drugs used showed controlled BP in 33.3% out of 132 patients on mono-therapy and in 32.1% out of 53 patients on 2 drug therapy. With 3 drug treatment, 100% of the subjects had uncontrolled BP. The association between the number of drugs and blood pressure control is not found in the study ($p>0.05$).

Table 12: List of side effects reported.

Side effect	Frequency	Percentage (%)
Dry cough	26	13.8
Rashes	3	1.6
Taste Disturbance	1	0.5
Peripheral oedema	23	12.2
Palpitation	29	15.4
Headache	19	10.1
Constipation	3	1.6
Broncho-spasm	1	0.5
Loss of libido	1	0.5
Forgetfulness	8	4.3
Fatigue	16	8.5

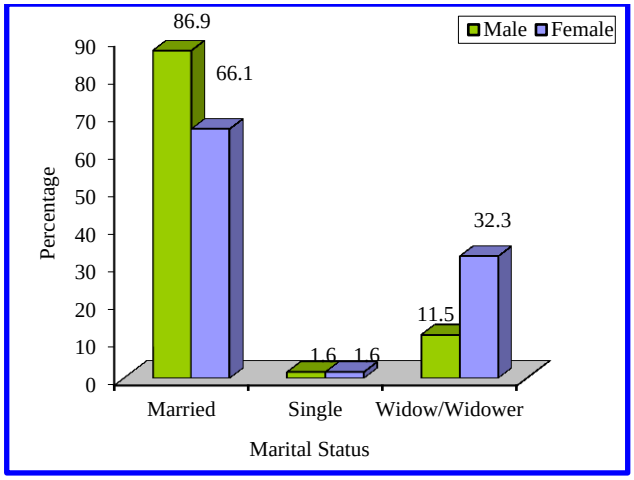

Figure 1: Distribution of the respondents by marital status.
N size male=61; N size female=127.

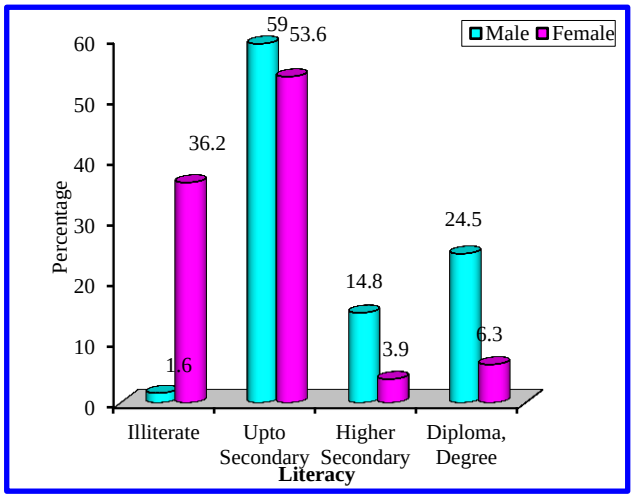

Figure 2: Distribution of the respondents by literacy.
N size male =61; N size female=127.

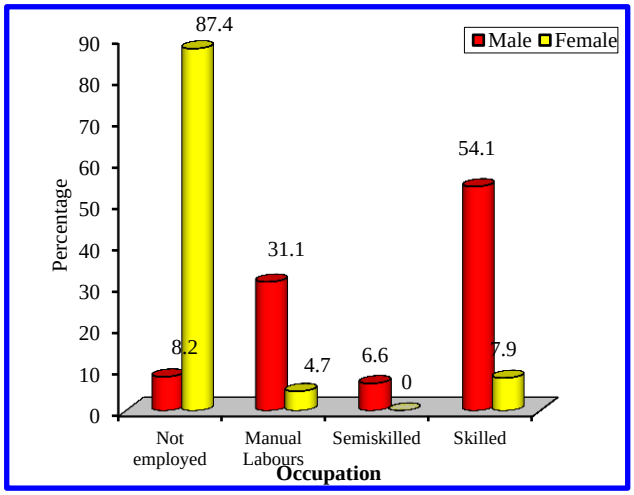

Figure 3: Distribution of the respondents by occupation.
N size male=61; N size female=127.

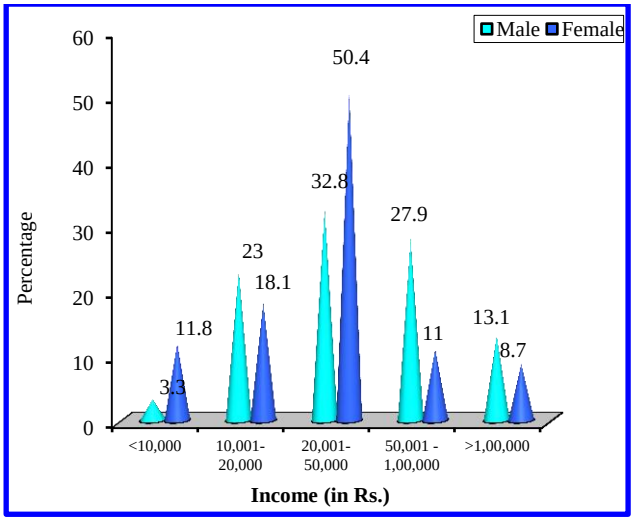

Figure 4: Distributions of the respondents by annual income (in Rs.).

