

ORIGINAL ARTICLE

Compliance and its determinants to pharmacologic management of hypertension

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Abstract

Background: Compliance to medications and lifestyle modifications is important in the management of hypertension. **Aims and Objectives:** The purpose of this study was to measure the compliance and its determinants to pharmacological management of hypertension. **Material & Methods:** A population based cross sectional survey was conducted among 221 known hypertensives in medical college health unit area of urban Trivandrum. **Results:** Mean age of the study subjects was 64.6 yrs (SD 10.6). The overall compliance with antihypertensives was 62.4%. Male gender, joint/extended family type, family support, co-morbidities, once daily regimen, awareness about the BP control status and adequacy of BP control were the predictors of good compliance. The barriers to compliance were alcohol abuse, out of pocket expenditure and more number of pills/day. **Conclusion:** Drug compliance among the study population was low compared to previous studies. Low drug compliance and poor blood pressure control among the hypertensives in the area warrants immediate actions to prevent the development of complications. The burden of morbidity and mortality due to hypertension and related complications on the family and health system will be immense if the situation is left unattended.

Keywords

Hypertension; Blood Pressure; Compliance; Cross sectional study; Antihypertensive Agents; Self Report

Introduction

Hypertension is the most common non-communicable diseases globally and common cause of premature death. It was estimated in 2008, that nearly 978 million adults, or 28% of the world's

population, had uncontrolled hypertension.(1) Studies on the prevalence of hypertension in Kerala had reported prevalence as high as 36.7% and women having increased prevalence (men 36.0%, women 37.2%).(2) Another study in 2000 gave a prevalence of about 51.8% (95% CI: 46.8%-56.8%),

which increase with age in both sexes. But only a quarter of these treated hypertensives had adequate control of their blood pressure (3)

One of the main reasons for inadequate control of blood pressure is the noncompliance to medications and lifestyle changes. The relationship between drug compliance and clinical outcomes has been clearly demonstrated, particularly in cardiovascular disease.(4,5) Self-reported measurement of compliance is a relatively simple and inexpensive method. (6,7,8)

Drug compliance and its determinants is complex and are often poorly understood. There is not much published Indian/Kerala studies that have estimated the prevalence of antihypertensive drug compliance in the community setting.

A comprehensive understanding of compliance and its predictors is necessary to determine strategies to improve medication compliance among hypertensives and hence this study was undertaken.

Aims & Objectives

To assess the compliance and its determinants to pharmacologic management of hypertension.

Material & Methods

Study design: Cross-sectional study

Study population: Adults already diagnosed with systemic hypertension were the study subjects.

Inclusion criteria: Patients aged 18 years and above who had been diagnosed as hypertensive and were prescribed antihypertensive/s for at least 12 months were included in this study. **Exclusion criteria:** Hypertensives not on the modern system of medicine and/or not willing to participate were excluded.

Study setting: The urban health unit area under a tertiary care hospital in Trivandrum. This health unit covers a population of 1,16,266.

Sample size: Based on the WHO compliance estimate of 50%, (9) the sample size for this study was calculated as 220 at 20% relative precision and power of 80%. To account for the cluster design in sampling, a design effect of 2 and 20% non-response rate was considered. The sample size was calculated using the formula,

$$n = z_{1-\alpha/2}^2 \frac{P(1-P)}{d^2}$$

Where n = sample size

$z_{1-\alpha/2}^2$ = Confidence level at 95%

P = Expected Prevalence or Proportion

d = Relative precision (20% of P)

Sampling technique: Since the sampling frame of diagnosed hypertensives was not available for the random sampling technique, cluster sampling was chosen. All the 10 subcentre areas were taken for sampling. As the list of hypertensives in each area was not available, it was assumed that the proportion of hypertensives is same in each area. Since the population size of each subcentre area was almost equal, equal number of clusters was studied from each subcentre area. 22 study subjects were covered from each area. In case a single household had 2 or more hypertensive subjects meeting the inclusion criteria, Kish table was used to select one among them.(10)

Study period: The study was conducted for a period of one year, from November 2013 to October 2014.

