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EFFECT OF PHARMACIST DIRECTED COUNSELLING SERVICES ON KNOWLEDGE, ATTITUDE, AND PRACTICE (KAP) AND BLOOD PRESSURE CONTROL IN HYPERTENSIVE PATIENTS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT: Pharmacists play a vital role in providing counseling to the hypertensive patients to understand disease, risk factors, medications, and non-pharmacological measures required in controlling Blood Pressure (BP). This study aims to evaluate the impact of pharmacist delivered counseling services on KAP levels and control of BP in hypertensive patients. A prospective, open-labeled, randomized control trial was conducted among hypertensive patients attending medical outpatient department of Non-governmental Organization (NGO) Hospital located in rural settings in Anantapur district, Andhra Pradesh, India. The study was performed after getting ethical clearance from the Institutional Review Board with a registration number of RIPER/IRB/2018/038 and in accordance with ICH-GCP and CONSORT guidelines. The study was carried out for a period of one year from February 2018 to January 2019. The findings of the study reveal that there was a significant difference in the mean systolic and diastolic BP levels in intervention (138 ± 10.5, 82.3 ± 7.2) and control group (146.0 ± 8.2, 87.2 ± 5.4) at final follow-up visits. The mean percentage of knowledge, attitude, and practice towards hypertension management were significantly improved in the intervention group compared to control group. The study concludes that pharmacist is an integral part of the health care team to improve the health outcomes in hypertension. The study shows that patients had positive attitude levels regarding the management of hypertension. Due to lack of knowledge and awareness, the patients were under irrational practices. Finally, the pharmacist mediated counseling had significantly improved the KAP levels and BP control.

INTRODUCTION: Hypertension (HTN) is a chronic disorder that requires close monitoring and control of blood pressure (BP) to prevent cardiovascular disease, stroke and end-stage renal disease [1].

Globally, more than 1.39 billion (31% of all adults) people are affected by hypertension [2]. Recently in India, an epidemiological study conducted by Gupta VK, *et al.,* shown a prevalence of 27.1% [3].

There was a rapid rise in the prevalence of HTN among both urban and rural people in the country [4]. In India, 42-89% of HTN patients have uncontrolled BP [5]. The major reason for the uncontrolled HTN is medication non-adherence and lack of knowledge regarding medications, lifestyle changes and non-pharmacological measures available to control BP level [6].

Uncontrolled high blood pressure will increase the morbidity, mortality, and health care costs [7]. This gives an urgent requirement of educational activities to improve knowledge, medication adherence and BP control.

The pharmacist plays a vital role in providing counseling to the hypertensive patients to understand disease, risk factors, medications, and non-pharmacological measures required in controlling BP. Patient's Knowledge, Attitude, and Practices (KAP) towards hypertension management is a very important outcome measure used to check the effect of any educational intervention. This study aims to evaluate the impact of pharmacist delivered counseling on KAP levels and control of BP in the hypertensive patients from various regions of Anantapur district.

MATERIALS AND METHODS: A prospective, open-labeled, randomized control trial was conducted among hypertensive patients attending the medical outpatient department of Non-governmental Organization (NGO) Hospital located in rural settings in Anantapur district, Andhra Pradesh, India. The study was performed after getting ethical clearance from the Institutional Review Board with a registration number of RIPER/IRB/2018/038 and in accordance with ICH-GCP and CONSORT guidelines. The study was carried out for a period of one year from February 2018 to January 2019.

Study Criteria: All the patients aged more than or equal to 18 years, irrespective of the gender suffering from hypertension and having co-morbidities were recruited in the study. The patients who are not willing to participate and unable to respond to the Telugu/English version questionnaire were excluded from the study.

Sample Size Calculation: The number of participants included in the study was calculated by using Epi-Info software, by considering 5 mm of Hg of difference in systolic BP between intervention and control group, 80% power, and a 5% margin of error. After accounting 15% of dropouts (two-sided test) 200 (100 per group) number of participants are required.