N size male=61; N size female=127.

The side effects of antihypertensive drugs when studied showed that among those who have reported side effects (47.3%), palpitation (15.4%), dry cough (13.9%), peripheral oedema (12.2%), head ache (10.1%) and constipation (9.6%), have been experienced by them (Table 12).

DISCUSSION

A follow up study of drug compliance on 188 known hypertensive patients identified from the field practice area of Chidambaram for a period of one year, with six visits at every two months interval to assess the factors influencing compliance, was conducted and the results are as follows:

The present study shows a significant association between the sex and compliance i.e., 93.4% of males and 82.7% of females reported compliance even in the first visit (Table 2). But other studies elsewhere showed that there was no significant relationship between gender and compliance (OR = 1.1; 95%. CI = 0.91, 1.32).[4] It may be explained by the different methods adopted by different researchers to assess compliance.

The present study shows that level of literacy in association to compliance is insignificant. Similar results are reported by other studies.[5] 67% of subjects with formal education were compliant $\geq$90% of days.[6] In another study poor compliance among illiterates had been observed (Figure 2).[7]

The self-reported compliance at the VI visit, when compared to the first visit is higher and may be explained by two factors (Table 6). The first reason being the method of measurement – subjective method is used for assessing compliance (patients self report). This subjective assessment may not have influenced the result very much, because the influence would get diminished during the repeat visits usually. Patients would come come-up with real facts, in course of time. The other factor is that the subjects under study reside in urban filed practice area and there is a marginal advantage of extra following up by the health workers. there is a significant association ($p<0.001$) between self reported compliance in the follow-up visit (VI) and BP control. Similar follow-up studies have shown, significant relationship ($p<0.02$) between self reported compliance blood pressure control.[8]

There is no significant association between the number of drugs used per day and compliant status, in this study (Table 10). Also a study in India showed 74% compliance with mono-therapy and 33% in more than 3 drugs.[9] But, another study showed better compliance with more drugs (drug 1 through 3: 47%, 59%, 60%).[10] In the present study, the number of antihypertensive drugs have no significant association over control of blood pressure ($p>0.05$). But a study done in Spain with combination of drugs achieved its goal of effective blood pressure lowering by 13.3±3 mmHg and better control of blood pressure.[11]

The frequency of clinic attendance has a significant association with compliance (Table 5). Similar results were shown in other studies.[12,13]

It is observed that the level of compliance is not related to the control of blood pressure in the study. The results show more than 90% compliance is seen only in 34% of subjects, whose blood pressure is under control. This may be explained by the influence of other factors in the control of blood pressure apart from the compliance.[14]

In this study, the reasons given by subjects for non-compliance were, forget to replenish the drug (24.4%), forgetfulness (22.0%), lack of funds to buy drugs (14.6%), absence of symptoms (14.6%), busy schedule (7.3%), normal BP during last clinic visit (2.4%) and side effects of the drugs (2.4%) (Table 3). Previous studies from India show that, the reasons reported affecting compliance were side effects of drugs (28.3%): forgetfulness (23.1%), non-availability of the drug (8.0%), normal BP during the previous clinic visit (3.6%), bad taste (15.2%), cost of the drug (10%), stressfulness (9%) and busy schedule.[6,9,13]

In the present study, the side effects are observed in 47.3% of the patients (Table 11). In contrast to this result, higher percentage of side effects (74%), have been reported to be influencing non-complaince.[13,15]

CONCLUSION

To conclude the socio demographic factors like age & sex, marital status, literacy, occupation and income (Figure 1- 4) have no role on the compliance status.

Sex has significant association with the compliance level (86.1%), where males have 93.4% and females have 82.7% compliance ($p<0.05$).

The type of drug, doses frequency, combination therapy and regularity in refilling the prescription, have no association with compliance status in this study.

Most of the patients (46.3%) do not know what is meant by normal blood pressure and their blood pressure status for the past three month period.

Frequency of clinical visits has significant association with compliance (visit fortnightly, monthly and occasionally is 94.1%, 85.1% and 75% respectively) $p<0.05$.

Significant improvement (73.1%) in compliance in the VI visit is seen among non-compliers from the first visit ($p<0.001$).

Significant drop in the mean systolic blood pressure (148.15±20.08 to 137.07±14.08 mmHg) and the mean diastolic blood pressure (94.34±13.03 to 84.36±8.28 mmHg) is observed in the VI visit compared to the first visit ($p<0.001$).

There is a role of the health care provider to improve the drug compliance status, which is observed in this follow up study, among 26 non-compliers (19 have switched over to compliance status).

Hence by implementing simple corrective measures suggested below the effectiveness of anti hypertensive therapy may be improved.

Patients should be prescribed a simple, once a day regimen, which is cost effective. The study findings also indicate that there is a relationship between simple regimen and compliance.

Patients should be monitored periodically for the achievement of blood pressure goal at least fortnightly, and the progress should be communicated by the health care professional to the patient. It is observed in the present study, 43.6% are not aware whether their blood pressure is under control or not.

Visits of health care provider are found to influence the compliance level. It is observed in the study that many patients from non-compliance status switched over to compliance group (26 to 7 subjects) during the one year follow up. This may be incorporated in the present health system, utilizing the services of MPW or ASHA, without any significant additional inputs.

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