Study variables: Exposure variables include socio-demographic variables, alcohol and tobacco use, physical activity, family history of hypertension, duration of hypertension, duration of treatment, comorbidity status, social factors, treatment related factors and outcome variables (compliance with treatment). Compliance can be defined as the degree to which the patient conforms to prescribed treatment. Compliance as a percentage was computed as follows: (Number of pills the patient consumed in the last week/Number of pills that were prescribed for that week) $\times 100$.(11) The adherence/compliance goal of 80% of the prescribed dose is conventionally used in clinical trials of safety and efficacy. (12,13) Patients who take $\geq 80\%$ of the prescribed dose were considered as good compliers and $<80\%$ compliance were considered as poor compliers.

Data collection tools and technique: A semi-structured questionnaire was used to collect data by interviewing each participant and a calibrated and standardized digital sphygmomanometer (Rossmax GB102) was used to measure blood pressure. Blood pressure was recorded twice for a person, 5 minutes apart on the right arm, and the average value was taken as the person's BP, expressed in mm of mercury.

Statistical analysis: The data were entered into Microsoft Excel software and analyzed using Statistical Package for Social Sciences (SPSS) software (trial version). The categorical variables have been summarized using frequencies and proportions with 95% Confidence Intervals. The quantitative variables are summarized using mean and standard deviation for normally distributed data

and using median and inter-quartile range for skewed data. The statistical significance of association was tested using independent sample t-test/Mann Whitney U test for quantitative variables and Pearson Chi-square test for qualitative variables and the strength of association was expressed using Odds ratio (CI). Binary logistic regression analysis was done to find out the determinants of good compliance.

Ethical statement: The study was approved by the scientific research committee and the Institutional Ethics Committee. The purpose of the study was explained and informed consent was obtained in the local language (Malayalam) from all respondents. Confidentiality and voluntariness ensured. Necessary referral advice was given

Results

The study was conducted among 221 hypertensives.

Sociodemographic details: Mean age of the study subjects was 64.59(±10.6) years. Majority were elderly. Males and females were almost equal in number. The effective literacy rate was as high as 100%. 77.8% were married and living with their spouse. Three fourth of the study subjects belonged to APL category. The habit of smoking and alcoholism was seen exclusively among males. But the use of smokeless tobacco was more among females than males. Only 14% of study subjects were physically active. 40% of study participants reported a family history of hypertension among their first degree relatives. 62.4% (138) had at least one co-morbidity [Figure 1].

Disease and treatment characteristics of hypertensive patients: The median duration of hypertension was 8 (5, 15) years. As per JNC VII criteria, once monthly BP checkup is advisable for all hypertensives. But it was noted that only 51.1% complied with this. 6.7% hypertensives had not checked BP for more than a year [Figure 2]. 114(51.6%) of the study subjects reported that their BP was normal or controlled during their last checkup while 45(20.4%) were not aware of their level of BP control. The overall median monthly direct medical cost for antihypertensive drugs alone was found to be 100(30,200). The median direct medical cost of anti-hypertensive drugs for those taking treatment from private health care providers was 140 with IQR (65,255) and 0 with IQR(0,95) for those seeking treatment from the public sector.

Compliance with pharmacologic management: 138(62.4%) of the study subjects were found to be compliant with the prescribed drug regimen [Figure 3]. Adequacy of blood pressure control was assessed for and among the 221 study subjects, 95 (43%) had their BP under control while 82 (86.3%) of them were good compliers. Among 138 compliant subjects, 82 (59.4%) had their BP under control [Table 2].

Table 1 shows bivariable analysis of certain selected socio-demographic correlates of compliance. The age and gender were found to be significantly different among compliers and non-compliers ($p < 0.05$). There was no significant association between marital status, literacy status, occupational status, socio-economic status and type of family with compliance. When other factors were subjected to bivariable analysis, presence of family history of systemic hypertension was found to be significantly associated with compliance. Proportion of Cardiovascular accident (stroke) and dyslipidemia was significantly different among compliers and non-compliers. The presence of family support in taking medicines, self-monitoring of blood pressure, fixed-dose combination drugs, once-daily dosage and awareness about control status of blood pressure on last check-up were significantly associated with good compliance [Table 2].

Those compliant to their prescribed medications were 7.8 times more likely to achieve adequate control of hypertension compared with those who were not compliant [Table 2]. Median SBP with IQR among compliers and non-compliers were 130(120,148) and 150(138,160) mm of Hg respectively. Median DBP with IQR among compliers and non-compliers were 80 (70, 86) and 90 (80, 94) mm of Hg respectively. Both SBP and DBP were found to be significantly different between compliant and non-compliant subjects ($p < 0.001$) [Table 3]. 82 (59%) of the hypertensives with better compliance had adequately controlled levels of blood pressure.

