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Original Research Article

An observational study on patient compliance and adverse drug reactions of antihypertensives drugs in a tertiary care center of Bihar

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ABSTRACT

Introduction: Hypertension is among the most common non-communicable and lifestyle disease in our country that affects adult population of both the genders from all socio-economic backgrounds and urban and rural population. In spite of this, early diagnosis and appropriate treatment are suboptimal. Adherence of prescribed treatment has been studied in patients of hypertension in this study.

Materials and Methods: An observational and cross-sectional study was conducted in the Department of Pharmacology, Jawahar Lal Nehru Medical College and Hospital, Bhagalpur, Bihar. Prior to the initiation of the study, clearance was obtained from the Institutional Ethics Committee. Study period was between January 2021 and June 2021. A predesigned pretested interview schedule was used to collect the data from the 247 study participants. This schedule contained information related to socio-demographic variables, comorbidity, a format to assess the compliance to antihypertensive drugs prescribed and any adverse event.

Results: A significant improvement in maintain optimal in blood pressure was observed in patients treated with one pill per day as compared to patients prescribed with two and three pills per day. Compliance was significantly better in patients in combination therapy as compared to monotherapy.

Conclusion: Low dose combination therapy has been stated to be more effective than high dose monotherapy in controlling blood pressure. It shows better compliance and lesser incidence of side-effects.

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1. Introduction

Hypertension is a common cardiovascular disorder and the most important etiological factor for development of coronary artery disease. In 2002, the World Health Report stated that majority of cerebrovascular accidents and ischemic heart disease are attributable to suboptimal blood pressure levels.¹

There are many antihypertensive drugs available in the market, but in spite of this advancement, poorly controlled hypertension is still a major challenge in both developed and even more prevalent in developing countries.^{2,3}

This poor compliance to the drugs prescribed by the clinicians is an impending catastrophe for the ever-growing pool of non-communicable diseases viz. hypertension, heart disease, depression and others. Patients' noncompliance with treatment is a predominant reason for failing to control hypertension.⁴

A special case of non-compliance is the primary non-compliance, patients not redeeming their prescriptions.⁵ It has been quoted time and again that the frequency of doses has a pivotal role to play, single dose has been found to improve compliance but 24-hour antihypertensive activity of the drug is inevitable in maintaining the optimal range of blood pressure.⁶⁻⁸

Since the time immemorial, non-adherence or non-compliance on the part of the patient to the prescribed

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therapeutic regimen has been a challenge for the clinicians. To add the pool of knowledge, this study was proposed to investigate the adherence and persistence of antihypertensive drugs among patients as well as monitoring adverse drug reactions and its relation to compliance.

2. Materials and Methods

An observational cross-sectional study was conducted in the Department of Pharmacology, Jawahar Lal Nehru Medical College and Hospital, Bhagalpur, Bihar. Prior to the initiation of the study, clearance was obtained from the Institutional Ethics Committee.

A predesigned pretested interview schedule was used to collect the data from 247 study participants. The schedule contained information related to socio-demographic variables, comorbidity, a format to assess the compliance to antihypertensive drugs prescribed and any adverse event.

Patients from all age group who were diagnosed with hypertension at the time of current visit to the medical outpatient department or were known cases of hypertension were approached over a period of 6 months that was between January 2021 and June 2021. All such patients were explained about the purpose of the study and after obtaining duly signed written consent forms from them, they were included in the study.

Patients were asked to come for a follow up visit after 1 month, and then during follow-up visit patient's BP was measured as an average with 2 readings taken at 10 minutes interval with a standard mercury sphygmomanometer. Patients were made to complete a medication compliance card and were assessed according to pro-forma. The level of compliance was determined by the medical compliance card at the end of study and a patient was considered compliant with the study medication if at least 86 percent of the study medications had been applied/consumed according to prescribed regimen. The compliance was considered satisfactory when the mean compliance was more than or equal to 86 percent, which corresponded to taking medication for six or seven days per week on an average. Adverse reactions were divided into mild, moderate, or severe and assessed for date of onset, duration and action taken regarding study drug.

2.1. Statistical analysis

The recorded data was compiled and analyzed using Statistical Package for Social Sciences version 19 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages. Test applied for the analysis was chi-square test. P-value less than 0.05 was considered significant.

