

A community-based study to assess the treatment adherence and its determinants among hypertensive patients residing in a rural area of Kancheepuram district, Tamil Nadu

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ABSTRACT


Background: Hypertension exerts a massive public health burden on cardiovascular health and health system in India. **Objectives:** The aim of this study is to assess the level of treatment adherence among the known hypertensive patients in a rural community and identify the determinants for non-adherence to treatment among them. **Materials and Methods:** A community-based cross-sectional descriptive study was conducted for 2 months in Sembakkam and Kottamedu villages under the rural field practice area of a medical college among known cases of hypertension diagnosed and initiated on antihypertensive therapy at least 3 months back. A total of 170 hypertensive patients were included as study participants using random sampling, and the desired information was obtained using a semi-structured schedule, and details about treatment adherence based on the Morisky Medication Adherence Scale. Ethical clearance was obtained from the Institutional Ethics Committee before the start of the study. Written informed consent was obtained from the study participants before eliciting any information from them. Statistical analysis was done using SPSS version 18. Frequency distributions were calculated for all the variables. Chi-square test was used for testing the significance of association at $P = 0.05$. **Results:** Among the study participants, 81 (47.6%) had good medication adherence, whereas 89 (52.4%) had poor adherence. A statistically significant association was observed between indulging in regular physical activity and use of salt-restricted diet and a good level of treatment adherence. Poor adherence to treatment was found more commonly among patients who were prescribed multiple antihypertensive drugs and those with more than once daily dose formulation. **Conclusion:** The study indicates that prevalence of treatment adherence among hypertensive patients in rural areas of Tamil Nadu was only 47.6% and there is a lot of scope for improvement. The study has also identified the crucial factors responsible for non-compliance to antihypertensive treatment which can assist the health-care policy makers to formulate a comprehensive strategy to achieve adequate compliance.

KEY WORDS: Hypertension; Tamil Nadu; Treatment Adherence

INTRODUCTION

Hypertension accounts for a major proportion of the burden attributed to impaired cardiovascular health and

the health-care delivery system in India.^[1,2] Hypertension has been identified as the direct cause of deaths in more than 55% and 25% of all stroke and all coronary heart disease-related deaths reported in India.^[3] Even on a global scale, hypertension is one of the most important causes of premature death as per the World Health Organization.^[4] Current estimates reveal that hypertension affects more than 30% of adults with age 25 years and above which accounts for almost 1 billion people worldwide.^[5] Furthermore, as per trend analysis, it has been estimated that more than 20 million cardiovascular deaths will be attributed to hypertension, by the year 2030, of which in excess of four-fifths will be from

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developing countries.^[5] Recent studies conducted across India indicate a higher prevalence of hypertension ranging from about 22-26%.^[6,7]

According to the World Health Organization, non-adherence with long-term medication for chronic conditions is a common problem leading to adverse health outcomes and grave financial aftereffects.^[8] Furthermore, non-compliance is the major reason for disease progression, the occurrence of complications, and failure of medical therapy.^[9] Even clinical trials have indicated the importance of pharmacological treatment in decreasing the morbidity and mortality associated with cardiovascular diseases.^[8]

Hypertension is a “triple paradox”: Easy to diagnose but often remains undetected; simple to treat but often remains untreated; despite the availability of drugs, treatment is not adequately effective. Uncontrolled or suboptimally controlled hypertension can lead to target organ damage and thus multiple adverse clinical outcomes including stroke, heart failure, or kidney failure.^[10]

Failure to adhere with the prescribed treatment not only causes medical complications of the disease but also adversely affects patients’ quality of life.^[11-14] Studies suggest that lack of treatment compliance would be responsible for about 67% of uncontrolled hypertension.^[15,16] Poor adherence to antihypertensive therapy is a multidimensional issue which depends on the patients, health-care providers, and health system as well as the community.^[17] Therefore, the present study aimed to assess the level of treatment adherence among the known hypertensive patients in a rural community and identify the determinants for non-adherence to treatment among them.

