



Study on effectiveness of pharmaceutical care on quality of life in hypertensive patients

Jisha B Krishnan^{1*}, KG Revikumar²

1. Research Scholar, Karpagam University, Coimbatore

2. Research Guide, Karpagam University, Coimbatore

Director, State Institute for Pharmacists Advanced Training and Research (SIPAT), Kerala.

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*Corresponding author:

Email : jishbk@gmail.com

ABSTRACT

Hypertension is reported to be the fourth contributor to premature death in developed countries and the seventh in developing countries. Pharmaceutical care can improve outcome, reduce cost of treatment and an effective approach in improving adherence to long term therapies. The aim of measuring quality of life is to provide information about well being of population and it has been a fundamental research topic in health, as its results are important to assess the effectiveness of health care. The objectives of the present study were to study the effect of pharmaceutical care on quality of life in hypertensive patients, to assess the adherence pattern among the hypertensive patients, to evaluate the outcome of patient education in hypertensive patients. A prospective study was carried out in a tertiary care multidisciplinary hospital for 15 months. The patients were grouped into 2 as intervention and usual care groups. Female patients were predominant and the mean age group was 51-60 years in both groups. Blood pressure and quality of life measured before implementation of pharmaceutical care and at the end served as main outcome measures. BP readings and quality of life scores were showed an improvement at the end of the study. The study confirmed improvement in medication adherence, which in turn has a positive impact on treatment outcomes and Quality of Life of hypertensive patients. The study emphasized the potential role of the pharmacist, as a patient educator, in the long term management of hypertensive patients.

INTRODUCTION

Hypertension is a global disease burden and an important health challenge due to the morbidity and mortality caused by cardiovascular diseases [1-2]. Hypertension is reported to be the fourth contributor to premature death in developed countries and the seventh in developing countries. Studies reported that nearly 1 billion adults (more than a quarter of the world's population) had hypertension in 2000, and this is predicted to increase to 1.56 billion by 2025. The prevalence rate of hypertension in India shows a significant increase almost compared to those in USA. The rate is higher in urban compare to rural population. With the current rate of hypertension, India will have the largest number of people with hypertension in the world, with the potential of becoming the 'Hypertension capital of world!' [3].

Hypertension may lead to various life threatening complications like, rapid and progressive end-organ damage,

particularly cerebrovascular, cardiovascular and renal damage; if not controlled. The management of hypertension depends not only on drug therapy but on several non-pharmacological approaches like life style modifications. Although, the effective medications and other non pharmacological therapies are available, the burden of hypertension and related complications are very high [4]. Hypertension clusters with smoking, obesity, dyslipidemia and diabetes mellitus. The presence of these metabolic risk factors correlates with uncontrolled blood pressure augments the cardiovascular risk in hypertensive patients. The probability of uncontrolled blood pressure significantly and independently increased with the increasing number of metabolic risk factors [5].

According to Hepler and Strand, Pharmaceutical care (PC) is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve the patient's Quality of life (QoL) [6]. Pharmaceutical care is a

process through which pharmacist can co-operate with the patient and other healthcare professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcome for the patients. Pharmaceutical care can improve outcome, reduce cost of treatment and an effective approach in improving adherence to long term therapies. Providing the patient education and information on diseases, administration of drugs, monitoring the adverse events are the essential part of pharmaceutical care, which improves the quality of life of the patients [7]. In the domain of physical health and illness, quality of life refers to participant's self-evaluation of health or on their perceived functional status and well-being. In chronic conditions such as hypertension and diabetes, health-related quality of life (HRQOL) is an especially important outcome, given their lifelong nature and the need for daily self-management [8]. The objective of measuring quality of life is to provide information about well being of population and it is important to assess the effectiveness of health care. The physical, emotional, and social impact of disease and treatments which is distinct from physiologic measures of disease can be assessed by HRQOL. The HRQOL of patients with hypertension may be influenced mainly by blood pressure, adverse effects of drugs or other factors, such as the labeling effect, or beliefs and attitudes about illness and treatment [9]. The objectives of the present study were to study the effect of pharmaceutical care on quality of life in hypertensive patients, to assess the adherence pattern among the hypertensive patients and to evaluate the clinical outcome.