3. Results

Based on recruiting criteria, a total of 247 patients were included in the study. The mean age of the patients was 43.7 years with a standard deviation of 7.2 years. Out of 247 patients, 232 patients turned up on the given date of the follow-up visit. Almost one-third of the patients were male. Of all the patients, 162 patients were prescribed with one pill a day that comes to 7 pills a week, another 43 patients were prescribed with 2 pills per day that means 14 pills per week and rest 27 patients were given 3 or more pills per day or 21 pills per week. Patient was considered compliant on the basis of number of pills taken in a week. Among the various groups of patients, 6 out of 7 pills, 12 out of 14 pills and 18 out of 21 pills were considered satisfactory compliance. [Figure 1]

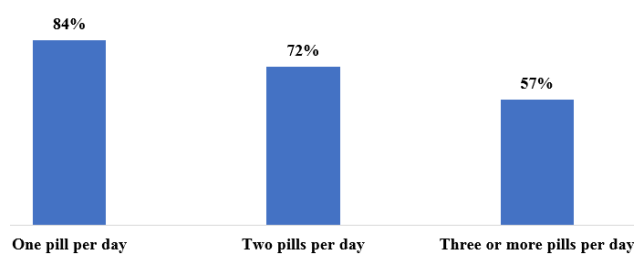


Fig. 1: Bar diagram showing compliance of patients in various groups of the patients

The mean blood pressure in the initial 247 patients was $162 \pm 28 / 106 \pm 12$ mm of Hg. Mean blood pressure at the follow-up visit at 1st month was $148 \pm 12 / 94 \pm 6$ mm of Hg. The mean difference in blood pressure before treatment and at follow-up was $14 \pm 6 / 12 \pm 4$ mm of Hg for participants who were compliant to the prescribed medications. Differences between complaint and non-complaint category were significant both for systolic and diastolic blood pressure measurements ($p < 0.05$).

Many adverse drug reactions were observed which included dry cough ($n=11$), which subsided in all patients except two who had to be shifted to losartan therapy, weakness ($n=15$), headache ($n=9$), mild dizziness ($n=17$), dryness of mouth ($n=15$) and one patient with ankle swelling [Table 1]. Low incidence of adverse drug reactions could be attributed to the use of low dose combinations instead of high dose monotherapy.

4. Discussion

The results of this study showed that overall, 73.7% of the participants were taking appropriate number of pills prescribed to them over a follow-up period of 1 month.

The lowest level of compliance was associated with patients taking three or more pills a day. This suggested that number of pills is directly proportional to compliance level. Percentage of drop outs from the therapy also increased with

Table 1: Distribution of incidence of various adverse events among the study participants consuming various antihypertensive agents according to number of pills prescribed per week and their compliance category

Event	Medication responsible	Incidence of adverse drug reaction					
		1 pill/week		2 pills/week		≥3pills/week	
		A	B	A	B	A	B
Dry cough	Enalapril, Losartan	3	2	2	1	2	1
Weakness	Atenolol, Thiazide	4	2	3	2	2	2
Headache	Amlodipine, Thiazide	3	1	1	0	2	2
Dizziness	Enalapril, Losartan, Amlodipine, Thiazide	5	3	3	1	3	2
Polyuria	Thiazide	5	1	1	0	2	1
Dry mouth	Atenolol	4	1	2	0	1	0
Ankle swelling	Amlodipine	1	0	0	0	0	0
Gastric irritation	Amlodipine & others	4	2	3	0	2	1

A: Complaint group, B: Non-complaint group

the increase in the number of pills per day. 15 patients did not turn up for follow-up at the end of 1 month period. Better response has been reported to the combination therapy as compared to monotherapy by some of the previous researchers.^{9,10} There has been emphasis given on the fact that compliance is better in patients taking simpler form of medication regimes than the complicated ones.^{11–13}

Blood pressure was found optimally reduced in significant number of study participants while the NHANES III survey found that optimal blood pressure control was only 23 percent in the American population.¹⁴ Satisfactory results for compliance were associated with a greater decrease in blood pressure as compared to poor compliance.^{15,16}

Patients on multiple therapy were more likely to develop adverse drug reaction as compared to patients on monotherapy.^{17,18} Dry cough was associated with enalapril and losartan while amlodipine and thiazide were associated with mild headache. Thiazide was also found associated with increased frequency of micturition in the patients. One patient on amlodipine therapy reported of ankle swelling. Mild severity of side effects could be attributed to low doses used in combination therapy.

5. Conclusion

Low dose combination therapy has shown more compliance and hence, more effectiveness. It has better tolerance among the patients than high dose monotherapy. Not only this, the incidence of adverse drug reactions was observed to be significantly lower with low dose combination therapy. The low level of compliance to antihypertensive medication found in this study is consistent with findings in other countries and studies in India. This calls for a nation-wide awareness program emphasizing the need of population wide primary prevention of elevated blood pressure and cardiovascular disease. Educational, legislative, and fiscal actions to encourage the switch to a healthier diet & lifestyle. Also to increase the facilities and opportunities for

physical activity at leisure need to be emphasized.

6. Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

7. Source of Funding

None.

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