MATERIALS AND METHODS

Study Design

This was a community-based cross-sectional descriptive study.

Study Duration

This study was conducted for 2 months (August and September 2016).

Study Area

Sembakkam and Kottamedu villages under the rural field practice area of Shri Sathya Sai Medical College and Research Institute, Kancheepuram, were selected as study area.

Study Population

All adults more than 18 years of age residing in Sembakkam and Kottamedu villages were considered eligible as the study population.

Inclusion Criteria

1. Known cases of hypertension diagnosed and initiated on antihypertensive therapy at least 3 months back.
2. Patients who were willing to give informed consent.

Exclusion Criteria

1. Newly diagnosed cases of hypertension or those diagnosed within 3 months.
2. Patients who were not willing to give informed consent.

Sample Size

Sample size was calculated using the formula:

$$N = \frac{4 \times P \times Q}{L \times L}$$

Here, P was taken as 58.4 on the basis of result of a study done in North India which showed adherence to antihypertensive medication among adults as 57.2%.^[18] Thus, sample size was calculated as:

Where, P - 57.2; Q - 42.8, L - Allowable error - 8.

$$N = \frac{4 \times 57.2 \times 42.8}{8 \times 8} = 153$$

Assuming a 10% non-response rate, the final sample size was approximated to 170.

Sampling Technique

Simple random sampling for selection of villages followed by systematic random sampling for selecting the households was used.

Study Tool

A semi-structured schedule comprising following parts (namely, sociodemographic parameters; details about hypertension and lifestyle-related factors; and details about treatment adherence based on Morisky Medication Adherence Scale (MMAS), an 8-item questionnaire, was prepared in English to meet the study objectives and was subsequently translated into the local language (Tamil).^[19] This schedule was pre-tested on 20 participants to check for validity and understanding by the participants and was then suitably modified based on the results of pilot study.

Study Variables

Sociodemographic parameters, parameters related to lifestyle (namely, use of tobacco/alcohol, physical activity, and diet), and parameters related to hypertension and health-care facility

such as nature of treatment, source of health care, number of drugs, frequency of antihypertensive drugs, regularity of taking prescribed medicines, distance of health-care facility, side effects of treatment, and associated comorbidities.

Data Collection

Rural field practice area of Shri Sathya Sai Medical College and Research Institute comprises 4 villages, namely, Sembakkam, Karanai, Kottamedu, and Arungkundram. Out of these 4 villages, 2 villages, namely, Sembakkam and Kottamedu comprising approximately 380 households and 270 households, respectively, were selected randomly using lottery method. Using systematic random sampling, every second household among the selected villages was visited starting from street across the Rural Health and Training Center. Every street in both the villages was covered systematically. Enquiry was made in every household about the history of hypertension among any of the family members. Study participants were thus selected based on the inclusion and exclusion criteria. The selected study participant was then interviewed face-to-face using the pre-tested schedule after obtaining her/his written informed consent. MMAS, an 8-item self-response questionnaire was used to determine the level of treatment adherence. The total score ranged from 0 to 8. The MMAS adherence was categorized as high, medium, and low (based on the MMAS scores of 8, 6 to 8, and <6, respectively). After participants were interviewed, three recordings of blood pressure (BP) in sitting position were taken in the right arm with pre-tested mercury sphygmomanometer and stethoscope approximately 2 min apart and the lowest of the three readings was used to determine the BP level. For all readings, Korotkoff Phases I and V were used to establish the levels of systolic and diastolic BP, respectively. Based on the Joint National Committee VIII Criteria, BP was said to be uncontrolled when the study participant with age of 18-59 years had a systolic BP ≥ 140 mm Hg and/or diastolic BP ≥ 90 mm Hg and participant with age >60 years had a systolic BP ≥ 150 mm Hg and/or diastolic BP ≥ 90 mm Hg.^[20] Furthermore, anthropometric measurements of height and weight were taken using standardized methods. Socioeconomic class of the families was ascertained using Modified B G Prasad classification.^[21]

Operational Definitions

Regular physical activity: At least 30 min of brisk walking for 4 days or more in a week. Regular BP checkup: Monthly checkup of BP. Salt-restricted diet: Consumption of <5 g of salt/day.

Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee before the start of the study. Written informed

consent was obtained from the study participants before eliciting any information from them. Utmost care was taken to maintain privacy and confidentiality.

Statistical Analysis

Data entry and statistical analysis were done using SPSS version 18. Frequency distributions were calculated for all the variables. Chi-square test was used for testing the significance of association at $P = 0.05$. For statistical analysis purpose, high and medium level of treatment adherence was together termed as good adherence level, whereas low adherence was termed as poor adherence level.^[18,22]

RESULTS

Table 1 revealed that high level of treatment adherence was found among only 22 (12.9%) study participants as per the MMAS, whereas medium and low level of adherence was observed in 59 (34.7%) and 89 (52.4%) participants, respectively. It was also reported that more than half of the female study participants, 43 (55.8%) had low level of treatment adherence.

Table 2 depicts the association between sociodemographic parameters and level of treatment adherence among hypertensive patients. For statistical analysis purpose, high and medium level of treatment adherence was together termed as good adherence level while low adherence was termed as poor adherence level. Thus, among the study participants, 81 (47.6%) had good medication adherence while 89 (52.4%) had poor adherence. It was observed that majority of the participants, 86 (50.6%), were in the age group of 45-59 years. None of the participants was below the age of 30 years. Furthermore, more than half of the participants were males, 93 (54.7%). Statistically significant association was found between having a higher level of education and good compliance to treatment with participants.

Similarly, occupation and level of medication adherence were also significantly associated with participants employed in skilled work 35 (64.8%) having higher levels of compliance than those employed in unskilled 13 (40.1%) or semiskilled work 33 (39.3%). No significant association was found

Table 1: Level of treatment adherence among hypertensive patients

Hypertensive patients	Level of treatment adherence (%)			Total
	High	Medium	Low	
Male	12 (12.9)	35 (37.6)	46 (49.5)	93 (100)
Female	10 (13)	24 (31.2)	43 (55.8)	77 (100)
Total	22 (12.9)	59 (34.7)	89 (52.4)	170 (100)

Table 2: Association between sociodemographic parameters and level of treatment adherence among hypertensive patients

Sociodemographic parameters	Level of treatment adherence (%)		Total	P value
	Good	Poor		
Age (in years)				
18-44	31 (55.3)	25 (44.7)	56 (100)	0.3164
45-59	39 (45.3)	47 (54.7)	86 (100)	
>60	11 (39.3)	17 (60.7)	28 (100)	
Sex				
Male	47 (50.5)	46 (49.5)	93 (100)	0.2035
Female	34 (44.2)	43 (55.8)	77 (100)	
Education				
Illiterate	11 (26.8)	30 (73.2)	41 (100)	0.0002
Primary/middle/high school	48 (48)	52 (52)	100 (100)	
Post-high school/graduate and above	22 (75.9)	7 (24.1)	29 (100)	
Occupation				
Unskilled	13 (40.1)	19 (59.9)	32 (100)	0.009
Semiskilled	33 (39.3)	51 (60.7)	84 (100)	
Skilled	35 (64.8)	19 (35.2)	54 (100)	
Socioeconomic class				
Lower	40 (41.2)	57 (58.8)	97 (100)	0.084
Middle	35 (59.3)	24 (40.7)	59 (100)	
Upper	6 (42.9)	8 (57.1)	14 (100)	
Marital status				
Married	78 (50)	78 (50)	156 (100)	0.04
Single/divorcee/widow/widower	3 (21.4)	11 (78.6)	14 (100)	
Total	81 (47.6)	89 (52.4)	170 (100)	

between age, sex and socioeconomic class, and level of treatment adherence.

