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Original Article

Pharmacist involvement in the patient care improves outcome in hypertension patients

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ABSTRACT

Objective: The main objective of this study was to assess the effects of pharmaceutical care interventions in patients with essential hypertension in Lakshmi Pat Singhania Institute of Cardiology, Kanpur, India.

Methods: The study was carried out from July 2010 to August 2011. Pharmaceutical care was provided for 54 patients (intervention group) which was comprised of the patient education, the prescription assistance and the life style modifications and motivation for health. Then the clinical outcome as well as health related quality of life (HRQOL) were compared with the control group (48 patients) in which the pharmaceutical care was not provided. Furthermore, the effect of pharmaceutical care intervention on HRQOL was assessed using Short Form-36 (SF-36), a general health related quality of life questionnaire used to evaluate the QOL of patients. Blood pressure (BP) measurements and QOL survey was performed at baseline and at the follow-up session.

Findings: The difference between blood pressure readings from the baseline to the second follow-up was significant for systolic [(P = 0.0001), 12.24 mmHg] and diastolic BP [(P = 0.001), 5.17 mmHg] in the intervention group. The questionnaire used to evaluate the QOL of patients also showed improvement in the mean score for intervention group.

Conclusion: Results from our study showed that applying pharmaceutical care to hypertensive patients can help in the control of these patients' blood pressure, and consequently lower the risk that hypertension poses in cardiovascular disease. Successful implementation of pharmaceutical care has the potential to increase patients' satisfaction with their pharmacists' activities and may increase patients' expectations that pharmacists will work on their behalf to assist them with their healthcare needs.

Keywords: Hypertension; pharmaceutical care; pharmacist; quality of life

INTRODUCTION

According to Hepler and Strand, pharmaceutical care is defined as the responsible provision of the drug therapy for the purpose of achieving definite outcomes which improve the patient's quality of life (QOL). The International Pharmaceutical Federation (FIP), redefined pharmaceutical care as the responsible provision of the drug therapy for the purpose of "achieving definite outcomes that improve or maintain a patient's quality of life".[1] This new redefined practice of pharmaceutical care distinguishes it from previous pharmacist practice, i.e., dispensing of prescription. The key words are "responsible provision" and "definite outcome". Pharmaceutical services can improve the outcome and reduce the cost of the treatment. This can be achieved by preventing or detecting and resolving drug-related problems that can lead to the drug-related morbidity and mortality, both by increasing the effectiveness of the drug therapy and by avoiding adverse effects.[2] The risk of cardiovascular morbidity and mortality is directly correlated to blood pressure (BP). Starting at a BP of 115/75 mmHg, the risk of cardiovascular disease

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doubles with every 20/10 mmHg increase in BP.[3] It is estimated that the worldwide prevalence of hypertension will increase from 26.4% in 2000 to 29.2% in 2024.[3] Pharmaceutical care has been proposed as an intervention to increase the therapeutic compliance and to guide the treatment decisions.[4] With this regard, it has been shown that with appropriate health education and monitoring by the pharmacist, the patients can become experts in their usage of antihypertensive medications.[5,6]

QOL is multidimensional including physical, mental, and social functioning, as well as perceptions of general well-being. Nowadays, QOL can be measured objectively with validated, reliable questionnaires (instruments) possessing sufficient sensitivity to evaluate intervention.[7] The SF-36 is a self-administered generic quality-of-life questionnaire that consists of 36 items with one item used to measure the health transition and the remaining 35 items, which may be grouped into scales used to assess eight domains of QOL in the patient. These are: Physical functioning, role limitation due to physical health, role limitation due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. The SF-36 and its modified form which has been called RAND 36-Item Health Survey are used extensively.

The aim of this study was to evaluate the impact of a pharmaceutical care intervention on the clinical outcomes and QOL of the patients with hypertension.

METHODS

The study was conducted in the outpatient unit of the medicine department in Lakshmi Pat Singhania. Institute of Cardiology, Kanpur. The study was a randomized clinical trial [Figure 1]. Baseline (pre-test) data were collected from July till October 2010. A total of 142 patients were enrolled in the study. The hospital's database was screened for patients diagnosed as hypertensive and a database containing these patients' contact details was then constructed. Eligible patients were newly diagnosed hypertensives aged 20 to 75 years who could visit the medicine department on an outpatient basis for treatment and had an average diastolic BP (DBP) > 90 mmHg or an average systolic BP (SBP) > 140 mmHg with or without other co-morbidities. Patients were excluded from the study if they refused to sign the informed consent forms, or if they were unwilling or unable to return to the hospital for scheduled appointments. Enrolled patients were randomized via the block randomization method into two groups "control" (n = 70) and "intervention" (n = 72).