Enrollment of the Subjects: A total of 1234 patients were eligible for the study after record screening, in which 634 subjects (un-willing = 380; No answer = 254) did not participate. Remaining 600 patients were called to the study site and screened for eligibility, in which 390 were excluded (Not meeting inclusion criteria = 210; absent or Cancellation = 180). Finally, 210 participants were randomized into test and control group by a simple randomization method. Verbal and written informed consent was obtained from the study participants after clear explanation about study objectives and outcomes. In test group 10 and in control group 8 participants were failed to attend follow-up visits. A total of 95 in the test group and 97 in the control group were subjected to analysis. The flowchart of the participants was shown in **Fig. 1**.
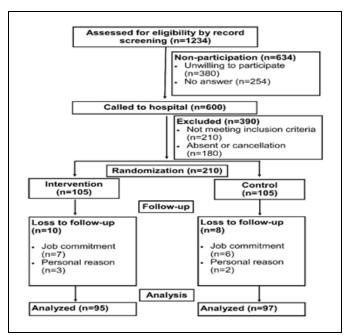

FIG. 1: FLOW CHART OF THE PARTICIPANTS

Data Collection: A suitably designed, pre-validated KAP questionnaire was used to collect the data from the study participants. The questionnaire comprises three parts. Part A collects information related to socio-demographic characteristics; Part B collects knowledge levels of patients concerning hypertension and its management strategies, Part C contains attitude and practices of patients in control of hypertension by using pharmacological and non-pharmacological measures.

A total of 14 questions were used in the questionnaire to obtain knowledge levels of study participants. Each question allotted '1' score for the

correct answer and '0' for a wrong answer. A maximum of 14 and a minimum of zero will obtained from each participant for knowledge domain. The knowledge score of each participant was translated into percentage by using a formula called, obtained score divided by the maximum expected score, multiplied with 100. According to bloom's cutoff criteria if a person scores 80% – 100%, considered as good knowledge, 60% - 70% scored, considered as moderate knowledge, and < 60%, considered as poor knowledge [8].

Attitude towards the management of hypertension was assessed by putting seven statements on 3 points Likert's scale, the statement on Likert's scale has positive and negative response ranges from agree 3, neither agree or nor disagree 2, and disagree 1. The maximum score expected was 21 and a minimum of 7. The attitude score of each participant was translated into percentage by using a formula called, obtained score divided by maximum expected score, multiplied with 100. If person scores ≥ 50%, considered as positive attitude and < 50%, considered as a negative attitude towards hypertension management.

Rational practice towards hypertension management was assessed by using eight questions. Each correct answer was given '1' score and wrong answer as '0'. The total score of practice question ranges between '8' and 'zero'. The obtained score of each participant was translated into a percentage by using a formula called obtained score divided by maximum expected score, multiplied with 100. If the person scores ≥ 80%, considered as rational practice and < 80%, considered as an irrational practice towards hypertension management.

Study Procedure: At the baseline socio-demographic characteristics like age, gender, marital status, educational status, occupation, comorbidities, BMI, and Blood pressure levels were collected from both test and control group. Patients in the test group were provided face to face counseling by the pharmacist. The counseling focused on hypertension definition, regular monitoring of BP and body weight, Dietary approach to stop hypertension (DASH) diet, physical exercise, stress management, salt restriction, lifestyle changes (Smoking and alcohol), and regular intake of medications as per physician instructions. The participants in the control group will follow the usual care given by the physician.

The complete study was divided into three visits: baseline, first follow-up visit (after three months), and second follow-up visit (after six months). At each visit KAP levels and BP was measured by using an electronic BP monitor. Finally, the impact of pharmacist mediated counseling on KAP levels and BP control was measured by comparing two groups at each follow-up visit.

