



Effect of an Intervention Program on Blood Pressure and Compliance to Antihypertensive Regimens among Patients attending Family Health Center-Cairo

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ABSTRACT: Hypertension affects billion individuals' worldwide. Health education programs for hypertensive patients are to control hypertension by diet, exercises, avoid risk factors, and improving compliance to medical and life style modifications. The aim of the paper is to develop and implement an intervention program for hypertensive patients to improve compliance to anti-hypertensive regimens and control blood pressure. Two arms study design (Randomized Clinical Trial). Carried on 280 hypertensive patients (plus 15% to compensate for drop outs) recorded in the family medical centers attached to Ministry Of Health. There was significant difference in intervention group as regards clinical data before and after intervention. (P value $<.001$). Mean of SBP and DBP decreased from 134/83 to 130/81 and from 133/82 to 132/82 in control group, which reflect the effect of the intervention program. There was highly significant difference between both groups as regards mean score of compliance to treatment (P value < 0.05), but improved greater in intervention group (53.19 ± 7.26) compared to (50.05 ± 9.16) in control group. There were significant increases in hypertension-related knowledge scores in both groups. However, it was significantly greater in the intervention group (increased from 15.98 ± 4.99 to 19.88 ± 2.31) and (increased from 16.58 ± 5.73 to 19.04 ± 3.56) in the control group. The implementation of the program leads to improvement of the patients' knowledge, adherence to the anti-hypertensive medications, and controlled blood pressure.

Key words: Hypertension, Intervention educational and practical program, Prospective two arms clinical trial.

INTRODUCTION:

Hypertension is a major health problem and a leading cause of mortality and morbidity worldwide (Ogedegbe et al.,

2013). It is the most important modifiable risk factor for heart diseases, stroke, renal diseases and retinopathy (Bani I.A., 2011). Hypertension is rarely accompanied by symptoms, and its



identification is usually through screening, or when seeking healthcare for an unrelated problem, but some symptoms that may occur are headache, heaviness of the head and sluggish movement (*Emtiazy M. et al., 2014*). The global age-standardized prevalence of hypertension was 25.9% in adults aged ≥ 20 years in 2000. From 2000 to 2010, there was an increase in hypertension prevalence of 5.2% over 10 years (*Katherine T.Mills, 2016*). Globally, the overall prevalence of raised blood pressure in adults aged 25 and over was around 40% in 2008 (*WHO, 2008*). In 2014, approximately one billion adults have hypertension (*Lancet, 2012*). Hypertension affects about 77.9 million (1 out of every 3) persons in United States (*American Heart Association, 2013*). Europe has a high prevalence of hypertension 44.2% with highest prevalence in Germany and this is 60% higher than the prevalence in North America (*Wolf/Maier K., 2003*). The World Health Organization reported that the prevalence of hypertension in the African region was highest globally in 2008, with an estimated prevalence of 46% (*WHO, 2011*). The prevalence of hypertension is high in the Middle East. Which is attributed to several factors including sedentary lifestyle, dietary habits, and social stress. Low levels of physical activity and increased frequency of overweight are predisposing risk factors for hypertension. Hypertension is confirmed to be a major health problem in Egypt with a prevalence rate of 30% (*El-Zanaty F. and Way A., 2009*), with highest prevalence in Cairo, Ismailia, Alexandria, Menya, Menoufia and Luxor governorates and Cairo have the highest prevalence (31.0%). (*Hasan D.M. et al., 2014*), it has increased dramatically as the drug cost of

hypertension (total antihypertensive market) during the year 2007 was 600 million Egyptian pounds increased to more than one billion in year 2011 (*Ibrahim MM., 2013*). There are ample reviews showing that adherence among patients suffering from chronic diseases is about 50% in the developed countries and the magnitude of this problem is greater in developing countries. The burden of chronic disease grows worldwide, it is expected to exceed 65% in 2020, (*Chaudri NA., 2004*). In Egypt a low rate of drug compliance was found in elderly patients (28.1%) and middle-aged group (36.2%) while it was (51.8%) among younger group of patients (*Mohamed EE. and Barakat A.M.E., 2010*). The main factor and the cornerstone in family medicine is the good doctor patient relationship that improved adherence to regimens either drugs regimen or life style modifications. Aim of the work: To assess the knowledge of hypertension and compliance to antihypertensive regimens among hypertensive patients attending El-Shrouk Family Medical Centers before and after implementation of an intervention program. To develop and implement an intervention program for hypertensive patients to improve compliance to anti-hypertensive regimens, to control blood pressure and to evaluate the effect of the intervention program on the blood pressure of those patients.

