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Effectiveness of an Interventional Program for the Management of Hypertension through Strengthening of the Health Care Delivery System: a Pilot Study

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ABSTRACT

Background: The aim of the study was to assess the effectiveness of an interventional program to improve hypertension management through strengthening of the health care delivery system.

Methods: A pilot study was conducted from February to December 2014 in two off-site Family Medicine clinics of the Aga Khan Hospital Karachi, Pakistan. Patients aged ≥ 40 years, with known hypertension were included. At the intervention site, Family Physicians were trained; individual and group education sessions were conducted for catchment population, while usual care was provided at the control site. Referral system between primary, secondary and tertiary levels of care was strengthened. Data was entered and analyzed in SPSS version 19. T-test for independent sample was used for comparison between intervention and control groups.

Results: 118 patients were recruited but 90 patients (44 intervention, 46 control group) were included in the final analysis. Mean age of patients in intervention group was 50.5 ± 8.7 years in comparison to 52.0 ± 8.3 years in the control group. A statistically significant mean difference was observed in systolic BP control in the intervention group (140.2 ± 14.6 mm Hg) after a follow-up of six months. There was a significant difference in the mean scores of satisfaction levels between intervention (3.9 ± 0.2) and control groups (3.7 ± 0.2 , $P=0.003$). Post intervention, 55% of patients in the intervention group and 39% in the control group were taking antihypertensive medications regularly.

Conclusion: Intervention at primary care level along with strengthening of the health care delivery system should be undertaken to better manage hypertension.

Key words: Hypertension, Primary Care, Family Physician, Health Care System

Introduction

Hypertension is an emerging public health challenge globally; with an increasing prevalence in developing countries.(1) Adverse impact of huge disease burden, arising from hypertensive patients in developing countries, is made worse because of weak health care delivery and lack of resources. Despite such adverse condition awareness, treatment and control of blood pressure among hypertensive patients is improving in these countries.(2, 3)

Pakistan is a developing country and 33% of the adult population suffers from hypertension.(4) This huge disease burden puts immense pressure on limited resources. A recent study has reported blood pressure control in accordance to guidelines, among 30.8% of hypertensive patients in Pakistan.(5) An earlier study has reported younger age and poor awareness about hypertension as factors that adversely affect adherence to antihypertensive medication and blood pressure control among hypertensive patients in Pakistan.(6)

Primary care is the frontline of a health care delivery system where patients are screened and managed for hypertension. It has been shown that strengthening of primary care can result in better blood pressure control among hypertensive patients.(7) It has been reported that training of General Practitioners in management of hypertensive patients results in better blood pressure control among patients in their clinical care.(8)

Limited evidence is available from Pakistan on effectiveness of intervention aimed at strengthening the primary care and health care system to effectively control hypertension. Based on this identified need, we conducted a trial on effectiveness of strengthening the primary care and health care delivery system to effectively control hypertension.

Methods

Study Settings:

A quasi-experimental study was conducted in two off-site "Integrated Medical Services" Family Medicine clinics, Aga Khan University Hospital Karachi, Pakistan, from February 2014 to December 2014. Integrated Medical Services (IMS) are community based health care facilities that offer Family Medicine services in addition to diagnostic support.

Patients:

Individuals aged 40 years or more, visiting the selected IMS centers with known hypertension or with consistently elevated BP on two separate visits (mean of last two of three measurements of systolic pressure ≥ 140 mmHg or mean diastolic pressure ≥ 90 mmHg) or already receiving treatment, were recruited in the study.

Those patients who require intensive care unit or coronary care unit admissions, or were diagnosed to have cognitive impairment, were agitated due to severe pain, non-resident of Karachi, or having language barrier were excluded from the study.

Intervention

Intervention arm:

Multiple interventions were used including training of family physicians, patient health education sessions and development of a referral system with secondary and tertiary levels of health care.

Training of Family Physician: Consultant Family Physicians conducted training sessions for Family Physicians regarding hypertension and they were given updated information for its management.

Patient Education Sessions: Patients in the intervention arm were provided with individual counseling during which the participants were given detailed information regarding their disease process, optimum blood pressure levels, lifestyle modification (exercise and diet) and importance of adherence to treatment. Participants were also given written brochures/pamphlets about hypertension management. The education session was conducted by a Research Medical Officer (RMO) who was trained for this task by a Consultant Physician. The Family Physician also provided customized education to patients according to their needs.

Initiating a Referral system (primary-secondary-tertiary) for hypertension management:

Primary care: Patients with uncomplicated hypertension were managed by the Family Physician at the IMS clinics. Those with complicated hypertension such as with target organ damage, CVD, CKD or needing more than 3 drugs were referred for secondary care.