Box plot showing the distribution of SBP and DBP for compliers and non-compliers is shown in [Figure 4].

Determinants of medication compliance: Binary logistic regression was done to identify the factors associated with good compliance. All variables having p -value < 0.2 in the bivariable analysis were put into the model. Age > 60 yrs, family history of hypertension and personal history of CVA and dyslipidemia were significant on bivariable analysis

but lost its significance after putting in the regression model. Male gender, joint and extended type of family, non-use of alcohol, presence of Diabetes Mellitus, good family support, once daily dosing of anti-hypertensives, prescribing Fixed Dose Combination drugs, less cost of drugs, self-awareness of blood pressure control status and adequacy of control emerged as predictors of good compliance among the study subjects [Table 4]

Discussion

At 80% cut off, the level of compliance was found to be 62.4% (95% CI- 52.2-72.1) without any significant age difference. WHO estimated a compliance of 50-70% for anti-hypertensive drugs and this study result fall in this range. Another study by R Susan *et al* in the same setting showed 85.5% compliance.(14) A study conducted among urban slum dwellers of Kolkata, a self-reported adherence of 73% was obtained.(15) C R Rao *et al* concluded that the prevalence of compliance was still higher, 82.2% in Karnataka, taking 80% of prescribed medications as cut off for compliance.(16) In a community-based cross-sectional study among the rural population in Tamil Nadu, using the 4-item Morisky Medication Adherence Scale (MMAS-4) prevalence of compliance was reported to be 24.1%.(17) The prevalence rates were lower (15.3%) in an institutional based cross-sectional study using MMAS-8, in Karnataka.(18)

Males were more compliant than females (55% vs 45%). A similar result was obtained in a study conducted in a hospital setting in Sunderland and in an urban health care setting.(19,20,21) This difference can be attributed to increased medical literacy and health issue awareness of males compared to females. Females are also more anxious about their spouse's health than their own.

Joint or extended family type was a facilitator for compliance. A similar finding was seen in research done at Sunderland and Pakistan.(13,20) The positive effect of joint/extended families on drug compliance could be possibly due to better social support and reduced self-reliance.

Smoking and alcoholism were the habitual factors studied in this research. Non-use of alcohol emerged as a predictor of good compliance. There is an American study by PS Wang *et al* that showed non-use or less consumption of alcohol is associated with better drug compliance and another study among blacks concluded that alcohol misuse is associated

with non-compliance to drugs.(22,23) Alcoholics are less concerned about their health issues and often neglect the importance of being compliant to the prescribed drug regimen. Smoking is a known factor which negatively influences the drug compliance. Several studies from Europe and the Middle East have demonstrated this association. But the present study failed to identify this as a factor influencing drug compliance. (24,25,26)

The co-existence of dyslipidemia, CVA and Type 2 DM were found to be positively associated with compliance. But the present study could not find any consistency in this finding except for Type 2 Diabetes Mellitus after adjusting for the confounders. There are shreds of evidence for poor drug compliance in the presence of co-morbidity as shown by a study done at a tertiary care centre in China by Wong *et al*.(27) This could be due to the fact that those with multiple medical conditions might encounter difficulties to comply with their daily medication, probably due to poorer bodily function and the higher possibility of polypharmacy, referrals or adverse drug events. In another primary care study in Romania, the co-morbid cardiac disease is associated with better drug compliance.(28)

Prescribing Fixed Dose Combination (FDC) drugs and once-daily dosing was found to be significantly associated with better compliance. A meta-analysis reported a 26% increase in compliance among hypertensives prescribed with FDC drugs.(29) Canadian and Nigerian studies comparing the dosing regimen had proved that once-daily regimen is more effective in improving therapeutic compliance.(30,31) Extended release tablets and FDC drugs are being used for once-daily dosing in the management of hypertension. FDC reduces pill burden and thereby improve compliance, especially among elderly who finds it difficult to take many drugs at a time. The direct cost of drugs can also be reduced using FDC among hypertensives requiring more than 2 drugs.

