



Pharmaceutical Care Intervention among Saudi Hypertensive Patients in Hospital Outpatients' Clinic at Taif City.

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ABSTRACT

Control of blood pressure (BP) remains a worldwide major challenge for health authorities as well as in Saudi Arabia. Innovative interventions, as pharmaceutical care, to improve BP control are therefore needed. Objectives of this study were to provide pharmaceutical care intervention to Saudi hypertensive patients in outpatient cardiology clinic in hospital setting, and to assess the impact of the practice on patient outcomes: blood pressure control, knowledge of disease, and adherence to medications. The study was non-randomized, uncontrolled, before-and-after designed. The inclusion criteria were: age 18 years and above, currently taking an antihypertensive medication. One hundred thirty seven patients were conveniently chosen. The study was executed for four months. Trained intern students interviewed the patients at baseline and end of the study. The baseline intervention consisted of: patient-specific data and medication-review, education about disease, diet and lifestyle measures and measurement of blood pressure. Patients were followed monthly by telephone contacts. Descriptive statistics (frequencies, percentages, means & standard deviations), student t-test, and one-way ANOVA were used. Blood pressure values at the end of the study showed a significant decrease in the systolic and the diastolic values by-5.4 mmHg (P=0.001) and-2.7 mmHg (P=0.005), respectively. Rate of knowledge improved from 75% to 86% (P=0.00), and rate of adherence from 46% to 54.7% (P=0.001). Pharmacists' intervention, provided to the patients, resulted in improvement in blood pressure control, knowledge and adherence to medications. Policies should be made to facilitate implementation of pharmaceutical care in hospital setting.

Keywords: Pharmaceutical care, hypertension, pharmacist, Saudi Arabia.

INTRODUCTION

High blood pressure or hypertension is one of the dangerous chronic diseases, which develops silently, and finally may lead to risks to cardiovascular system. Globally hypertension accounts for 9.4 million deaths every year, and is responsible of at least 45% of deaths due to heart disease, and 51% of deaths due to stroke.¹

In Saudi Arabia the overall prevalence of hypertension among the population was 25.5%, and only 37% were controlled.² A situation which emphasizes the importance of developing proper programs for screening and education, in which the pharmacists should be an essential part.

Pharmaceutical care is considered as an important practice that contributed to the shift of pharmacy profession towards patient care. The practice is initiated in United States of America (USA), 1990, and later adopted by various pharmacy organizations as the future of pharmacy practice. Although in developed countries there is some implementation of this new practice, developing countries still lag behind. Pharmaceutical care is the responsible involvement of the pharmacist in management of drug therapy to improve patients' outcomes.³

Pharmaceutical care practice targets mainly the patient's drug-related needs which are appropriateness, safety,

effectiveness, and compliance of medications. Pharmacist should resolve drug related problems, related to these needs, and these are categorized as: unnecessary drug, need for additional drug, ineffective drug, too low dosage, too high dosage, and noncompliance. Pharmaceutical care practice is an individual face-to-face meeting with the patient which starts with assessment of the drug problems; developing of a care plan and follow-up evaluation.⁴

Pharmaceutical care application faced many barriers summarized in the following: time constraint for pharmacists, pharmacists limited clinical and therapeutic knowledge, fear of patients' rejection, lack of patient clinical information and understanding of pharmacist 'new role'.⁵ These barriers should be resolved by changing the pharmacy practice culture through: changes in education to be more patient focused; orientation to the community about the new role of the pharmacists, and involvement in team work with doctors and other health professionals.

Although pharmaceutical care practice started as a general practice, chronic diseases gained the real practical way for implementation of this new practice. Many documented pharmaceutical care studies are directed to: hypertension, diabetes, and hyperlipidemia.⁶⁻⁸ The role of the pharmacist in chronic diseases is expected to improve the quality of care, increase the awareness of the patients about their diseases, and



improve their knowledge about medications. The role of the pharmacist in this new practice should not be viewed as replacing the that of the physician; as the main focus of the pharmacist is the medication problems; a field in which the competent pharmacist should be an expert.

Many documented studies in literature elaborated the role of the pharmacist' intervention in improving the control of blood pressure, knowledge and adherence to medications.⁹⁻¹¹

In Gulf countries the concept of pharmaceutical care is not adopted as a part of the health system. The clinical pharmacy graduates are still not yet utilized properly. The traditional role of dispensing is mostly prominent.

In Saudi Arabia there is scarcity of studies of pharmaceutical care among hypertensive patients. The implication of the current study is expected to reveal problems that may possibly face the implementation of this new pharmacy practice and to build a pathway for its introduction to Saudi hospitals.