Secondary care: Community Health Center, Aga Khan University Hospital served as the secondary care service provider. Patients with CVD, CKD or needing more than 3 drugs, not responding to treatment, or patients with secondary hypertension were referred to tertiary care level.

Tertiary care: Cardiologist at AKU managed secondary, resistant and difficult to treat hypertension. The patients were then referred back to the Family Physician at primary care level.

Control Arm: Standard Care: Patients coming to the control clinic of IMS were given usual hypertension care received at the IMS centers.

Outcome Ascertainment:

The primary outcome was to observe a difference of at least 20 points in the blood pressure levels among the intervention and control groups within 06 months of follow-up. The other secondary outcomes of this study were: adherence to life style modification (exercise, and medication) by the patients. Cost of hypertension treatment, this included: cost of medication (self-report by patient), cost of physician visit (clinic data), and cost of laboratory work. Patient Satisfaction to the care was inquired through PSQ-18. (9) It is a short form of the PSQ III which has

80 questions and includes seven dimensions of satisfaction that is general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with doctor, and accessibility and convenience.

Baseline Assessment: Baseline assessment included detailed history, physical examination, laboratory investigations and a care plan.

Follow up visits:

At 3 and 6 months: Patients in both arms were reassessed at 03 and 06 months intervals and outcome assessment was carried out. The study covered anthropometric measurements, blood pressure assessment and lab investigations. Adherence to medications and life style modification (diet, exercise) were evaluated through self-report and counting of empty medication blisters.

Questionnaire Development: The questionnaire was initially developed in English language and was then translated into local language and back translated in English. The consistency in the back translated questionnaire was checked by the principal investigator/co-investigators, and any discrepancies found were removed.

Ethical Consideration: The study was reviewed and approved by the Ethical Review Committee of Aga Khan University. The trial was also registered at clinical trial.gov (NCT02186067).

Written Informed Consent was obtained from all participants after explaining to them about the study protocol. All study personnel were trained in procedures for maintaining patient confidentiality. No personal identifiers were used in any report or publication arising from this study.

Statistical Analysis:

Sample Size: The study was designed to enroll 90 patients (45 patients in each group). This number of patients would provide the study with the ability to detect a 20 percent difference among groups (treatment and control) in six months with a power of 80%. The proportion in the treatment group is assumed to be 0.60. The sample size was calculated using NCSS PASS.

Analysis: Data was entered and analyzed in SPSS version 19. For continuous variables (e.g. SBP, DBP) means with standard deviations (SDs) were reported. For dichotomous data, we calculated proportions. Independent t-test was used to identify the difference in mean BP level among intervention and control groups. Chi-square test was applied to observe effect of intervention on exercise habits and medication adherence. Items within each scale of PSQ 18 are averaged after scoring. These scale scores represent the average for all items in the scale that were answered. High scores on PSQ 18 reflect satisfaction with medical care. Intention to treat analysis was carried out for all participants.

Results

A total of 126 (intervention: 62, control: 64) patients were recruited at baseline, out of which 90 patients (44 intervention group, 46 control group) completed the study protocol and were included in the final analysis. The overall attrition rate was 29% in the control group and 19% in the intervention group (Figure 1 - next page).

The mean age of the participants in the intervention group was 50.5+ 8.7 years and 52.0 +8.3 years in the control group. The socio demographic characteristics of study participants are given in Table 1 (page 7). Both the study groups had preponderance of female participants (intervention: 61.4% v/s control: 69.6%). About 11% of the participants in the intervention group and 8.7% in the control group were unable to read or write. Over 80% of the participants in both the groups had family history of hypertension. Both the study groups were similar in terms of the demographic characteristics such as age, gender, educational status etc.

A statistically significant mean difference of 17.35 mm Hg was observed in systolic BP of intervention (140.2 + 14.6 mm Hg) and control group (157.6 + 17.5) after a follow-up of 06 months (Table 2 - page 8). Likewise a 7 point difference was observed in diastolic BP (intervention: 86.0 + 6.6). Changes in blood markers of blood pressure control at six months follow-up are presented in Table 2.

Satisfaction with services was assessed through PSQ-18 scale which has seven dimensions. There was a significant difference in the mean scores of satisfaction levels between intervention (3.9 + 0.2) and control groups (3.7 + 0.2) with a P-value of 0.003 (Table 3) .

The average monthly cost of hypertension treatment was PKR.653 + 376 among the intervention and PKR.753 + 817 in the control group. This difference however, was not statistically significant (P=0.45).