The pharmaceutical care intervention

Patients in the intervention group received pharmaceutical care including the written health education material (Hindi and English) which had been modified and validated by physicians, nurses and pharmacists. The pictograms in the leaflet were useful in educating patients about lifestyle modifications, the importance of adherence to diet and drug therapy, physical activity, yoga as well as smoking and alcohol cessation. In addition, patients were verbally counseled on the names of their antihypertensive medications, the respective indications, specific instructions on the administration of medication, adverse effects, and the importance of adherence to medication therapy. Physical activity or exercise performed by patients was assessed by interviewing the patients. Common adverse drug reactions (ADR) and drug interactions that may be encountered, ways to minimize them and action to be taken in the case of such side effects or interactions, were explained. Appropriate storage conditions, means to obtain follow on supplies of medication and action to be taken in the event of a missed dose were also made clear. All the points covered during the counseling were documented in the patient counseling documentation form, which was developed for this study. The BP readings were noted in the data collection form at baseline and again at the time of first and second follow-up. The control group did not receive any pharmaceutical care, and only the patient details were taken from the medical records and entered into the patient data collection form.

Patients were followed up either at the outpatient department (OPD) visit or at a domiciliary visit. The readings at follow-up were compared with the baseline reading. Potential problems which were viewed as important to the patient were also assessed discussed with physicians and documented. Drug-related problems were also assessed during the study and appropriate action was taken to correct these problems. The SF 36 questionnaire was self-administered although when necessary, questions were read to the study participants.

A patient information leaflet containing the information regarding the disease, symptoms, laboratory tests required, and lifestyle modifications to be made was prepared using the standard literature and distributed to the patients in the intervention group.

A baseline survey was carried out by surveying the medical records of the patient who were treated for hypertension in outpatient settings. This baseline survey helped to understand the challenges and problems that can occur in conducting the pharmaceutical care program for patients in the outpatient department.