Table 3 shows the association between lifestyle-related parameters and level of treatment adherence among study participants. It was found that out of the 170 study participants, only 18 (10.6%) were indulging in regular physical activity and only 34 (20%) were practising use of salt-restricted diet on a daily basis. Statistically significant association was observed between indulging in regular physical activity and use of salt-restricted diet and good level of treatment adherence while no significant association was observed between use of alcohol or tobacco and level of treatment compliance. It was also observed that majority of the study participants, 116 (68.2%), were either overweight or obese and none of the participants was found to be underweight.

Table 4 reveals the association between hypertension and health-care facility-related parameters and level of treatment adherence among study participants. It was observed that only

Table 3: Association between lifestyle-related parameters and level of treatment adherence among hypertensive patients

Lifestyle-related parameters	Level of treatment adherence (%)		Total	P value
	Good	Poor		
Physical activity				
Regular	14 (77.8)	4 (22.2)	18 (100)	0.025
Irregular	11 (45.8)	13 (54.2)	24 (100)	
Never	56 (43.7)	72 (56.3)	128 (100)	
Salt-restricted diet				
Always	24 (70.6)	10 (29.4)	34 (100)	0.0008
Not always	19 (59.4)	13 (40.6)	32 (100)	
Never	38 (36.5)	66 (63.5)	104 (100)	
Alcohol use				
Yes	22 (46.8)	25 (53.2)	47 (100)	0.8924
No	59 (48)	64 (52)	123 (100)	
Tobacco use				
Yes	13 (42)	18 (58)	31 (100)	0.4813
No	68 (48.9)	71 (51.1)	139 (100)	
Body mass index				
Normal	24 (44.4)	30 (55.6)	54 (100)	0.5684
Overweight/obese	57 (49.1)	59 (50.9)	116 (100)	
Total	81 (47.6)	89 (52.4)	170 (100)	

half of the participants 87 (51.1%) had BP within the normal range at the time of examination, out of which 59 (67.8%) had good adherence to treatment which was statistically significant compared to those having uncontrolled BP, 22 (26.5%).

A majority of the participants, 116 (68.2%), were diagnosed with hypertension <5 years ago, and among them, most of the patients were found to have a good compliance to antihypertensive treatment 67 (57.8%) as opposed to those who were diagnosed with hypertension for more than 5 years, 14 (25.9%), with the difference being statistically significant. More than half of the participants, 102 (60%), had a positive family history of hypertension. Furthermore, among the 170 study participants, only 54 (31.8%) were going for regular follow-up to health-care facility for regular BP monitoring. It was also observed that 88 (51.8%) of the hypertensive patients were having comorbidities, most common being diabetes mellitus 45 (51.1%) followed by coronary heart disease 21 (23.9%).

Poor adherence to treatment was found more commonly among patients who were prescribed two or more antihypertensive medications per day, 60 (83.3%) in contrast to those with only one medication prescription per day, 29 (29.5%) and the difference was statistically significant. Poor adherence was also found significantly higher among

Table 4: Association between hypertension and health-care facility-related parameters and level of treatment adherence among hypertensive patients