The prime aim of this study was to investigate the impact of the hospital-based pharmaceutical care intervention on the controls of blood pressure, disease knowledge, and adherence to medications.

MATERIALS AND METHODS

This study was an interventional, non-randomized, uncontrolled one, which was conducted in the Cardiology Outpatient Clinic, at King Faisal Hospital in Taif City, Kingdom of Saudi Arabia. Final year (internship students) performed the pharmaceutical care intervention (four male and three female students). The study was conducted during the period from September 13, 2015 to January 13, 2016. Convenient sample of 137 hypertensive patients were recruited consecutively, till the number was suitable for patients to attend their second usual care appointment (usually after four months) and before the end of the academic year for the Pharm D students.

Inclusion criteria

Adult patients (age ≥ 18 years) with controlled and uncontrolled hypertension, taking antihypertensive medications for more than six months, and who consent to participate in the study.

Outcomes Assessment

Outcomes assessed include: blood pressure control: the study employed the Joint National Commission version 8 (JNC8) guidelines criteria for evaluation, drug related problems, adherence to medications and knowledge about disease and medications

Data collection tools

The following documents were used in the pharmaceutical care interventions:

1-Dader Assessment and Pharmacotherapy follow-up forms: which were developed by Spanish Granada

Group.¹²The assessment form documents general data as gender, age, allergies and weight; health problems and their medications and the assessment according to necessity (N), efficacy (E) and safety(S). Patient 'clinical data as blood pressure measurement and laboratory results were also recorded. This form was used at the baseline meeting with the patient. Pharmacotherapy follow-up form consisted of identification of drug problem, action taken by the pharmacist to resolve the problem, the communication route with the physician, and whether this intervention was accepted or not. This form will be used whenever the patient meets the pharmacist after the baseline meeting.

2-Knowledge questionnaire: This was a modified questionnaire from literature.¹³ It was consisted of ten closed questions (Yes and No type). The questionnaire measures patient' knowledge about: blood pressure level, causes of the disease, ways of controlling blood pressure, consequences of untreated hypertension, drug therapy--- etc. Patients were considered knowledgeable if they obtained correct answers in 75% of the questions.

3-Morisky scale¹⁴ for measurement of patient 'adherence to their medications, which was consisted of four items assessing patients 'forgetfulness, carelessness about taking medications, stopping medication when feeling better and when feeling worse. The questions were of 'yes' and 'No' type. Scores ranging from 0 to 4. Non-adherence defined as score greater than zero.

4-Patient consent form: Telephone number was taken if the patient gave his/her consent.

5-Physician communication Form: which conveys the pharmacist recommendations to the doctor regarding drug problems discovered.

Pharmaceutical care intervention

A training session was provided for PharmD. students for three days in which they were briefed about the Joint National Committee document version-8(JNC8)¹⁵, the main drug related problems expected, and the procedure of documentation, measurement of blood pressure and communication with patients, doctors and nurses.

The study was pre-piloted in 10 hypertensive patients in a similar clinic, and some changes were done in the assessment format e.g. addition of education and smoking habits in Dader assessment form. After patient' consent, every patient was interviewed by the intern student before entering to the consultant or the specialist, in a separate room near to the physician. A nurse prepared patient's file and introduced the patient to the pharmaceutical care room. The interview took about 15-20 minutes.

The data were collected by face-to-face interview at the baseline of the study and after 4 months. At the baseline the following information were obtained from the patients and their medical files: demographic information, medication review, blood pressure (BP), and



weight, and this was documented in Dader format. The patient was interviewed for knowledge about disease and medications using knowledge questionnaire. Then adherence was investigated using Morisky scale. The pharmacist started educating the patients about the disease, adherence to medications, proper use of medications, diet, and lifestyle modification. The patient was given a leaflet, containing information in a simple language, about the diet, lifestyle measures, and also educated verbally. Blood pressure was measured using a calibrated blood pressure monitor (DINAMAP monitor). Two measurements were taken and the average was recorded. If therapeutic outcome was achieved for BP. The patient was assigned for follow-up. If not the pharmacist recorded the appropriate recommendations. Any recommendations regarding: modifying dose regimen or frequency, adding or changing any drug was communicated to the physician, and if the recommendations were to modify use of medication, lifestyle, adherence and compliance, the pharmacist started to give the proper advice directly to the patient. The patients were contacted monthly by the telephone for follow-up. During the telephone contacts education about disease – medications - lifestyle modification - adherence to medication were further stressed. Patients were advised to measure their blood pressure in the nearby primary health center. After 4 months the patients came (at their usual appointment in the clinic). Patients were interviewed about their Knowledge and adherence using the same questionnaires at baseline. Blood pressure was checked and recorded. Any new drug problem was recorded and recommendation conveyed directly to the physician.