Statistical Analysis: Epi-Info 7 for DOS version 3.5.1 software (Centers for Disease Control and Prevention, Clifton Road, Atlanta, USA) was used to analyze collected data from all study participants. The baseline demographic and clinical characteristics were represented as descriptive statistics like frequency, proportion, mean and standard deviation. Analytical statistics like chi-square and unpaired t-test were used to assess the significant effect of patient counseling on blood pressure and KAP percentage levels. A P value less than 0.05 was considered a statistically significant result.

RESULTS: The various socio-demographic characteristics like age, gender, marital status, educational qualification, occupation, lifestyle habits, co-morbid conditions, drug therapy, BMI, BP and KAP levels were equally distributed between intervention and control group. Most of the patient in both intervention and control group were belongs to male gender (79; 75.2% & 82; 78.1%), married (82; 78.1%, 59; 84.8%), no education (44; 41.9%, 49; 46.6%), private job (39; 37.1%, 35; 33.3%), both alcoholic and smoker (48; 45.7%, 45; 42.8%), no comorbidities (57; 54.3% & 60; 57.1%), and on anti-hypertensive medication therapy (92; 87.6% & 90; 85.7%). The baseline mean age, BMI, SBP, DBP, and KAP levels towards the management of hypertension was represented in **Table 1**.

The participant's correct responses towards knowledge, attitude, and practices inventories on hypertension management were high in the intervention group compared to the control group at final follow-up visits. The results were depicted in **Tables 2** and **3**.

TABLE 1: BASELINE SOCIO-DEMOGRAPHICS AND CLINICAL PROFILE OF STUDY PARTICIPANTS (n=210)

Variable	Intervention group (n=105) Frequency (%)	Control group (n=105) Frequency (%)	*P* value
Mean age (±SD)	43.7 ± 9.11	43.9 ± 8.26	0.872
Gender			
Male	79 (75.2)	82 (78.1)	0.624
Female	26 (24.7)	23 (21.9)	0.624
Marital status			
Single	14 (13.3)	11 (10.5)	0.523
Married	82 (78.1)	89 (84.8)	0.214
Others	9 (8.6)	5 (4.8)	0.268
Education			
No education	44 (41.9)	49 (46.6)	0.487
Primary school	31 (29.5)	28 (26.6)	0.645
High school	18 (17.1)	17 (16.2)	0.853
College/university	12 (11.4)	11 (10.5)	0.825
Occupation			
Farmer	35 (33.3)	38 (36.2)	0.664
House wife	13 (12.4)	11 (10.5)	0.664
Private job	39 (37.1)	35 (33.3)	0.563
Government job	8 (7.6)	7 (6.6)	0.789
Others	10 (9.5)	14 (13.3)	0.386
Life style habits			
Smoker	18 (45.7)	15 (14.3)	0.569
Alcoholic	12 (11.4)	14 (13.3)	0.675
Both	48 (45.7)	45 (42.8)	0.677
None	27 (25.7)	31 (29.5)	0.537
Co-morbidities			
Diabetes	23 (21.9)	20 (19.0)	0.608
Heart failure	11 (10.5)	14 (13.3)	0.523
AMI	6 (5.7)	4 (3.8)	0.517
Stroke	8 (7.6)	7 (6.6)	0.789
None	57 (54.3)	60 (57.1)	0.677
On anti-hypertensive medication	92 (87.6)	90 (85.7)	0.685
Mean no. of anti-hypertensive medications (±SD)	1.4 ± 0.5	1.5 ± 0.5	0.741
Mean BMI (kg/m^2) (±SD)	28.7 ± 3.7	28.6 ± 4.1	0.962
BP (mm of Hg)			
Systolic BP	147.6 ± 10.5	149.0 ± 9.6	0.464
Diastolic BP	89.3 ± 7.2	88.2 ± 6.4	0.783
Knowledge (±SD)	40.6 ± 16.2	42.4 ± 17.8	0.432
Attitude (±SD)	69.4 ± 11.2	69.0 ± 12.5	0.895
Practice (±SD)	58.7 ± 21.6	59.0 ± 22.2	0.726