The majority (54.6%) of the patients in the intervention group were taking antihypertensive medications regularly, in comparison to 39.2% of the patients in the control group (P=0.001). About 50% of the participants in the intervention group started some level of exercise (at least thrice a week for 30 minutes) after the intervention (Table 3 - page 9).

Figure 1: Flow of Study participants

Table 1 : Descriptive Characteristics of Intervention and Control Groups

Characteristics	Intervention (n=44)	Control (n=46)	*P-value
Age	50.5 ± 8.7	52.0 ± 8.35	0.34
Gender			0.41
Female	27 (61.4)	32 (69.6)	
Male	17 (38.6)	14 (30.4)	
Marital Status			0.75
Married	39 (88.6)	39 (84.8)	
Widowed	5 (11.4)	7 (15.2)	
Educational Status			0.77
Can't read or write	5 (11.4)	4 (8.7)	
Up to primary	3 (6.8)	6 (13.0)	
Secondary to Intermediate	18 (40.9)	19 (41.3)	
Graduate or above	18 (40.9)	17 (37.0)	
Current Occupation			0.82
Employed	13 (29.5)	12 (26.1)	
House Wives	25 (56.8)	29 (63.0)	
Unemployed	6 (13.6)	5 (10.9)	
Comorbid			0.81
None	24 (54.5)	22 (47.8)	
1 comorbid	16 (36.4)	19 (41.3)	
More than 1 comorbid	4 (4.1)	5 (10.9)	
Family History of Hypertension			0.85
Yes	37 (84.1)	38 (82.6)	
No	7 (15.9)	8 (17.4)	
Family History of DM			0.21
Yes	22 (50.0)	29 (63.0)	
No	22 (50.0)	17 (37.0)	
Family History of CVD			0.39
Yes	19 (43.2)	24 (52.2)	
No	25 (56.8)	22 (47.8)	
Ever Smoked			0.45
Yes	6 (13.6)	4 (8.7)	
No	38 (86.4)	42 (91.3)	
Currently Smoking			0.94
Yes	5 (11.4)	5 (10.9)	
No	39 (88.6)	41 (89.1)	

*P value=chi square P value, significance kept at ≤ 0.05

Table 2: Intervention and Control Groups at baseline and six months follow-up

Blood Pressure Changes				
	Intervention Mean $\pm$ SD	Control Mean $\pm$ SD	Mean Difference	P-Value*
Baseline				
Systolic BP	160.6 $\pm$ 10.2	160.5 $\pm$ 16.4	0.1	0.96
Diastolic BP	95.2 $\pm$ 8.6	95.4 $\pm$ 7.8	0.2	0.90
Follow-up				
Systolic BP	140.2 $\pm$ 14.6	157.6 $\pm$ 17.5	17.3	<0.001
Diastolic BP	86.0 $\pm$ 6.6	93.7 $\pm$ 5.6	7.6	0.01
Changes in Cardio Vascular risk factors				
Total Cholesterol				
Baseline	178.8 $\pm$ 30.9	183.7 $\pm$ 40.0	4.8	0.52
Follow-up	151.6 $\pm$ 31.4	169.7 $\pm$ 43.0	18.4	0.02
Triglycerides				
Baseline	158.5 $\pm$ 55.4	150.4 $\pm$ 41.1	8.0	0.43
Follow-up	122.3 $\pm$ 38.9	143.3 $\pm$ 46.6	17.9	0.04
HDL				
Baseline	54.9 $\pm$ 5.7	54.6 $\pm$ 4.5	0.3	0.78
Follow-up	45.3 $\pm$ 8.2	51.3 $\pm$ 46.0	6.0	0.03
LDL				
Baseline	104.9 $\pm$ 29.8	105 $\pm$ 33.3	0.3	0.73
Follow-up	100.2 $\pm$ 30.4	101.9 $\pm$ 33.6	1.7	0.32
FBS				
Baseline	130.9 $\pm$ 43.9	130.0 $\pm$ 40.8	0.9	0.92
Follow-up	97.5 $\pm$ 17.2	115.1 $\pm$ 3.87	17.6	0.02
BMI				
Baseline	25.2 $\pm$ 2.8	26.7 $\pm$ 2.8	1.5	0.55
Follow-up	22.4 $\pm$ 2.8	26.0 $\pm$ 4.2	4.6	0.02

*P value=Two independent T-test P value, significance kept at ≤ 0.05

Table 3: Participant's Satisfaction and Changes in life style of study participants (n=90)