Compliance was more among those who were aware of their BP control status on their last visit to a Physician. Hypertensives' knowledge and awareness regarding the control status of their own blood pressure will invariably affect the drug compliance. (32) By knowing the control status, they could comply better and seek specialist care when needed. Medication compliance decision depends heavily on the out of pocket expenditure for the drugs. Hypertensives in this study with less out of pocket

expenditure are found to be good compliers. In a study in Ghana, 96% of the non-compliant subjects cited the high cost of drugs as the reason for non-compliance.(33,34) The cost is still a problem in developing nation like India. The government of India had implemented the national programme, NPCDCS in the country and the states are now providing the anti-hypertensives at free of cost starting from the primary level of health care. Generic drug substitution is an effective strategy to decrease drug cost.

Those compliant were 7.8 times more likely to achieve adequate control of hypertension compared with those who were not compliant. In spite of high medical literacy and improved accessibility to health facilities in Kerala, the drug compliance has not reached an adequate level. Poor compliance severely compromises the treatment effect which makes this a public health problem both in terms of QOL and health expenditure. In Kerala, a study published in 2012, it was found that 58.5% of hypertensives had well controlled BP. Compared to this; our subjects had a low level of control (43%). A study in Central India, among urban hypertensives, 68% had adequate blood pressure control.(35) Rural Indians have poor control of hypertension as evident from a systematic review and meta-analysis; 10.7% vs 20.2% respectively.(36)

Self-reported reasons for poor compliance and forgetfulness, lack of symptoms, lack of family support, fear of adverse effects, lack of awareness about complications, complicated drug regimen, polypharmacy and a high cost of drugs.

Since drug compliance forms an important aspect in patient care, especially in case of long-term illness, use of medical technology in monitoring compliance and addressing the problems faced in complying with drug regimen is important to reduce the incidence of potentially life-threatening complications associated with non-compliance

Conclusion

Hypertension is a chronic condition, often termed as "A silent killer" with a tremendous economic and public health impact contributing to patient disability, high health care costs and mortality. The mortality and morbidity can be reduced by controlling blood pressure using effective pharmacological and non-pharmacological management. But the control of hypertension appears to be far low. One important factor

determining ideal or adequate blood pressure control is compliance with antihypertensives. Therapeutic compliance, adequacy of blood pressure control and the determinants of drug compliance are assessed in this study. Low drug compliance and poor blood pressure control among the hypertensives in the area warrants immediate actions to prevent the development of future complications.

Recommendation

The importance of complying with the therapeutic regimen should be made aware to all and especially to females, younger hypertensives, and hypertensives living in nuclear families. Hypertensives on multiple drugs can be prescribed with fixed dose combination pill to improve compliance and reduce adverse effects. The once-daily regimen can be opted for, with the use of extended-release drugs wherever possible. The government should give priority to the procurement of antihypertensive drugs and take appropriate measures to reduce the cost of the same. Doctors should monitor their patients for drug compliance during the follow-up visits. Reminders for pill taking and diary keeping can avoid the issue of forgetfulness. The blood pressure control status should be conveyed and communicated properly to the patient on each visit. The care takers of elderly hypertensives should be aware of the medication regimen and assist them in taking drugs as prescribed

Limitation of the study

The strength of the study is that it was a population-based survey. Hence it measures the true prevalence and it can be generalized in to that community. A shorter recall period of one week was used to minimize recall bias. The findings of this study need to be considered along with the following limitations. Here the self-reported compliance was assessed. Hence there is a chance that the data can be skewed towards the direction of social desirability leading to over-estimated compliance. Compliance to non-pharmacological therapy like dietary and life style modifications was not assessed in this study which is an important factor which is also important in the management of raised blood pressure determines the control of systemic hypertension. Being a cross sectional study, it may not give the exact determinants of compliance.

Relevance of the study

Direct measures of compliance are much resource intensive. Hence assessment using population based self reports of compliance is important. Also, even if the literacy is much good, people are less aware about the importance of drug compliance. This study revealed low drug compliance in the urban setting when compared to previous published studies.