Data analysis

Data were recorded in Microsoft Excel and after revision transferred to statistical package for social sciences (SPSS) version 21. Descriptive statistics was used (frequency, percentage, Means & Standard deviation) . For inferential statistics: t-test was used for differences between two groups (gender). And One Way Anova for more than two groups (Age, education). Significance was taken as P-value below 0.05.

The study was approved by the Ethical Committee of the Faculty of Pharmacy, Taif University and King Faisal Hospital Committee of Research and training.

RESULTS

Demographic profile and General information

Most of the participants were females (59.9%). The majority of the patients were in the age range of 46 to 60 years and above (91.2%). Those 60 years and above were (41.6%). About half of the participants were illiterates (51.1%), and 40.1% having primary and secondary education. The majority has no allergy towards medications (87.6%) and were not smokers (82.5%), 69.3% of them are using (1-4) medications, for hypertension and other comorbidities. Comorbidities are

various, of which diabetes alone (41.6%) and diabetes with other comorbidities (18.2%). These results are shown in Table-1.

Table 1: Demographic profile and general information.

Demographics	Frequency	Percent %
Sex		
Male	55	40.1
Female	82	59.9
Age		
18 – 25	2	1.5
26 – 35	2	1.5
36 – 45	8	5.8
46 – 55	37	27
56 – 60	31	22.6
+ 60	57	41.6
Education:		
No education	70	51.1
Primary education	38	27.7
Secondary education	17	12.4
Post-secondary education	12	8.8
Allergy:		
Yes	17	12.4
No	120	87.6
Smoking		
Yes	24	17.5
No	113	82.5
Number of drugs used:		
1 – 4 drugs	95	69.3
5 or > 5 drugs " poly pharmacy"	42	30.7
Associated disease:		
Diabetes Mellitus	57	41.6
Dyslipidemia	17	12.4
Ischemic heart disease	7	5.1
Atrial fibrillation	5	3.6
Hypothyroidism	3	2.2
Diabetes Mellitus& Ischemic heart disease	14	10.2
Diabetes Mellitus& Atrial fibrillation	5	3.6
Diabetes Mellitus& dyslipidemia	4	2.9
Diabetes Mellitus& hypothyroidism	2	1.5
Others	23	16.8
Total	137	100

Changes in Blood Pressure Measurement

The blood pressure values at the end of the study showed a significant improvement in the systolic and the diastolic blood pressure measurements. This is displayed in Table 2. There was a reduction of -5.4 mmHg and -2.7 mmHg in systolic and diastolic pressure, respectively (P=0.001 and



0.005).The rate of blood pressure control improved from 45.3% (62 patients) to 59.1% (81 patients) after the pharmacists intervention.

Table 2: Blood pressure measurement (Mean & Standard deviation)

Variable	At baseline : Mean ± SD	End of the Study : Mean ± SD
Systolic	145.56(±23.88)	140.13±22.35
Diastolic	78.35±13.51	75.62±9.68

Table 3: Knowledge of patient at baseline and end of the study

Question	Baseline of study Frequency (%)		End of study Frequency (%)	
	Yes	No	Yes	No
Q1: Do you Know your Blood pressure level?	47 (34.3%)	90 (65.7%)	91 (66.4%)	46 (33.6%)
Q2: Do you know normal blood pressure?	38 (27.7%)	99 (72.3%)	90 (65.7%)	47 (34.3%)
Q3: Do you know your weight?	63 (46%)	74(54%)	87 (63.5%)	50 (36.5%)
Q4: Do you know your Height?	29 (21.2%)	108 (78.8%)	62 (45.3%)	75 (54.7%)
Q5: How often should blood pressure is checked?	99 (72.3%)	38 (27.7%)	126 (92%)	11 (8.0%)
Q6: Do you know the causes of high blood pressure?	82 (59.9%)	55 (40.1%)	119(86.9%)	18 (13.1%)
Q7: Do you know the ways of controlling hypertension?	70 (51.1%)	67(48.9%)	119(86.9%)	18 (13.1%)
Q8 : Nature of disease				
a) Hypertension has no drug therapy?	85 (62%)	52 (38%)	77 (56.2%)	60(43.8%)
b) Therapy is life long?	95 (69.3%)	42 (30.7%)	114(83.2%)	23 (16.8%)
c) Blood pressure can rise without feeling it?	44 (32.1%)	93 (67.9%)	62 (45.3%)	75 (54.7%)
Q9: Do you know the complications of untreated hypertension?	71 (51.8%)	66 (48.2%)	120(87.6%)	17 (12.4%)
Q10: Do you know about drug therapy of hypertension?	96 (70.1%)	41 (29.9%)	111(81%)	26 (19.0%)