SD: Standard Deviation, Intervention: Pharmacist-mediated counseling, Control: Care by physician, CAD: Coronary Artery Disease, COPD: Chronic Obstructive Pulmonary Disease

TABLE 2: KNOWLEDGE ABOUT HYPERTENSION AND ITS MANAGEMENT AMONG STUDY PARTICIPANTS AT FINAL FOLLOW-UP

Variable	Intervention group (n=95) Frequency (%)	Control group (n=97) Frequency (%)
Knowledge about the definition of hypertension	72 (75.8)	47 (48.4)
Knowledge about normal blood pressure level	70 (73.7)	34 (35.0)
Knowledge about common symptoms presented in hypertension	81 (85.3)	37 (38.1)
Knowledge about blood pressure can raise without any warning symptom	69 (72.6)	29 (29.9)
Knowledge about untreated hypertension may cause damage to the kidney, heart, brain, and eyes	90 (94.7)	57 (58.8)
Knowledge about hypertension is a lifelong disease	88 (92.6)	43 (44.3)
Knowledge about smoking is one of the major risk factors to develop hypertension	74 (77.9)	34 (35.0)

Knowledge about obesity is one of the major risk factors to develop hypertension	80 (84.2)	36 (37.1)
Knowledge about regular check-ups like blood pressure, blood glucose, BMI, lipid profile, and cardiovascular tests required in hypertensive patients	70 (73.7)	29 (29.9)
Knowledge about salt restriction will improve blood pressure control	79 (83.1)	61 (62.8)
Knowledge about stress is associated to increase blood pressure levels	82 (86.3)	53 (54.6)
Knowledge about regular exercise helps in control of blood pressure	68 (71.6)	43 (44.3)
Knowledge about DASH diet?	64 (67.4)	27 (27.8)
Knowledge about the importance of adherence towards anti-hypertensive medications	92 (96.8)	46 (47.4)

DASH = Dietary approach to stop hypertension

TABLE 3: ATTITUDE AND PRACTICE TOWARDS HYPERTENSION AND ITS MANAGEMENT AT FINAL FOLLOW-UP

Variable	Intervention group (n=95) Frequency (%)	Control group (n=97) Frequency (%)
Attitude		
Hypertension affects both rich and poor		
Agree	80 (84.2)	25 (25.7)
Neither agree or nor disagree	12 (12.6)	36 (37.1)
Disagree	3 (3.1)	36 (37.1)
Prolong rise in blood pressure may cause damage to brain, kidney, eye and heart		
Agree	76 (80.0)	38 (39.2)
Neither agree or nor disagree	12 (12.6)	25 (25.7)
Disagree	7 (7.4)	34 (35.0)
Moderate amount of drinking may allow in hypertensive patient		
Agree	68 (71.6)	33 (34.0)
Neither agree or nor disagree	24 (25.3)	32 (33.0)
Disagree	3 (3.1)	32 (33.0)
Quit smoking will help in the control of BP		
Agree	70 (73.7)	46 (47.4)
Neither agree or nor disagree	18 (18.9)	33 (34.0)
Disagree	7 (7.4)	18 (18.5)
DASH diet, regular exercise and stress management will reduce the risk of cardiovascular disease		
Agree	82 (86.3)	39 (40.2)
Neither agree or nor disagree	10 (10.5)	38 (39.2)
Disagree	3 (3.1)	20 (20.6)
Medication alone can't control blood pressure		
Agree	76 (80.0)	52 (53.6)
Neither agree or nor disagree	15 (15.8)	28 (28.8)
Disagree	4 (4.2)	17 (17.5)
Adherence towards medication, diet, and exercise play a vital role in control of BP		
Agree	67 (70.5)	40 (41.2)
Neither agree or nor disagree	22 (23.1)	36 (37.1)
Disagree	6 (6.3)	21 (21.6)
Practice		
How often do you check your BP		
Monthly once	68 (71.6)	35 (36.0)
1– 6 Months once	14 (14.7)	34 (35.0)
6 – 12 Months once	13 (13.7)	28 (28.9)
How often you will do brisk walking (Any exercise)		
Daily OR at least three times in a week	42 (44.2)	28 (28.9)
Weekly once	11 (11.6)	10 (10.3)
Monthly twice	2 (2.1)	6 (6.2)
No walking OR exercise	40 (42.1)	53 (54.6)
Are you taking diet as per your physician's advice?		