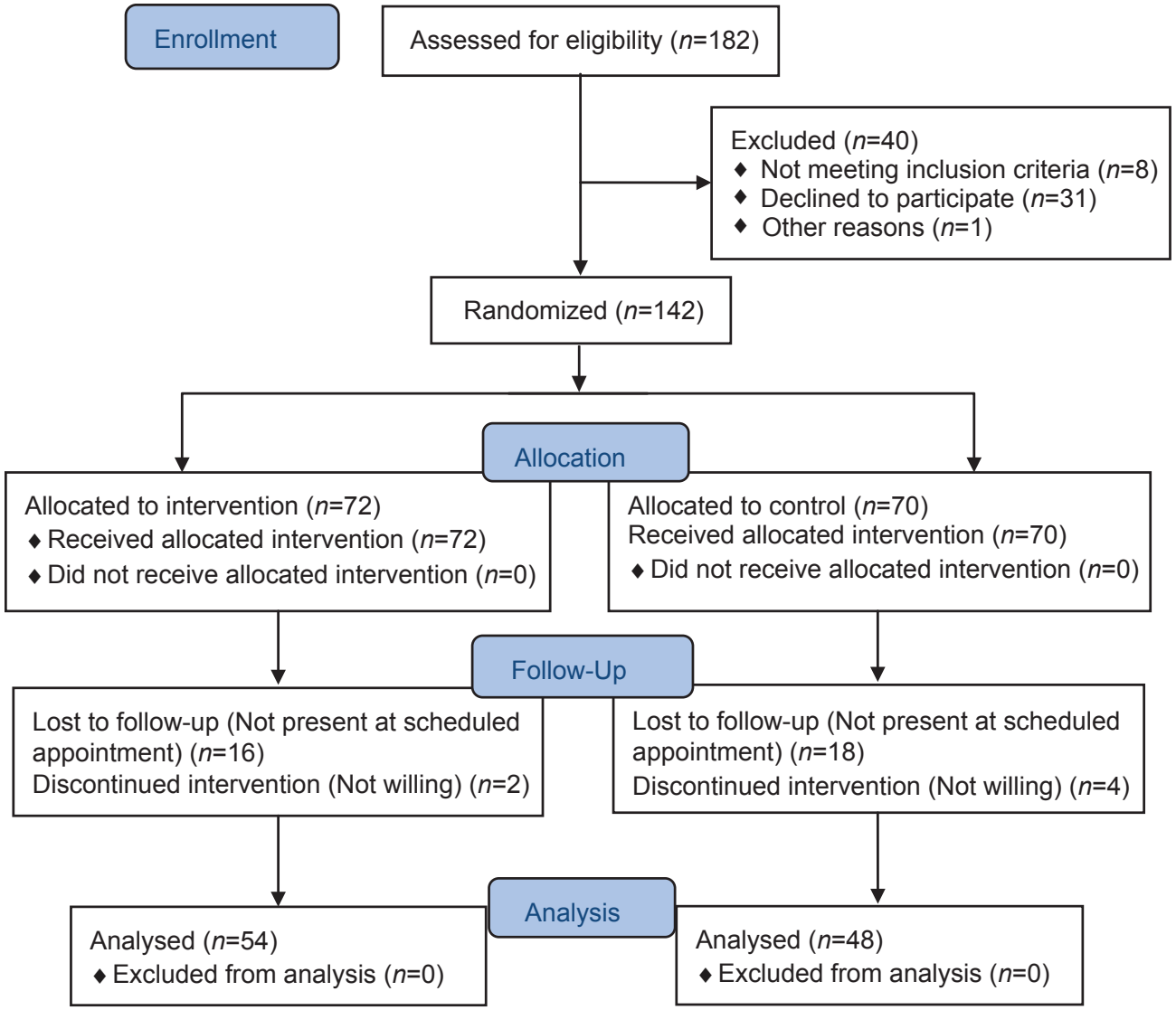

Figure 1: CONSORT diagram of the study

Data management and analysis

All the patient data was confidentially stored in the departmental computer, and it was entered manually in the excel sheets. The patients who completed all the follow ups scheduled every 3 months, were included in the analysis of results.

Statistical analysis was performed using Statistical Package for Social Sciences (version 16.0) software (SPSS; Chicago, Illinois, USA). We analyzed continuous data using Student *t* tests: Paired-sample tests for within-group analysis and independent-sample tests for between-group comparisons. Also, repeated measure ANOVA was applied to compare the BP readings of intervention and control groups at base line, first and second follow-up measurements. Categorical data were analyzed using *X*2. Significance was set at $P < 0.05$.

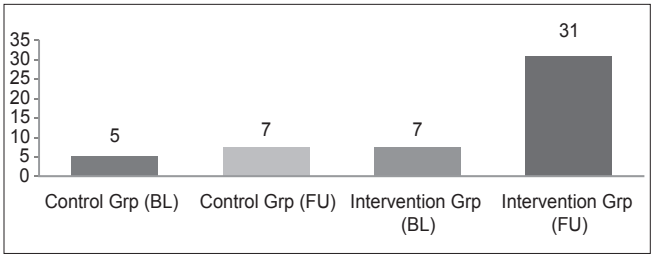

Figure 2: Number of patients performing regular physical exercise in both groups, Grp: Group; BL: Baseline; FU: Follow-up

RESULTS

Of the 142 patients enrolled, 102 patients completed the study. Demographic and clinical characteristics of these patients are presented in Table 1.

The number of patients performing regular physical exercise was more in the intervention group at the time of follow up [Figure 2].

Table 1: Demographic and baseline clinical characteristics of the studied patients

Variable	Control group	Treatment group
Number of patients	48	54
Age	60.62±8.32	59.50±8.55
Females	26	31
Males	22	23
Family history of hypertension	36	40
Comorbid conditions		
Hypertension alone	5	10
Hypertension and diabetes	19	22
Hypertension with any other illnesses	16	15
Hypertension with diabetes and any other illnesses	8	7
Smoking status	10	12
Alcoholic consumption	5	13

Data are presented as number of patients or Mean±SD, where applicable.

Table 2: Comparison of systolic and diastolic blood pressures at baseline and two follow-up visits

BP readings	Systolic BP* (mean±SD)		Diastolic BP* (mean±SD)	
	Intervention group (*N*=54)	Control group (*N*=48)	Intervention group (*N*=54)	Control group (*N*=48)
Baseline reading	163.20±11.64	157.89±9.78	93.42±7.53	90.56±6.68
First follow-up	147.46±10.00	146.31±9.88	89.05±6.31	87.47±6.11
Second follow-up	132.50±9.03	139.43±9.47	84.42±5.16	86.72±5.10
P value**	0.504	0.324	0.50	0.30

*mmHg, **Within-group analysis using repeated measure ANOVA, BP=Blood pressure, SD=Standard deviation

Among the various drug-related problems, the most common problem encountered was non-compliance to drug therapy. Out of 54 patients in the intervention group, 33 were prescribed single drug and 21 were prescribed a combination of drugs. The SDP and DBP readings of the patients were compared from baseline to the first and second follow-ups in Table 2.