Dimensions/Variables	Intervention		Control	*P-value
Technical quality	3.9 (0.7)		3.8 (0.5)	0.50
Interpersonal manner	3.8 (0.4)		3.7 (0.4)	0.39
Communication (doctor-patient)	4.0 (0.3)		3.7 (0.5)	0.02
Financial aspects	4.0 (0.5)		3.9 (0.5)	0.38
Time spent for patient	3.6 (0.7)		3.4 (0.6)	0.42
Convenience	3.9 (0.8)		3.5 (0.7)	0.005
Accessibility	3.9 (0.4)		3.9(0.3)	0.65
Overall satisfaction	3.9 (0.2)		3.7 (0.2)	0.003

	Intervention N=44		Control N=46	
	Baseline	Follow-up	Baseline	Follow-up
Exercise				
At least three times a week	10 (22.7)	22 (50)	11 (24.1)	14 (30.4)
No	34 (77.3)	22 (50)	35 (76.0)	32 (69.5)
P-Value	0.023		0.62	
Adherence to anti-hypertensive medications				
Adherent	16 (36.3)	24 (54.6)	14 (30.4)	18 (39.2)
Non-Adherent	28 (63.7)	20 (45.4)	32 (69.6)	28 (60.8)
P-Value	0.04		0.49	
Change in diet				
Some changes	10 (22.7)	21 (47.7)	9 (19.5)	12 (26.0)
No change	34 (77.3)	23 (52.3)	37 (80.5)	34 (73.9)
P-Value	0.06		0.32	

*P- Value for difference in satisfaction dimensions by intervention & control group based on independent-T-test

*P value=chi square P value, significance kept at < 0.05

Discussion

The primary aim of this study was to evaluate the effectiveness of strengthening the health care delivery system in general and primary care in particular to control epidemic of hypertension. The program included patient group education sessions regarding hypertension and training of Family Physicians along with strengthening of health care delivery system at primary, secondary and tertiary levels. This study has found a favorable impact on lowering Blood Pressure and can therefore be implemented on a larger scale. This is consistent with several similar intervention programs conducted in various countries on varied populations.(10-13)

In this study, lifestyle changes including dietary modification and physical exercise, along with medication adherence, responded favorably to the intervention. In the study, the mean reduction in Systolic Blood Pressure (SBP) at six months follow-up was 17.3 mmHg. The findings are consistent with numerous studies where in community based/behavioral intervention had achieved a difference of 15-20 points in the SBP.(14-19)

This study strengthened the referral system in which the hypertensive patients are managed in primary care settings, and referred to secondary and tertiary care settings if the patients are more challenging or develop complications. In this study, none of the patients were referred to secondary or tertiary care settings. This is most likely because, the Family Physicians were better trained to manage non-complicated cases. Besides that, it can also be due to the fact that patients didn't have hypertension for a longer duration of time so the chances of developing the complications were less; hence they were effectively managed at the primary care level. An additional reason could be small sample size.

In this study, Family Physicians were trained based on latest guidelines to manage hypertension. The group education sessions provided patients with latest information on lifestyle modifications. It is evident that regular visits of patients allow doctors to monitor patients closely and the physicians can encourage self-care among patients, and it can help in better treatment adherence and reduction in blood pressure.(17, 20)

Repeated reminder calls for medication adherence and life style modifications have yielded the desired results observed at six months interval. Regular contact with physicians increases patients comfort level with doctors. This is consistent with our study wherein patients in the intervention group had higher satisfaction scores than control.

It is reported that weight loss leads to blood pressure reduction on a long term basis.(21) In the current study; there was a significant improvement in Body Mass Index (BMI) levels post intervention. This adds to the favorable impact of weight management in the current study on blood pressure control.

Lack of adherence to medications is the common cause for uncontrolled hypertension. Prevalence of non-adherence to hypertensive medication is demonstrated to be a significant for lack of control of blood pressure. (22) This study demonstrates positive impact of intervention that improves adherence to treatment with resultant favorable outcome on blood pressure control.

Significant results were observed in this study, however, the findings of this study should be interpreted cautiously as it was conducted in two study clinics located at a reasonable distance to one another and with less attrition rates observed as compared to other community based intervention trials. Moreover, the lack of blinding of patients and assessor could have resulted in more impact of intervention; as the patients in the intervention arm have received the best possible treatment. Moreover, the follow-up period of this study was only six months so we were unable to determine the long-term sustainability of BP and effect of the interventions on cardiovascular outcomes. Despite these limitations, there is evidence emerging from this pilot study that intervention at primary care level along with strengthening of the health care system results in better blood pressure control among patients with hypertension.

Conclusion

Hypertension can be effectively managed in the primary care setting through interventions even in developing countries with weak primary health care structure. Such intervention at primary care level along with strengthening of the health care system should be undertaken to better manage hypertension.

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