Yes	68 (71.6)	40 (41.2)
No	27 (28.4)	57 (58.7)
Do you add an extra amount of salt to your food		
Yes	24 (25.3)	35 (36.1)
No	71 (74.7)	62 (63.9)
Do you smoke cigarette/any nicotine-containing products		
Yes	15 (15.8)	45 (46.4)
No	80 (84.2)	52 (53.6)
Do you consume binge amount of alcohol on a regular basis		
Yes	3 (3.1)	32 (33.0)
No	92 (96.8)	65 (67.0)
Are you taking your medication as per your physician advice		
Yes	82 (86.3)	44 (45.4)
No	13 (13.7)	53 (54.6)
Have you ever missed your medicine in the last week		
Yes	17 (17.9)	41 (42.3)
No	78 (82.1)	56 (57.7)

At baseline most of the participants shown poor knowledge and irrational practice in practice in both and intervention (75; 78.9%, 83; 87.4%) and control groups (82; 84.5%, 86; 88.6%). The positive attitude levels were higher at baseline in both groups (85; 89.5%, 88; 90.7%). The study shows a significant improvement in the knowledge and practice levels at first and final follow-up visits with a *P*-value of less than 0.05. The results were presented in **Table 4**.

TABLE 4: ADEQUACY OF KNOWLEDGE, ATTITUDE, AND PRACTICE REGARDING HYPERTENSION AND ITS MANAGEMENT AT BASELINE AND FOLLOW-UP VISITS

Variable	Intervention group (n=95) Frequency (%)	Control group (n=97) Frequency (%)	Chi-square	*P*-value
Baseline				
Knowledge				
Good knowledge	6 (6.3)	3 (3.1)		
Moderate knowledge	14 (14.7)	12 (12.4)	1.078	0.299
Poor Knowledge	75 (78.9)	82 (84.5)		
Attitude				
Positive attitude	85 (89.5)	88 (90.7)	0.083	0.773
Negative attitude	10 (10.5)	9 (9.3)		
Practice				
Rational practice	12 (12.6)	11 (11.3)	0.075	0.783
Irrational practice	83 (87.4)	86 (88.6)		
First follow-up (After three months)				
Knowledge				
Good knowledge	44 (46.3)	6 (6.2)		
Moderate knowledge	23 (24.2)	20 (20.6)	32.63	<0.0001
Poor Knowledge	28 (29.5)	71 (73.2)		
Attitude				
Positive attitude	89 (93.7)	91 (93.8)	0.001	0.970
Negative attitude	6 (6.3)	6 (6.2)		
Practice				
Rational practice	35 (36.8)	16 (16.5)	10.13	0.001
Irrational practice	60 (63.1)	81 (83.5)		
Final follow-up (After six months)				
Knowledge				
Good knowledge	78 (82.1)	10 (10.3)		
Moderate knowledge	10 (10.5)	15 (15.5)	9.741	0.002
Poor Knowledge	7 (7.4)	72 (74.2)		
Attitude				
Positive attitude	92 (96.8)	86 (88.6)	4.728	0.029
Negative attitude	3 (3.1)	11 (11.3)		
Practice				
Rational practice	74 (77.9)	13 (13.4)	80.14	<0.0001
Irrational practice	21 (22.1)	84 (86.6)		

The findings of the study reveal that there was a significant difference in the mean systolic and diastolic BP levels in the intervention (138 ± 10.5, 82.3 ± 7.2) and the control group (146.0 ± 8.2, 87.2 ± 5.4) at final follow-up visits.