Authors Contribution

All the authors have contributed to the study. JJ did the protocol, literature search, questionnaire preparation, data collection, data analysis and manuscript writing. VK contributed to the concept, hypothesis generation, ZTN helped in designing, results interpretation and manuscript reviewing. PMT was involved in data acquisition and cleaning

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Tables

TABLE 1 SOCIO-DEMOGRAPHIC FACTORS RELATED TO COMPLIANCE ON BIVARIABLE ANALYSIS

Factors	Category	Compliers N (%)	Non-compliers N (%)	p value	OR (95% CI)
Age *	≥ 60yrs	132 (95.7)	71 (85.5)	0.008	3.8 (1.3-11.1)
	< 60 yrs	6 (4.3)	12 (14.5)		
Gender *	Male	76 (55.0)	31 (37.3)	0.01	2(1.2-3.5)
	Female	62 (45.0)	52 (62.7)		
Marital status	Married and living with the spouse	102 (74.0)	70 (84.3)	0.07	1.9 (0.94-3.8)
	Unmarried/widowed/separated	36 (26.0)	13 (15.7)		
Literacy status	Illiterate	10 (7.0)	2 (2.4)	0.12	3.2 (0.6-14.8)
	Literate	128 (93.0)	81 (97.6)		
Occupational status	Unemployed	48 (35.0)	30 (36)	0.8	0.94 (0.53- 1.6)
	Employed	90 (65.0)	53 (64)		
Socioeconomic status	APL	100 (72.5)	64 (77)	0.4	0.78 (0.4-1.47)
	BPL	38 (27.5)	19 (23)		
Type of family	Nuclear	63 (45.7)	45 (54.2)	0.13	0.7 (0.4-1.2)
	Joint/extended/three generation	75 (54.3)	38 (45.8)		

*Significant by Chi-square test at 5% alpha level

TABLE 2 FACTORS RELATED TO COMPLIANCE BY BIVARIABLE ANALYSIS (N=221)

Factors	Category	ComplierN (%)	Non-complierN (%)	p value	OR (95% CI)	
Personal and family history	Smoking	Smoker	9 (6.5)	7 (8.4)	0.6	0.75 (0.27-2.1)
		Non - smoker	129 (63.5)	76 (91.6)		
	Alcoholism	Alcoholic	5 (3.6)	7 (8.4)	0.13	0.4 (0.12-1.3)
		Non - alcoholic	133 (93.4)	76 (91.6)		
	Exercise	Regular	20 (14.5)	10 (12)	0.6	1.2 (0.54-2.8)
		Irregular or nil	118 (85.5)	73 (88)		
The family history of hypertension*	Present	90 (65.2)	42 (50.6)	0.03	1.85 (1.05-3.2)	
	Absent	48 (34.8)	41 (49.4)			
Co-morbidity status	Dyslipidemia*	Present	33 (24)	10 (12)	0.03	2.3 (1.06-4.9)
		Absent	105 (76)	73 (88)		
	CVA*	Present	6 (4)	0	0.008	1.6 (1.5-1.8)
		Absent	132 (96)	83 (100)		
	CAD	Present	17 (12.3)	15 (18)	0.2	0.6 (0.3-1.3)
		Absent	121 (87.7)	68 (82)		
	Type 2 DM	Present	72 (52.2)	35 (42.2)	0.1	1.5 (0.86-2.6)
		Absent	66 (47.8)	48 (57.8)		
Others	Family support*	Present	31 (22.5)	1 (1.2)	< 0.001	23.8 (3.2- 166)
		Absent	107 (77.5)	82 (98.8)		
	Self-monitoring of BP*	Present	16 (11.6)	2 (2.4)	0.01	5.3 (1.2- 23.7)
		Absent	122 (88.4)	81 (97.6)		
	FDC drugs*†	Yes	40 (69)	10 (35.7)	0.001	4 (1.5 –10.4)
		No	18 (31)	18 (64.3)		
	Once-daily dosing*	Yes	96 (70)	45 (54.2)	0.02	2 (1.1-3.4)
		No	42 (30)	38 (45.8)		
	Awareness about control status*	Aware	120 (87)	55 (66.3)	< 0.001	3.3 (1.7-6.6)
		Unaware	18 (13)	28 (33.7)		
BP control*	Adequate	82 (59.4)	13 (15.7)	< 0.001	7.8 (3.9-15.6)	
	inadequate	56 (40.6)	70 (84.3)			

*Significant by Chi-square test at 5% alpha level, †Applicable only for 86 study subjects who were prescribed more than one drug, CVA – Cardiovascular Accident, CAD – Coronary Artery Disease, DM – Diabetes Mellitus, FDC – Fixed Dose Combination

TABLE 3 COMPARISON OF SBP AND DBP AMONG COMPLIANT AND NONCOMPLIANT SUBJECTS

Category	Median among compliant subjects (IQR)	Median among non-compliant subjects (IQR)	p-value
SBP (mm of Hg)	130 (120,148)	150 (138,160)	<0.001*
DBP (mm of Hg)	80 (70,86)	90 (80,94)	<0.001*