Figures 3a and b shows the decline in mean blood pressure in both intervention and control groups. Point 1, 2 and 3 in the figures (3a and b) indicates BP readings at the baseline, first follow up and second follow up visits, respectively.

Repeated measure ANOVA was applied to compare the BP readings of intervention and control groups at base line, first and second follow-up measurements. There was a significant decrease in BP readings ($P < 0.001$) for both intervention and control groups from baseline to second follow-up visit.

Since there was significant decrease in both groups, an independent sample *t*-test was applied to assess the mean difference between the blood pressure readings from baseline to the second follow up. Student *t*-test for independent samples showed a significant difference ($P = 0.0001$) of 12.24 mmHg between variation of means of SBP in the intervention group at the end of the study and a significant difference ($P = 0.001$) of 5.17 mmHg in DBP.

QOL of patients in intervention group in which pharmaceutical care was provided showed a significant increase from baseline ($P < 0.0001$; $t = 6.957$) in comparison to the control group in which the increase in QOL was less ($P < 0.0001$; $t = 3.273$). The mean difference in QOL was greater for the intervention group when compared with the mean difference of the control group [Table 3].

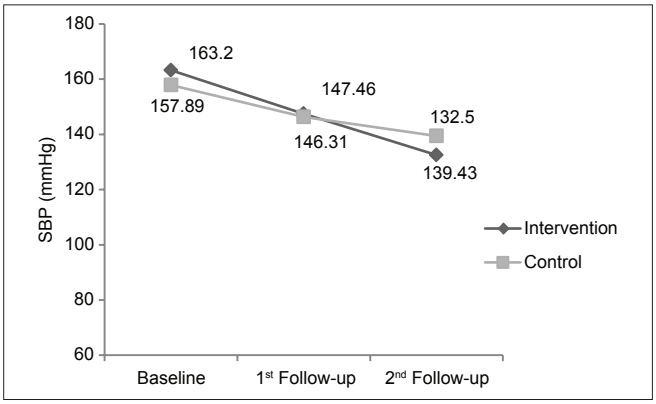

Figure 3a: Mean systolic blood pressure in the intervention and control groups in the baseline and two follow-up visits, SBP: Systolic blood pressure

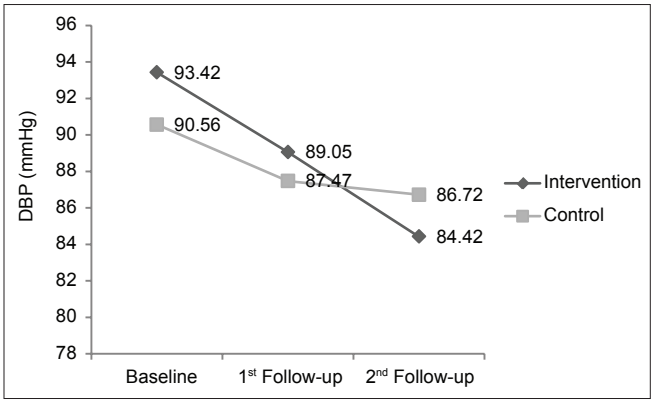

Figure 3b: Mean diastolic blood pressure in the intervention and control groups in the baseline and two follow-up visits, DBP: Diastolic blood pressure

Table 3: Mean scores for each health domains of SF-36 questionnaire for the assessment of quality of life for both groups

Health domain	Control group (mean score±SD)		Intervention group (mean score±SD)	
	Baseline	Follow up	Baseline	Follow up
Physical functioning	50.93±35	50.93±30.89	50.92±32.93	58.33±31.43
Role limitation due to physical health	59.37±49.2	62.5±48.53	62.03±48.64	73.61±44.17
Role limitation due to emotional problems	54.16±50	57.63±49.58	56.79±49.69	66.66±47.26
Energy/fatigue	28.64±13.19	39.16±20.34	27.68±12.73	48.98±16.89
Emotional well-being	68±15.39	69.83±15.08	68.29±16.43	74.59±16.50
Social functioning	68.22±19.01	70.31±18.24	71.06±19.07	80.78±17.95
Pain	60.26±13.57	63.28±13.58	62.17±12.81	72.17±14.58
General health	49.68±17.33	52.29±14.99	51.85±17.54	64.07±18.57
Change observed in health	54.16±14.88	56.25±13.14	55.55±15.09	62.03±12.60
Total score	54.82±11.89	58.02±9.87	56.26±12.73	66.80±9.68