Materials and Methods:

An interventional two arms study design was used (Randomized Clinical Trial). Carried out at outpatient clinics of the El-Shrouk health centers in Cairo that belong to Ministry of Health. The study subjects comprised 280 hypertensive patients plus 15% to overcome drop outs



recorded in EL-Shrouk health centers. The patients had been selected according to the following criteria: having primary hypertension, hypertension diagnosed for at least one year and taking their prescribed medications, aged 25-60 years old, able to communicate. The sample size was calculated assuming a rate of compliance to antihypertensive ranging between 74% - 85% in control group, and study groups (Al-Wehedy A. et al., 2014). The subjects were divided into two groups; the intervention group (161) patients recorded in (El-mostakabal center), they received the intervention educational and practical program and the control group (161) patients recorded in (60 meter center) received only the educational program.

Ethical consideration: The study protocol was approved from the Research Committee, faculty of medicine, Ain Shams University. Approval to carry out the study was obtained from the ministry of health. Informed consent was obtained from participants in both groups before conducting the study. All participants had the right not to participate in the study or to withdraw prior to its completion and confidentiality was ensured.

Study Tools and data collection: Data were collected using three tools:

1- Tool I: Socio-demographic and clinical data sheet: It was developed by the researcher in simple Arabic language and consisted of two parts: Part I: Socio-demographic characteristic of the study sample such as age, sex, marital status, level of education, income, Part II: Physiological measurements which include: measurement of blood pressure, calculation of the body mass index, waist

hip ratio, and lipid profile, urea-creatinine ratio.

2- Tool II: Hypertension knowledge an interview questionnaire: Derived from WHO questionnaire implemented in Ghana in 2011 and had been translated by the researcher into Arabic language and a pilot study was done for its validation on 10% of the sample size. the questionnaire assessed the baseline knowledge of patients about the disease and identified patients learning needs before applying the program includes questions about importance of taking medications, regularity of taking medications, complications of the disease, role of the healthy life style behaviors as diet and exercise and reduction of risk factors in controlling hypertension (Karen PA. et al., 2011).

3- Tool III: Assessment of Compliance to anti-hypertensive regimens questionnaire An interview questionnaire that included two parts **a- Drug compliance assessment:** the was questionnaire derived from the Hill Bone High Blood Pressure Compliance scale and a research study developed in Muhimbili University of Health and Allied Science, it had been translated by the researcher into Arabic language and a pilot study was done for its validation also on 10% of the sample size. **b - Life style modification assessment -Risk factors assessment:** the questionnaire was derived from WHO steps Arabic questionnaires for hypertension and a study by Ashraf N. in Egypt it included questions about; Duration of the disease, Family history, Physical inactivity, Body Mass Index, Smoking (particularly cigarettes), Stressful life, high salt diet (Joint National Committee, 2003). - **Nutritional assessment:** the questionnaire was derived from WHO



steps for hypertension questionnaires and Ain-Shams new cardiology center questionnaire; both were in Arabic language and included questions about; Daily Number of meals, Daily salt intake, weekly and monthly intake of fruits and vegetables, Type of fat intake, Intake of preservative food, daily intake of tea and coffee, Number of weekly meals not prepared at home (*WHO, 2015*), (*The Academy of nutrition and dietetics, 2013*). -*Physical activity assessment*: the questionnaire was derived from WHO steps for hypertension questionnaires and included questions about; Type of work (hard, average), Does it affect heart rate, How long does it consume (in hours and days), Does he/she walk regularly or ride a bike, For how long, How long does he/she stay relaxed (in hours), Does he/she attend any kind of simple exercise regularly at least 10 minutes.