*Test of significance - Mann - Whitney U test

TABLE 4 DETERMINANTS OF GOOD COMPLIANCE, THE RESULT OF BINARY LOGISTIC REGRESSION

Category	Adjusted OR (95% CI)	p-value
Male gender	9.08 (3-25)	< 0.001
Joint/extended family type	3.1 (1.3-7.4)	0.01
Non-use of alcohol	19.6 (2.2-166)	0.008
H/o Type 2 DM	3.04 (1.2-7.4)	0.01
Good family support	52.6 (4.56-500)	0.001
Less cost of drugs	1.002 (1.001-1.004)	0.03
Once daily dosing	2.7 (1.004-7.4)	0.049
FDC	2.02 (1.01-4.01)	0.047
Adequate control of BP	17.1 (5.9-49.5)	<0.001
Self-awareness about BP control status	2.9 (1.2-7.4)	0.01

Model summary – Cox and Snell r2 for the model – 0.451, Sensitivity of the model was 88.4% and specificity was 75.9%

Figures

FIGURE 1 BAR DIAGRAM SHOWING THE PROPORTION OF CO-MORBIDITIES AMONG STUDY SUBJECTS (N=138)

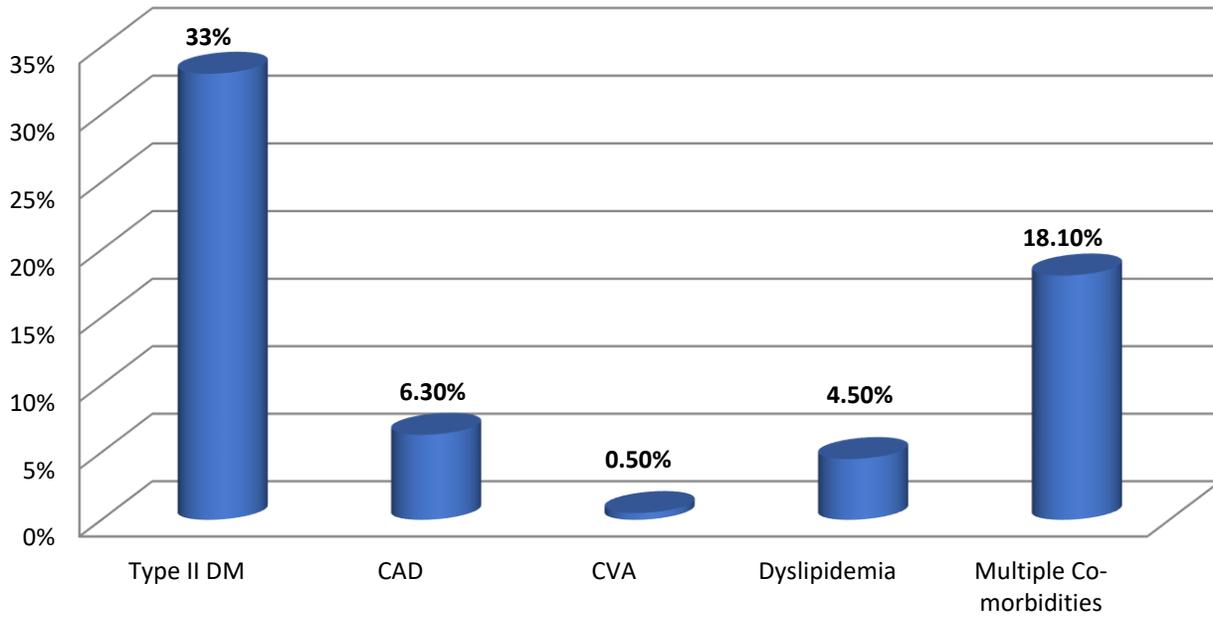


FIGURE 2 THE BAR GRAPH SHOWING FREQUENCY OF BLOOD PRESSURE CHECK UP (N=221)