Adherence to Medications

Adherence to hypertensive medications was more evident in the end of the study compared to the baseline results (Table4).The rate of adherence improved from 46% at baseline to 54.7%at the end of the study (P<0.001).

Gender (P=0.565), age (P=0.658) and education (0.555) did not show significant differences with all adherence items.

Antihypertensive medications used

Table 5 shows the antihypertensive medications used by the patients. The trend of the prescribing was towards preference of combination therapy. The Angiotensin Converting Enzyme Inhibitors (ACEIs) were mostly used

Knowledge about disease and treatment

A comparison of the knowledge of the patients before and after the pharmacist intervention indicated improvement in the knowledge after the intervention. This illustrated in Table 3. The rate of knowledge changed from 75% to 86 % (P= 0.00).

Education (P=0.601), gender (P=0.637) and age (P=0.629) have no statistical difference with different knowledge parameters.

with all the combinations. These combinations consisted mainly of: diuretics, Calcium channel blockers and B-blockers.

DISCUSSION

The results of this study showed that pharmacists' intervention improved the blood pressure control in Saudi hypertensive patients. Knowledge and adherence of patients to their medication were also improved at the end of the study when compared to results at baseline. The difference in blood pressure was smaller compared to the status before the intervention due the fact that the patients recruited for the study were all under treatment with hypertensive agents, nevertheless, an improvement in blood pressure control was obtained. The systolic blood pressure which was



reduced from 145.56 mmHg to 140.13 mmHg was considered as a step towards more control, for patients 60 years and above in age (systolic blood pressure goal according to the JNC8 is below 150 mmHg). In the

current study 41.6% of patients were in this age range, and this could explain that they were most of the patients who benefited from the pharmacists' intervention.

Table 4: Adherence of patient to their hypertensive medications

Question	Baseline of study Frequency (%)		End of study Frequency (%)	
	Yes	No	Yes	No
Q1: Do you ever forget to take your medicine?	50 (36.5%)	87 (63.5%)	35 (25.5%)	102 (74.5%)
Q2: Are you careless at times about taking your medicine?	40 (29.2%)	97 (70.8%)	24 (17.5%)	113 (82.5%)
Q3: When you feel better, Do you sometimes stop taking your medicine?	30 (21.9%)	107 (78.1%)	19 (13.9%)	118 (86.1%)
Q4: Sometimes if you feel worse when you take the medicine, Do you stop taking it?	39(28.5%)	98 (71.5%)	28(20.4%)	109(79.6%)

Table 5: Anti-hypertensive medications used.

Medications	Frequency	Percentage
ACEI	16	11.7
ACEI +Diu +B.B	21	15.3
ACEI +Diu +CCB	15	10.9
ACEI+B.B	20	14.6
ACEI +Diu	9	6.6
B.B+CCB	14	10.2
Other(ARBs +vasodilators—etc)	42	30.7

ACEI=Angiotensin Converting Enzyme Inhibitors, Diu=Diuretics, B.B=Beta Blockers, CCB=Calcium Channel Blockers, ARBs=Angiotensin Receptor Blockers.

Drug Related Problems

Drug related problems were discovered mostly during the baseline interview with the patients. These problems almost cover all types of the drug problems' classification. The most frequently encountered were problems related to non-compliance (56.3%), need for additional drug (11.8%), and high dose (11.8%). These are categorized in Table 6.

Most of the studies in literature, investigating pharmacists' role in controlling blood pressure, were randomized controlled.¹⁶ A randomized controlled trial from Brazil¹⁷ attained, approximately, similar reduction in systolic and diastolic blood pressure values (-6.8/-2.9 mmHg), respectively. The current study differ in that adherence rate was lower (54.7%), and this may be explained by the fact that telephone contacts were used for the monthly follow-up, compared to the quarterly direct contacts in the mentioned study, and rate of knowledge (86%) was better, compared to the mentioned study, which showed no significant difference in knowledge between treatment and control groups.

Table 6: Drug related Problems.