Hypertension and health-care facility-related parameters	Level of treatment adherence (%)		Total	P value
	Good	Poor		
BP				
Controlled	59 (67.8)	28 (32.2)	87 (100)	0.0001
Uncontrolled	22 (26.5)	61 (73.5)	83 (100)	
Duration of hypertension				
<5 years	67 (57.8)	49 (42.2)	116 (100)	0.0001
>5 years	14 (25.9)	40 (74.1)	54 (100)	
Family history of hypertension				
Yes	48 (47.1)	54 (52.9)	102 (100)	0.8508
No	33 (48.5)	35 (51.5)	68 (100)	
Frequency of blood pressure checkup				
Regular	47 (87)	7 (13)	54 (100)	0.0001
Occasional	34 (29.3)	82 (70.7)	116 (100)	
Comorbidities				
Yes	37 (42)	51 (58)	88 (100)	0.1299
No	44 (53.7)	38 (46.3)	82 (100)	
History of any complications				
Yes	33 (48.5)	35 (51.5)	68 (100)	0.8508
No	48 (47.1)	54 (52.9)	102 (100)	
Number of antihypertensive medications				
1/day	69 (70.5)	29 (29.5)	98 (100)	0.0001
2 or more/day	12 (16.7)	60 (83.3)	72 (100)	
Frequency of taking medications				
Once a day	71 (53.8)	61 (46.2)	132 (100)	0.0028
Twice or more/day	10 (26.3)	28 (73.7)	38 (100)	
Side effects of medications				
Yes	3 (37.5)	5 (62.5)	8 (100)	0.5561
No	78 (48.1)	84 (51.9)	162 (100)	
Source of medication				
Government	39 (52.7)	35 (47.3)	74 (100)	0.2473
Private	42 (45.4)	54 (56.3)	96 (100)	
Cost of medication				
Free	49 (66.2)	25 (33.8)	74 (100)	0.0002
Purchase	32 (33.3)	64 (66.7)	96 (100)	
Distance of health-care facility				
<2 kms	55 (52.9)	49 (47.1)	104 (100)	0.0861
>2 kms	26 (39.4)	40 (60.6)	66 (100)	
Conveyance facility				
Transport	56 (52.8)	50 (47.2)	106 (100)	0.0861
Walking	25 (39.1)	39 (60.9)	64 (100)	

BP: Blood pressure

participants who were prescribed medications twice a day or more, 28 (73.7%) than those with once a day prescription 61 (46.2%). Side effects to medications were observed only among 8 (4.7%) participants. Source of medications

for majority of the patients was private, 96 (56.5%). Good adherence was found to be significantly associated with free availability of medication, 49 (66.2%) in contrast to purchase of medication 32 (33.3%).

Table 5: Determinants for non-adherence to antihypertensive treatment

Determinants for non-adherence to treatment*	n (%)
Forgetfulness	84 (49.4)
Too many medications	41 (24.1)
No symptoms	54 (31.8)
High cost of treatment	33 (19.4)
BP is normal now	27 (15.9)
Non-availability of free medication	12 (7.1)
Health facility is too far	17 (10)
Side effects of treatment	6 (3.5)
Lifelong treatment	14 (8.2)
Others	22 (12.9)

*Multiple responses were obtained, BP: Blood pressure

Table 5 reveals the various determinants for non-adherence to antihypertensive treatment. Forgetfulness was observed to be the most common reason leading to non-adherence to medication in 84 (49.4%) participants. No symptoms perceived by the patients, 54 (31.8%) was another common reason for non-adherence to treatment followed by prescription of too many medications 41 (24.1%). Other common deterrents to hypertensive treatment as cited by the study participants were found to be high cost of treatment, 33 (19.4%); no need of treatment since BP is normal now, 27 (15.9%); non-availability of free medication 12 (7.1%); and lifelong treatment 14 (8.2%).

DISCUSSION

In this study, it was observed that 81 (47.6%) study participants had good medication adherence while 89 (52.4%) had poor adherence. Statistically significant association was observed between indulging in regular physical activity and use of salt-restricted diet and good level of treatment adherence. Poor adherence to treatment was found more commonly among patients who were prescribed multiple antihypertensive drugs and those with more than once daily dose formulation. Various determinants for non-adherence to antihypertensive treatment were forgetfulness (49.4%), asymptomatic nature of the disease (31.8%), polytherapy (24.1%), and high cost of treatment (19.4%).

In the present study, good adherence to antihypertensive medication was found to be 47.6% using the Morisky 8-item medication adherence scale. In a similar study done in Northern India, adherence was observed to be on a higher side, i.e., 57.2%, which could be probably due to the fact that it was a center-based study conducted in an urban area as opposed to the current study which was community based and in rural settings.^[18] In another study done in rural South India, adherence to medication was found to be only 24.1% using the Morisky 4-item self-report measure of medication-taking behavior scale.^[23] However, in other studies done across the