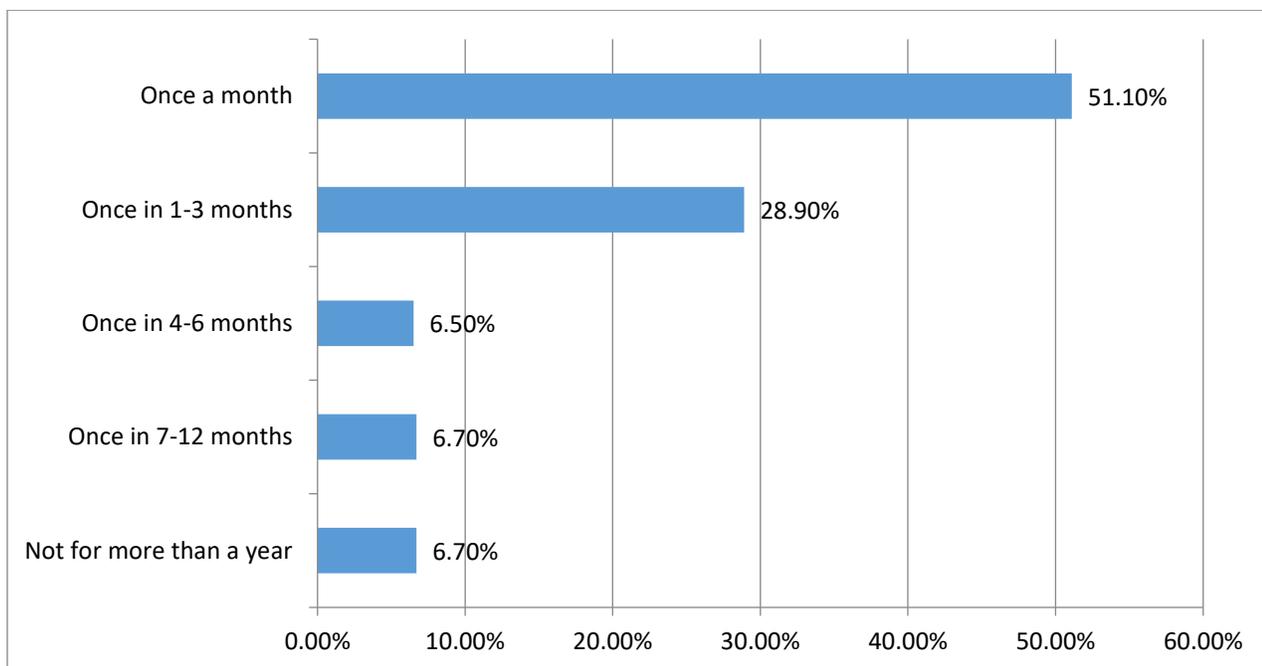


FIGURE 3 PIE-CHART - COMPLIANCE WITH ANTI-HYPERTENSIVE DRUGS (N=221)

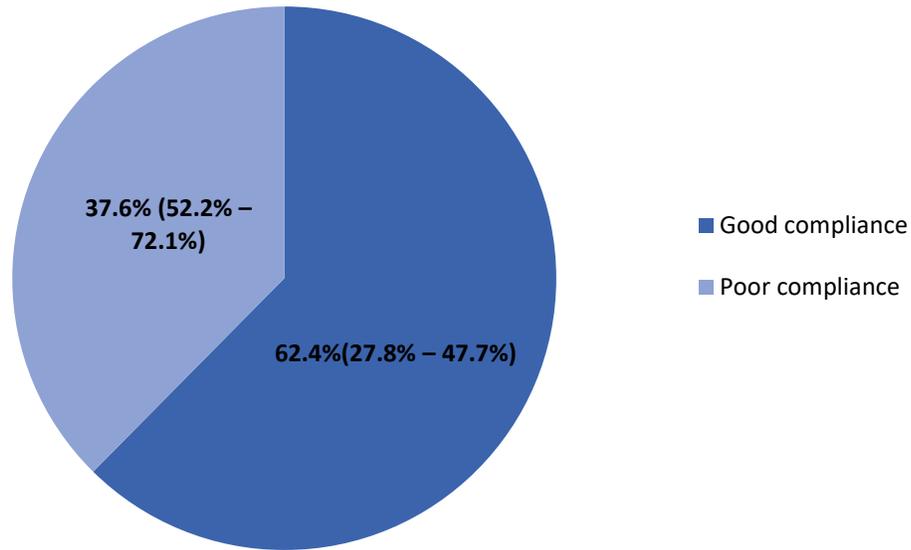


FIGURE 4 DISTRIBUTION OF SBP AND DBP AMONG COMPLIERS AND NON-COMPLIERS