The mean percentage of knowledge, attitude, and practice towards hypertension management were significantly improved in the intervention group compared to the control group, as represented in **Table 5**.

TABLE 5: EFFECT OF PHARMACIST MEDICATED COUNSELING ON MEAN BLOOD PRESSURE AND KAP LEVELS AT FINAL FOLLOW-UP VISIT

Variable	Intervention (Mean ± SD)	Control (Mean ± SD)	*P*-value
Blood pressure (mm of Hg)			
Systolic	138 ± 10.5	146.0 ± 8.2	0.039
Diastolic	82.3 ± 7.2	87.2 ± 5.4	0.047
Knowledge	76.5 ± 12.9	43.8 ± 16.3	<0.0001
Attitude	75.3 ± 11.2	71.4 ± 13.6	0.004
Practice	81.5 ± 8.6	61.3 ± 20.1	<0.0001

SD; Standard Deviation

DISCUSSION: Pharmacist plays a significant role in providing patient counseling services to patients suffering from chronic disorders [9]. This study will generate evidence on role pharmacist mediated counseling in hypertension management. It is very difficult to control blood pressure with medication alone. So, a combination of non-pharmacological and pharmacological therapy will have a significant effect on blood pressure control in hypertension. The study findings reveal that there was a significant improvement in KAP and BP control in the intervention compared to the control group.

Most of the patients in the study were belongs to the male gender, which was similar to the study conducted in Guntur [10]. The mean age of the study was 43.7 ± 9.11 years in the intervention and 43.8 ± 8.26 in control groups. These findings slightly contrast with a study conducted by Ramanth KV *et al.*, where the majority of the persons belong to 50-70 years [11]. All the socio-demographic and clinical characteristics of the study participants were equally distributed between intervention and control groups.

Our study shows a significant improvement in knowledge and practice levels in the intervention group compared to the control group with a P value less than 0.05. Most of the patients in both intervention and control groups have a positive attitude towards the management of hypertension at baseline. Due to lack of knowledge, the patients are showing irrational practices towards hypertension management. Pharmacist mediated counseling regarding hypertension management in the intervention group had significantly improved their knowledge levels, which in turn improves the rational practice. Our study findings were slightly contrasted with the study conducted by Ramanth KV *et al.,* their study had shown a significant improvement in the KAP levels at first, second, and third follow-up visits. These findings support repetitive interventions will bring significant improvements in the KAP towards hypertension management [12, 13].

The study findings reveal that there was a significant reduction in the mean SBP and DBP in the intervention group (138 ± 10.5; 82.3 ± 7.2) compared to the control group (146.0 ± 8.2; 87.2 ± 5.4) at final follow-up visit with a P-value of 0.039 and 0.047. A similar type of significant improvement in BP was observed in various pharmacist mediated intervention studies [14-16].

Strengths and Limitations: The study was conducted in out-patient department of hospitals located in rural settings in Anantapur district. So, the findings were not extrapolated to in-patients and critically ill patients. The study highlights and synthesizes the evidence relating to pharmacist role in the management of hypertension. Extending and utilizing the clinical pharmacist services in the chronic disorder management will improve the economic, clinical and humanistic outcomes [17].

CONCLUSION: The study concludes that pharmacist mediated patient counseling services were significantly improved the patient's knowledge, attitude, and practice towards hypertension management. There was a significant reduction in both SBP and DBP levels in the

intervention group compared to control group. The study suggests future researchers incorporate the patient reporting outcomes like quality of life into the study to evaluate the effectiveness of pharmacist intervention.

CONFLICT OF INTEREST: Nil

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