: The study included three phases: 1- *Assessment phase*: Each hypertensive patient in both groups this was interviewed individually before applying the planned program to collect the baseline patient's data using all study tools (I, II, and III); this interview took about 20-25 minutes for each patient. 2- *Implementation phase*: An intervention program had been implemented in the form of group discussion in about 30-45 minutes to the patients in the waiting area after dividing them into small homogenous groups, in each group there were 15 patients share the same social class, it included two parts educational and practical parts. The educational part aimed to improve patient's knowledge and attitude towards hypertension and its treatment, and was given to patients in both groups. The intervention program part was included in the booklet and explained personally by the researcher to

each patient in the intervention group only, the physical exercise program which was 20-40 minutes treadmill walk three days per week for six months duration, and also the dietary program which was followed for six months with tables included items of breakfast, lunch and dinner, and a list of the allowed and forbidden food; it was written and demonstrated in pictures to help those had difficulty in reading. The practical part contained two parts; appropriate Diet Program and appropriate Physical Exercise Program. 3- *Evaluation phase*: Immediately after implementation of the intervention program, each patient of this group had been interviewed to evaluate his/her knowledge using tool II (hypertension knowledge questionnaire), and repeat the questionnaire after three months, and at 6 months, add Tool I part (B) (physiological measurements), and Tool III (assessment of compliance to antihypertensive regimens questionnaires).

STATISTICAL ANALYSIS: Analysis of data was done using SPSS (Statistical Package for Social Science) version 24. Quantitative data were presented as mean and standard deviation. Qualitative data were presented as frequency and percentage. Student- t test was used to compare quantitative data between two groups and Paired t test was used to compare quantitative data before and after intervention for the same group. Chi-Square test was used to compare qualitative data between two groups. McNemar and Marginal homogeneity tests were used to compare qualitative data before and after intervention for the same group. P value < 0.05 was considered statistically significant (*IBM corp., 2016*).



RESULTS AND DISSCUSSIN:

Hypertension is a major health problem and the goal of its treatment is to prevent complications by achieving and maintaining the blood pressure at 140\90 mm hg or lower (*Lambert EV. Et al., 2006*), Through Lifestyle modifications and pharmacotherapy both are called antihypertensive

regimen (*Lemone and Burke, 2008*). Compliance to this regimen is the corner stone of treatment but it is difficult as both patient and health care provider affect it, and a positive physician-patient relationship is the most important factor in improving compliance (*WHO, 2003*).

Table (1): Comparison between the two studied groups regarding demographic data

		Intervention group		Control group (N=150)		T	P value
		Mean	SD	Mean	SD		
Age (years)		50.72	8.23	49.98	8.75	0.75	0.45
		N	%	N	%	χ^2	P value
Sex	Male	83	54.6%	85	56.7%	0.13	0.72
	Female	69	45.4%	65	43.3%		
Marital status	Single	7	4.6%	6	4.0%	1.87	0.60
	Widow	14	9.2%	9	6.0%		
	Divorced	15	9.9%	20	13.3%		
	Married	116	76.3%	115	76.7%		
Job	Don't work	12	7.8%	15	10.0%	1.41	0.92
	Skilled Work	42	27.6%	40	26.7%		
	Employee	42	27.6%	44	29.3%		
	Others	7	4.6%	4	2.7%		
	Seasonal	16	10.5%	17	11.3%		
	Housewife	33	21.7%	30	20.0%		
Education	Illiterate	6	3.9%	7	4.7%	0.39	0.1
	Read and Write	11	7.2%	10	6.7%		
	Primary	12	7.9%	14	9.3%		
	Preparatory	9	5.9%	8	5.3%		
	Secondary	38	25.0%	36	24.0%		
	University	76	50.0%	75	50.0%		
Salary/ month	<1000 LE	20	13.2%	22	14.7%	0.29	0.87
	1000-2000 LE	41	27.0%	37	24.7%		
	>2000	91	59.9%	91	60.7%		

Regarding demographic data of intervention and control groups as age

(mean age was 50.7+8.2 and 49.8+8.7 respectively), and this agrees with



(Vasan RS. *Et al.*, 2002) where 1298 participants from the Framingham Heart Study who were aged 55 to 65 years undergo community-based prospective cohort study to estimate the residual lifetime risk for hypertension in older US adults, because blood pressure tends to rise as one gets older, according to gender (men were more than women in both

groups) and this goes with the WHO studies. But our results were inconsistent with the majority of studies where there were high percentage of females probably because the effect of postmenopausal hormones deficiency and some risk factors as obesity, stressful situation which have more influence on females rather than males.

Table (2): Comparison between clinical data before and after intervention (6 months duration) in the intervention group.