Drug Problem	Frequency	Percentage (%)
Unnecessary drug	6	5
Need for additional drug	14	11.8
Ineffective drug	5	4.2
Low dose	8	6.7
High dose	14	11.8
Adverse reaction	5	4.2
Non-compliance	67	56.3

In the present study most of the drug related problems were discovered at the baseline interview, which was the same situation for a study from China⁹, and most of them were related to non-compliance, need for additional drug and high doses. The mentioned study reported the need for new hypertensive drug as the major problem faced by the pharmacists.

The pharmacists were able to discover many drug-related problems, and most of them were resolved directly with physicians. A high blood pressure is the primary signal of ineffective treatment, low dose or a



problem with adherence. The Adverse drug reaction which was noticed include as example: the decrease in the sinus rhythm to near or below 60 beats per minute with use of b-blockers.

Knowledge of the patients was improved at the end of the study and this could be explained by the following: the oral education in the end of the first interview, leaflet of information given to patients or caregivers, and the continuous monthly telephone contacts. Patients became more knowledgeable about: importance of weight and height measurement, frequency of checking BP, causes of high blood pressure, lifestyle measures and complications of untreated BP.

The current study resulted in improvement in adherence to medications. This is in agreement with other studies.^{18,19} Slight percentage of patient were noncompliant to medications and this affect the level of the control of blood pressure obtained (59.1%). This necessitates a well-planned pharmaceutical care program with strict follow-up system, since adherence needs continuous coaching.

In Saudi hospitals, with exception of few highly specialized ones in Riyadh city, pharmaceutical care is not part of the health system. Although there is some sort of clinical pharmacy practice, pharmaceutical care is not a routine practice in hospitals. With the trend of introduction of PharmD Programs in Saudi colleges of pharmacy²⁰, strategic planning for utilization of graduates should be devised. These graduates should focus on patient-oriented practice, rather than proceed with the traditional practice of medications' dispensing. Pharmacy policy makers should make real efforts to improve the role of the clinical pharmacists in hospitals.

Most of the patients in this study were having different comorbidities: Diabetes, dyslipidemia, and ischemic heart disease, this expected since they were patients chosen from the cardiology outpatient clinic, and 30.7% of them were taking five and above medications. This situation emphasizes the importance of the involvement of the clinical pharmacists in pharmaceutical care programs to resolve the many drug related problems which can occur due to the use of polypharmacy. The pharmaceutical care interventions should be extended for most of the chronic diseases which affect Saudi population.

The use of antihypertensive medications mostly followed the JNC8 guidelines: the focus is in the use of four antihypertensive classes: ACEIs, Angiotensin receptor blockers (ARBs), Calcium channel blockers (CCBs) or diuretics, but it was noticed that combination of ACEIs and ARBs is still prescribed (which is not recommended in these new guidelines), and doctors accepted the pharmacists' recommendation when communicated.

This study had some limitations. The study used a convenient sample. The pharmacy intern students, although trained for short period, were not experienced in detecting therapeutic problems. Most of the patients were reluctant to the monthly meeting in the clinic and were not familiar with this new type of practice. This led to changes in the plan of monthly meeting, to monthly contacts by telephone to assure adherence, lifestyle and healthy food measures, stress blood pressure measurement and to check medications use. The study was done at single site in Al-Taif city and may not be generalized for the situation in all Saudi Arabia hospitals.

Doctors and nurses showed a good understanding and cooperation during the study. A fact which gives importance to the team work in patient care, nevertheless physicians and nurses should be more oriented by pharmacy staff about this type of pharmacy practice. A satisfaction survey for doctors and nurses could have reflected more information about acceptance of this new practice.

The current study is considered one of the first studies in Saudi Arabia which targets hypertensive patients and the results of this study are expected to start the road for the implementation of pharmaceutical care in Saudi hospitals. It is a new practice which improves the type and quality of care provided to patients. Models of practice especially in management of chronic diseases should be investigated before routine practice comes to reality.

Saudi Arabia as well as other Gulf countries are envisaged to be the pioneers for implementation of pharmaceutical care in the developing countries, due the availability of suitable infrastructure, institutions and qualified PharmD graduates.

CONCLUSION

The findings of this study give evidence of the importance of the pharmacist in the patient' care team. The pharmaceutical care intervention, done by Saudi PharmD graduates improved blood pressure control, knowledge of the patients and medication adherence among Saudi hypertensive patients. Due to drug related morbidity high cost, health authorities should incorporate pharmaceutical care practice in the health system as a routine practice. Authorities should also encourage research projects in pharmaceutical care.

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