SF-36=Short form-36, SD=Standard deviation

DISCUSSION

This study has shown that the clinical services provided by the research pharmacist to hypertensive patients were effective in improving treatment results. Sookaneknun *et al*., and Garcao *et al*., conducted a similar study, in which the services provided by the pharmacist were helpful in improving health outcomes.[8,9] The study conducted by Sookaneknun *et al*., showed that diabetes is the most common comorbidity that occurs in hypertensive patients, with 60% of patients having both diabetes and hypertension.[8] In our study, there were 28% of patients who dropped out and did not complete the study for reasons ranging from an improvement in disease symptoms, lack of cooperation, patient's lack of belief in any health-related added value in the study or patient moving out of the area. Most of the patients had a family history of hypertension. There was no significant difference between the classes of antihypertensive drugs prescribed to the patients in both the groups. Large randomized studies have demonstrated that most patients require two or more agents to control blood pressure; accordingly, the most recent hypertension guidelines recommend combination therapy as the first-line treatment, especially in patients with severe hypertension.[10] Despite these recommendations, nearly 58% patients in this study were receiving monotherapy. A similar trend was reported in France, where a general practice survey revealed that 58% of all hypertensive patients received monotherapy.[11] This study revealed that pharmaceutical care programs for hypertensive patients could produce a beneficial reduction in blood pressure and improve their health related QOL. Positive results were obtained in the various outcome measures. After pharmaceutical care implementation, more of the patients exercised frequently. Three patients stopped smoking and the patients also complied with alcohol moderation. Many of the patients became aware of salt restriction and they complied well with this restriction. A study conducted by Vollmer *et al*., has shown that systolic BP reductions of 2-8 mmHg can be achieved with restricting sodium intake to ≤2.4 g daily.[12] The Mean BMI of the patients in both the groups was in overweight category. The mean BMI for the intervention group decreased by 0.8 kg/m^2, while it increased by 0.5 kg/m^2 for the control group. A study conducted by Droyvold *et al*., suggested that being overweight and obesity increase the risk of elevated blood pressure and that people who increase their BMI are at increased risk for high blood pressure.[13] The primary outcome indicator, blood pressure control, was favorably influenced by the activities of the pharmacist. However, the number and type of antihypertensive agents prescribed did not change appreciably from baseline to the final assessment or in other words. There were no significant differences in the number of antihypertensive therapies prescribed per person. It may be concluded that the increased contact between patient and pharmacist contributed to increased awareness of the importance of drug therapy management (including compliance) as well as patient knowledge. Studies in various countries have demonstrated that the active involvement of a pharmacist on the health care team can improve the poor hypertension control and inadequate management of drug therapy.[14-18] Health-related quality of life (HRQOL) is considered as a viable patient outcome and an important measure of clinical or provider interventions.[19,20] In a study conducted by Kusek *et al*., mean SF-36 scores increased significantly (for most of the health dimensions used to assess the QOL) from baseline to the last follow-up

visit, due to control in blood pressure.[21] Successful implementation of pharmaceutical care has the potential to increase patients' satisfaction with their pharmacists' activities and may increase patients' expectations that pharmacists will work on their behalf to assist them with their health care needs. However, more high-quality studies are needed for a comprehensive quantitative assessment.

Determining specifically which pharmacist-implemented approach (non-pharmacologic measures versus the Drug related problems approach) led to reduction in BP was not within the scope of this study, but it is certainly an interesting topic for future research. Because of the short duration of the study and the fact that patients used various insurance companies or had no insurance coverage, it was not possible, with the resources available, to conduct an adequate cost analysis which could be an excellent topic for future research. An in-depth cost analysis should include not only the drug costs (either to the patient or the insurer), but also health resource use data such as number and cost of the clinical visits and hospitalizations related to the disease and its management, productivity assessment based on absenteeism from work or poor work performance due to a disease or its management, costs of monitoring therapy such as laboratory test and diagnostic assessments, and costs of complication. Some other issues of drug management including the number of doses taken daily, the impact of prescription cost on the patient's budget, and the patients self image are areas not directly measured by most available health-related QOL questionnaires. Indirectly, the SF 36 domains may detect changes such as decreased social contacts due to financial burdens placed on the patients by expensive antihypertensive agents. There likely is a need to develop a tool to assess directly the impact of the drug management on patient's lives.

AUTHORS' CONTRIBUTION

All authors contributed in the idea of research, design of study, data analysis and manuscript preparation.

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