	Intervention Group				t*	P value
	Before intervention		After intervention			
	Mean	SD	Mean	SD		
SBP	134.41	16.40	130.33	12.13	5.16	<0.001
DBP	83.62	9.08	81.81	5.74	2.86	0.01
BMI	26.93	3.27	27.82	18.15	0.61	0.54
waist to hip ratio	0.82	0.09	0.81	0.09	6.82	<0.001
Cholesterol level	201.97	66.23	192.25	59.83	7.40	<0.001
LDL	125.90	55.26	121.28	55.27	8.78	<0.001
HDL	58.04	18.67	60.78	18.44	6.52	<0.001
TGA	113.12	62.79	108.47	62.64	6.65	<0.001
urea/creatinine ratio	74.08	22.86	73.05	21.12	2.08	0.04

****paired samples t test***

There was significant difference in intervention group as regards clinical data before and after intervention. (P value < 0.001). This means that our

intervention group was successful; this agrees with the study of Tayside Centre for General Practice in United Kingdom where Randomized controlled trials were



carried out for patients with hypertension. Blood pressure control is the main finding in the present study which revealed significant decline in systolic and diastolic blood pressure among patients in the intervention group

at 6 months evaluation. This is explained by the fact that high adoption of healthy lifestyle associated with better blood pressure control, but patients in the control group reported slight reduction in systolic and diastolic blood pressure.

Table (3): Comparison between the two studied groups regarding clinical data after intervention.

	Group				t*	P value
	Intervention group (N=152)		Control group (N=150)			
	Mean	SD	Mean	SD		
SBP	130.33	12.13	132.77	14.70	1.57	.12
DBP	81.81	5.74	82.57	6.23	1.1	.27
BMI	27.82	18.15	26.77	3.19	0.7	.49
waist to hip ratio	0.81	0.09	0.81	0.09	.15	.88
Cholesterol level	192.25	59.83	209.51	70.77	2.29	.023
LDL	121.28	55.27	130.83	60.60	1.43	.15
HDL	60.78	18.44	57.19	19.35	1.65	.10
TGA	108.47	62.64	119.33	64.12	1.49	.14
urea/creatinine ratio	73.05	21.12	73.83	21.48	.32	.75

****Independent samples t test***

There was insignificant difference between intervention and control groups as regards clinical data after intervention except cholesterol level; it was higher in control group than intervention group.

A study carried out in outpatient clinics at Mansoura University Hospital, data collected from 50 patients randomly selected, a questionnaire (pre and posttest) was used to collect data on socio-demographic characteristics, knowledge. Also some physical assessment and health promoting lifestyle profile II, the intervention was a program written in a simple Arabic language and photos and this agrees with

our program implementation where a booklet was given to all patients in our study of 28 pages in Arabic language, colored photos and illustrations. It was found that there is significant decrease in cholesterol level, LDL, and TGA level in intervention group after intervention, compared to control group. (*Weheida SM. et al., 2009*), and this agrees with the evident that life style modification including diet control with low salt intake and physical activity improve health and decrease blood pressure and this is consistent with the results of the Iranian study in primary health-care settings where the mean systolic BP changed from 158.8 (±8.1) mmHg to



145.5 (± 4.6) mmHg after 6 months in the intervention group ($P < 0.001$), there was a significant difference between two groups of study. A significant correlation was detected between systolic BP and diastolic BP with body mass index, waist

circumference, salt intake, and physical activity level ($P < 0.001$). Stepwise regression analyses indicated that the weight, dietary salt intake, and physical activity level were significant predictors of SBP and DBP (*Hasandokht T. et al., 2015*).

Table (4): Comparison between intervention group and control group regarding their change in compliance score after the intervention.

		Compliance score after intervention				t*	P value
		Minimum	Maximum	Mean	SD		
Group	Intervention group	27.00	60.00	53.19	7.26	3.30	0.001
	Control group	24.00	60.00	50.05	9.16		

**Independent samples t test*

There was highly significant difference between intervention and control groups as regards compliance to treatment after intervention; the intervention group was more compliant to treatment than control group. (P value < 0.05). It was found that baseline medication adherence score mean did not significantly differ in both groups. However, at the end of the study there was a significant difference ($P = 0.001$) in the mean of compliance

score between the both groups, And this is in concomitant with the study developed in Shiraz Healthy Heart House in Iran where the percentage of patients taking medications during the 3 months educational program period increased (*Beige M.A. et al., 2014*), which is a likely reason for better BP control in the Intervention Group because antihypertensive medications additions did not differ through the study.