MATERIALS AND METHODS

Study Design: A prospective study was carried out in a tertiary care multidisciplinary hospital for 15 months. Patients who were treated for hypertension of either sex, aged between 20-80 years with an average Diastolic Blood Pressure (DBP) >80mmHg or Systolic Blood Pressure (SBP) >140 mmHg with or without other co-morbidities were included in the study. Patients who refused to sign the informed consent form, patients who were unwilling or unable to return to the hospital for scheduled appointments, patients who had planned to move out from the area during the study period, pregnant and mentally impaired patients were excluded.

Materials used:

A suitably prepared consent form in English and Malayalam were used during the enrollment of the patients. A common patient profile form was prepared as per the need of study, to enter the patient data. A separate patient counseling documentation form was used for the study. Patient information leaflet (PIL) containing information on the disease, symptoms, complications and life style modification to be made was prepared using standard literatures and distributed to the patient belonging to the intervention group. SF-36 Health survey questionnaires was used to assess the Quality of Life which contains different domains like physical functioning, role limitation due to physical health, role limitation due to emotional problems, energy or fatigue, emotional well-being, social functioning, pain, general health and single item to assess the change in health status [10, 11]. A separate adherence form was used to assess the medication adherence.

METHOD

The study was carried out as per approved protocol by the institutional ethics committee (GL/01/05/536/09-10). The patients, who had satisfied the inclusion criteria, were enrolled in

the study. Informed consent was taken from all the patients before enrollment in the study. The patients were randomly divided into two groups as 'intervention' and 'usual care' using block randomization method. On the first day of hospital visit, the baseline BP readings were taken for both groups. The data of all patients were documented in the patient data collection form. The patient's quality of life was assessed using SF-36 Health survey questionnaire. The patient in the intervention group were provided with Pharmaceutical care, which involves provision of written health education material, oral counseling of patients. The oral counseling was provided about the names of the antihypertensive medications used by the patients and the indication of the medication, specific instructions are provided on medication administration, adverse effects, and the importance of the medication adherence.

The patient record was reviewed prior to counseling and the purpose of counseling was explained. Initial patient related information (family history, smoking habits etc) was obtained from the patient's record and also by interviewing them. Common ADRs and other drug related problems, methods to minimize them and action to be taken if such side effects occur were explained. Appropriate storage requirements and action to be taken in case of missed doses was also explained. All the points covered during the counseling were documented in the patient counseling documentation form. The BP readings are noted in the data collection form at the base line and again at the time of first (3rd month) and second follow up (6th month).

The usual care group continue to receive routine therapy provided by the present system. Patient details were collected from the medical records into the patient data collection form. Their QoL scores were assessed. The participants' state of improvement was followed up during first (3rd month) and second follow up (6th month). All the data were analyzed by using SPSS version 18.0. Descriptive analysis for the demography, BP reading and Wilcoxon method was used to compare baseline and follow-up quality of life scores in both the groups. *p* value <0.05 was considered as statistically significant.

RESULTS & DISCUSSION

A total of 210 patients were enrolled in the study of which, 106 patients were in the usual care group and 104 patients were in the interventional group. The female patients were predominant in both the groups. The female patients in usual care group were 54.7% and male patients were 45.3% where as in intervention group 60.6% were female and 39.4% were male. The patients were divided into 5 age groups such as 20-40, 41-50, 51-60, 61-70, and 71-80. In usual care group, the number of patients in the age groups 51-60 was higher than other groups (48.1%) and in the intervention group also the same age group was predominant (46.2%). These findings were similar to the study results by Erickson et al [9].

The patients were divided according to the educational status as secondary, higher secondary, graduates and post graduates. The majority of the patients in the study were graduates. The patients were divided into normal weight, over weight and obese. Majority of patients in both the groups were in normal weight category. The patients were divided according to their occupation as agriculturists, private employee, government employee, health professionals and unemployed. In both groups private employees were more than other groups.