world, adherence to treatment was found to be ranging from 53.4% to 88.6%.^[24-27] Varied sociocultural factors including self-care practices across different developing and developed nations can be responsible for such difference in treatment adherence rates. There was no significant association found between age and sex with the level of treatment compliance which is in accordance with the results of other studies.^[27,28] In contrast to our findings, other studies have reported adherence to be higher among people above 60 years of age and females.^[23,29] In this study, good adherence was found to be associated with higher level of education and employment in a skilled occupation which may be due to better knowledge about the disease and its treatment. Similar results were obtained in a study done in Iran as well as in India.^[22,28] Some of the studies did not find any such association.^[18,23] In this study, patients indulging in regular physical activity and those practising salt-restricted diet had good compliance to therapy while alcohol and tobacco usage had no effect on adherence to treatment. This finding is in accordance with results from similar other studies.^[18,23,26] Lifestyle modification, in itself, is a part of non-pharmacological management of hypertension resulting in better control of BP levels. However, a systematic review found minimal role of lifestyle modification in treatment compliance.^[30] In our study, poor adherence was found among patients with uncontrolled BP, 73.5%, which is due to non-compliance to the prescribed medicines leading to uncontrolled BP, which in the long term, can result in complications. Similar findings were obtained in studies done in Malaysia and Canada.^[25,26] Poor adherence was also found among patients with duration of hypertension more than 5 years, which is in accordance with the results of the study done in Ontario.^[31] This could most probably be as a result of better patient and physician communication during the initial years of starting antihypertensive therapy leading to better treatment compliance. In contrast, findings of other studies done in India and Malaysia reported either a reverse association or no such association between duration of the disease and treatment compliance which could most probably be because of better knowledge of the disease and its lifelong therapy among the patients with hypertension of longer duration.^[18,25] Good adherence was observed in patients who were on monotherapy, 70.5%, than those on polytherapy, 29.5%, and also among those on once a day prescription, 53.8%, which is similar to the results obtained in various studies done all over the world.^[18,23,25,29] This suggests the importance of keeping the prescription of antihypertensive drugs and its dosing to a minimum to improve the treatment compliance. In another study done in North India regarding prescription practices for antihypertensive drugs, it was observed that monotherapy (81.7%) with calcium channel blockers was more common than combination therapy (34.8%).^[32] Free availability of medication was also an important determinant positively influencing the adherence level in our study as reported in even in another study.^[18,33] High cost of treatment is a hindrance to better treatment compliance owing to non-affordability by the patient. Various

determinants influencing the compliance of treatment which was identified in the current study were forgetfulness (49.4%), asymptomatic nature of the disease (31.8%) polytherapy (24.1%), and high cost of treatment (19.4%). Another study carried out in Kuwait found additional factors responsible for non-compliance as drug side effects, shortage of drugs, etc.^[27] A study conducted in UAE reported the use of traditional remedies for hypertension as an important determinant of non-adherence.^[29] A qualitative study done in Spain to determine the factors related to non-compliance identified complex web of factors, including patient-related as well as physician-related parameters implicated in non-compliance. The major factors identified were the patients lack of basic knowledge about the disease and a poor physician-patient interaction.^[34] These results reveal the importance of behavioral aspects of the management of hypertension and considering the lifelong nature of treatment, quality of the doctor-patient relationship is of utmost value. It also suggests that keeping the number of antihypertensive medications prescribed and its daily dose regimen to a minimum will go a long way in improving the compliance to treatment of hypertension.

The strengths of this study were being a community-based study, and it minimized selection bias to a great extent; as it was conducted in a rural area, it not only provided an insight into the level of treatment adherence in rural population but also identified crucial factors associated with non-compliance to therapy among this population. The limitation of the study was that sample size was not exhaustive and the study catered to only rural population and did not include the urban population.

CONCLUSION

The community-based cross-sectional descriptive study indicates that prevalence of treatment adherence among hypertensive patients was only 47.6%. The findings of the study provide an insight into the multidimensional issue of treatment adherence. The study has identified the crucial factors responsible for non-compliance to antihypertensive treatment and provides adequate evidence to the health-care policy makers as well as the treating physicians to formulate a comprehensive strategy to achieve adequate compliance, thereby reducing the morbidity and mortality associated with hypertension.

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