Table (5): Comparison between the two studied groups regarding their score of knowledge before intervention.

		Knowledge score before intervention				t*	P value
		Minimum	Maximum	Mean	SD		
Group	Intervention	0.00	21.00	15.98	4.99	0.97	0.33
	Control	0.00	21.00	16.58	5.73		

**Independent samples t test*

There was insignificant difference between intervention and control groups as regards knowledge assessment before intervention. (P value > 0.05)



Table (6): Comparison between intervention group and control group regarding their change in score of knowledge about hypertension and its risk factors immediately after lecture, one month, and 3 months after the intervention.

		Knowledge score				t*	P value
		Minimum	Maximum	Mean	SD		
Group (immediately)	Intervention group	10.00	21.00	20.35	1.51	2.13	0.04
	Control group	4.00	21.00	19.80	2.78		
Group (after one month)	Intervention group	10.00	21.00	20.07	1.85	2.58	0.01
	Control group	4.00	21.00	19.28	3.28		
Group (after 3 months)	Intervention group	7.00	21.00	19.88	2.31	2.43	0.02
	Control group	4.00	21.00	19.04	3.56		

****Independent samples t test***

There was significant difference between intervention and control group as regards knowledge score immediately, one month, and 3 months after intervention, where score was better in the intervention group in all times. (P value <0.05)

The score increased significantly in both groups. However, the increase was significantly greater in the intervention group (mean score increased from 15.98±4.99 to 19.88±2.31) than in the control group (mean score increased from 16.58±5.73 to 19.04±3.56) And this is in concomitant with the results of Shiraz Healthy Heart House Study in Iran where the patient's mean scores of knowledge improved from 2.77+2.7 before the intervention to 7.99+1.78 after 3 months (P<0.001). And also a study carried out in Egypt by **(Soliman H., 2007)** which concludes a significant increase in knowledge level post program. And **(Dawes MG. et al., 2010)** in Canada the Canadian Hypertension Education Program annually appraises data from hypertension research and updates clinical practice recommendation for the

diagnosis and management of hypertension. Disseminating these recommendations to target groups, it stated that most patients who received education booklet about hypertension have a good baseline about hypertension. In contrast to one conducted in Spain by **(Guirado EA. Et al., 2011)** revealed no relation between knowledge about hypertension and compliance with therapeutic treatment to control blood pressure, through a prospective, cluster-randomized trial with 18 of 36 urban primary care centers in Barcelona. This is may be justified by knowledge was not enough to achieve compliance and changing in lifestyle.

There are several studies that concluded that individuals with high blood pressure can make multiple lifestyle changes that lower blood pressure and reduce their cardiovascular risk for example a study conducted in 2014 in Egypt by Al-Wehedy **(Al-Wehedy A. et al., 2014)**.

In the current study, risk factors as stressful life as a risk factor decreased in



intervention group after intervention and didn't change in control group, this is likely due to the effect of regular follow up for the participants in intervention group that helped stress management and due to the benefits of social interaction, positive reinforcement, and positive peer group effect which were helpful on stress changes, Several studies agreed with our study including a meta-analysis by (*Gasperin D. et al., 2009*), showed that chronic stress and tension negatively affect blood pressure, as A systematic review followed by a meta-analysis was conducted aiming to assess the effect of psychological stress on blood pressure increase.

CONCLUSION:

From this study, it can be concluded that there was significant improvement in SBP and DBP in intervention group after intervention program, and also significant improvement in lipid profile, which proves that educational and practical intervention implemented to intervention group were more effective in controlling blood pressure than only educational one implemented to the control group. There was significant difference in the mean score of medication compliance between both groups, as the mean score of compliance increased in intervention group more than in control group. Knowledge score of the intervention group improved significantly after applying the intervention program. This means that the lifestyle interventions were effective as non pharmacological intervention. Some recommendations are suggested: Increase knowledge about risk factors, complications of hypertension and importance of compliance to anti-hypertensive regimens including both drugs and life style modifications is essential to control the disease, the

cornerstone in family medicine is the good doctor patient relationship, that improved adherence to regimens, the life style modifications are as important as medications in controlling blood pressure so a comprehensive treatment plan has to be instituted before discharging patients to help them understand accurately the required therapeutic regimen, and the new healthy life practices.

Conflict of interests: I declare that there is no financial or non-financial conflict of interests between the authors.

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