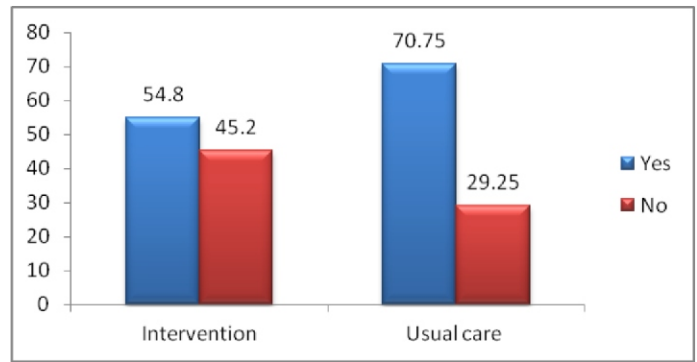
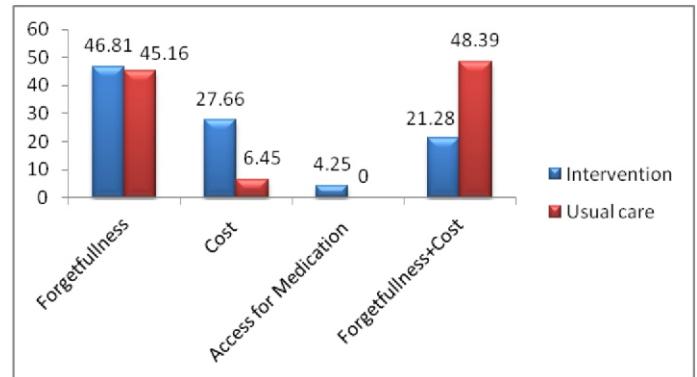
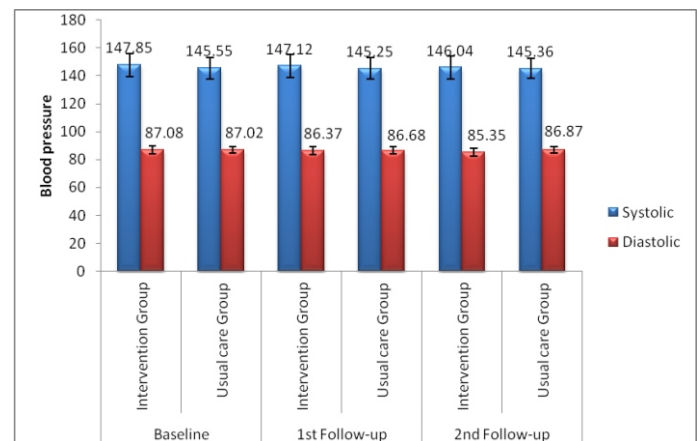
The duration of illness of the patients were divided into <1 year, 1-3 years, 3-5 years and 5-10 years. In both the groups

Table 1. Demography of Patients

Demography	Frequency (%)	
Gender	Intervention	Usual
Male	41 (39.4%)	48 (45.3%)
Female	63 (60.6%)	58 (54.7%)
Age group		
20-40	6 (5.8%)	6 (5.7%)
41-50	29 (27.9%)	30 (28.3%)
51-60	48 (46.2%)	51 (48.1%)
61-70	16 (15.4%)	19 (17.9%)
71-80	5 (4.8%)	0
BMI		
18.5-24.9	82 (78.8%)	76 (71.7%)
25-29.9	18 (17.3%)	25 (23.6%)
>30	4 (3.8%)	5 (4.7%)
Education		
SSLC	17 (16.3%)	8 (7.5%)
Plus two	36 (34.6%)	31 (29.2%)
Graduates	35 (33.7%)	47 (44.3%)
PG	16 (15.4%)	20 (18.9%)
Occupation		
Agriculturist	22 (21.2%)	23 (21.7%)
Private employee	29 (27.9%)	31 (29.2%)
Govt employee	19 (18.3%)	22 (20.8%)
Health professional	5 (4.8%)	14 (13.2%)
Unemployed	29 (27.9%)	16 (15.1%)
Duration		
<1yr	25 (24.0%)	14 (13.2%)
1- 3yr	31 (29.8%)	44 (41.5%)
3-5yrs	27 (26.0%)	40 (37.7%)
5-10	21 (20.2%)	8 (7.5%)
Co-morbidity		
DM	36 (34.6%)	43 (40.6%)
Cardiac	13 (12.5%)	16 (15.1%)
Renal	3 (2.9%)	7 (6.6%)
Nil	52 (50.0%)	40 (37.7)
Social history		
Smoking	16 (15.4%)	17 (16.0%)
Alcohol	11 (10.6%)	18 (17.0%)
Tobacco chewing	14 (13.5%)	13 (12.3%)
Smoking + Alcohol	4 (3.8%)	11 (10.4%)
Nil	59 (56.7%)	47 (44.3%)
Family History		
No	62 (59.6%)	55 (51.9%)
Yes	42 (40.4%)	51 (48.1%)

patients in the range of 1-3 years of duration of illness was higher than other groups. Family history of hypertension was present in patients of both groups. In usual care group 48.1% of the patients had family history of hypertension while in intervention group 40.4% of the patients had family history. Social habits like smoking, alcohol consumption, tobacco chewing was observed in patients of both groups. When the co-morbidities along with hypertension were observed, diabetes mellitus, cardiac disorders and renal disorders were noted, among which, diabetes mellitus was found to be prominent in both groups. (Table-1)

It was observed that 27.4% of the patients in the usual care group and 45.2% of the patients in the intervention group were non adherent to the therapy and the major reasons for non

**Fig. 1.** Adherence pattern**Fig. 2.** Reason for Non-adherence**Fig. 3.** Blood pressure reading

adherence were forgetfulness and cost. (Figure-1&2)

A slight reduction in BP reading was observed in the intervention group. In usual care group the systolic and diastolic BP reading at baseline was 145.55 ± 7.631 and 87.02 ± 2.457 , while in the final follow up it was 145.36 ± 7.373 and 86.87 ± 2.326 respectively. In intervention group the BP reading was 147.85 ± 8.224 and 87.08 ± 2.882 at baseline and 146.04 ± 8.248 and 85.35 ± 2.665 at the final follow up. Studies on hypertensive patients by De Souza et al., and Aguwa et al reported significant difference in BP reading in the intervention groups [12-13]. In the present study though the drop in BP in the intervention group is statistically significant, it was not clinically significant. (Fig.-3)

Table 2. Quality of life scores

Domains	Baseline		Follow-up	
	Intervention	Usual care	Intervention	Usual care
Physical Functioning	59.52 ± 19.614	56.08 ± 14.293	61.68 ± 18.858	56.75 ± 14.360
Role Limitation due to Physical Health	51.68 ± 25.425	46.46 ± 20.820	57.69 ± 29.162	46.93 ± 20.031
Role Limitation due to Emotional Problems	57.08 ± 20.790	49.64 ± 22.827	63.84 ± 22.954	51.84 ± 22.761
Energy/Fatigue	51.72 ± 16.311	49.58 ± 14.144	55.32 ± 16.217	50.94 ± 13.838
Emotional Well being	55.23 ± 16.441	51.06 ± 13.427	59.67 ± 15.694	52.91 ± 13.593
Social Functioning	55.17 ± 13.694	53.38 ± 15.684	59.33 ± 14.393	53.61 ± 15.545
Pain	61.89 ± 18.306	57.53 ± 17.049	63.34 ± 17.290	58.22 ± 16.477
General Health	51.59 ± 14.751	50.85 ± 12.353	54.66 ± 13.261	52.50 ± 12.483
Change in Health Status	41.35 ± 13.388	38.68 ± 12.503	47.12 ± 12.222	38.92 ± 12.479

The SF-36 Health survey scores of patients before and after intervention were compared using the Wilcoxon method, which found to be significantly higher in intervention group (p value <0.05) than the usual care groups. In some domains like role limitation due to physical health, social functioning and change in health status were not significant in usual care groups. These results were similar to the findings of other studies [2, 12, 14]. (Table-2)

CONCLUSION

There was a slight increase in the quality of life score and blood pressure control. The study confirmed that improvement in adherence to therapy which in turn has positive impact on treatment outcomes and Quality of Life of hypertensive patients. The study emphasized the potential role of the pharmacist, as a patient educator, in the long term management of hypertensive patients.

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