Research Article

EFFECTIVENESS OF COUNSELING FOR HYPERTENSIVE PATIENTS ON ADHERENCE AND BLOOD PRESSURE OUTCOME IN PRIMARY CARE PROVIDER IN INDONESIA

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ABSTRACT

The aim of the study was to evaluate the effectiveness of counseling in home pharmacy care (CHP) on patient adherence to antihypertensive medications and blood pressure control. A quasi-experiment was conducted in four primary health centres in Yogyakarta province, Indonesia. The study participants were 150 patients recruited from November 2015 to February 2016, who were ≥ 45 years of age, on antihypertensive medication, with systolic blood pressure (SBP) of ≥ 160 mmHg and or a diastolic blood pressure (DBP) of ≥ 90 mmHg. Patients who received usual care with those who received CHP during a follow up period of 4 weeks were compared. Antihypertensive medication adherence was measured by Morisky Green Levine Scale (MGLS), blood pressure control, and patients' satisfaction among CHP group. Of 150 patients, the average age was 59 years, 66.7% were women, 93.3% were up to senior high school and 70% were not employed. Medication adherence level improved from 3.5 at pre-test to 1.6 at post-test for CHP group ($p < 0.001$) and 3.4 to 3.5 for usual care ($p > 0.05$). Mean SBP decreased 8 mmHg in CHP group compared to increased 5.3 mmHg in controls ($p < 0.001$). The majority of CHP group were satisfied with the program. The CHP program was found to be effective to improve medication adherence and blood pressure outcome among hypertensive patients. This program can be implemented routinely to control patients with hypertension or with other related chronic diseases, is likely to improve clinical outcomes and potentially decrease healthcare costs of hypertensive management.

Keywords: Counseling; Pharmacy; Hypertension; Primary Care

INTRODUCTION

Hypertension is one of the most important public health problems and considered as the leading risk factor for global mortality. Hypertension currently is responsible for 13% of deaths worldwide¹ and is a major risk factor in developing cardiovascular disease, affecting 25% of adults.² A potential cardiovascular complication due to uncontrolled blood pressure is caused by inadequate treatment non-adherence,³ which can be defined as the degree of compliance following recommendations from a health provider about patient's behavior taking medication, following a diet, and lifestyle changes.

Low adherence to antihypertensive medication is a major factor in uncontrolled blood pressure. The World Health Organization (2003) estimated that adherence rates range from 50% to 70%, with various demographics and clinical characteristics, follow-up point of time, and method used to evaluate adherence. Non-adherence of patients with treatment regimens is important factor affecting blood pressure control.^{4,5} Therefore, non-adherence is healthcare issue and associated with poor blood pressure control⁶ and increased cost of hypertension treatment.⁷

The 2013 National Basic Health Survey reported that the estimated prevalence of patients diagnosed with primary hypertension in Indonesia was 25.8%,⁸ an increasing trend was observed compared with previous surveys. Among the patients with primary hypertension, 78.4% of them were used oral antihypertensive medications and only 53.2% had sought healthcare treatment at primary health facilities. The level of treatment adherence was found lower among patients with hypertension receiving free treatment in

primary care clinics (62.3%), under national health insurance system.⁹

In this context, a major factor affecting the effectiveness of blood pressure control is inadequate patient monitoring by pharmacists. This is most evident that a number of hypertensive patients were not attend scheduled follow-up intervention, estimated about 50%.⁵ The problem of inadequate monitoring might be exists for patients who miss appointment in healthcare clinics, fail to follow their physicians' medical care advice, or who have changes in their blood pressure level not easily detected in periodic office visit with their providers.

In this study we initiated a counseling for hypertensive patients at home visit for the purpose of monitoring and evaluating their medication adherence and blood pressure control. We designed the counseling in home pharmacy care (CHP) to be practical for use of pharmacists in primary care setting to integrate the counseling strategy in the follow up visit. This CHP program was evaluated for hypertensive patients in primary health centres by assessing the medication adherence and blood pressure control.

MATERIALS AND METHODS

Study design

The study was quasi-experimental pre-test post-test with control group design. The two groups of patients with hypertension were randomly assigned to Counseling in Home Pharmacy care (CHP) and participants who received their regular medical care only (usual care).

Study population and sample

Subjects selection was performed at 4 representative primary health centres, named Jetis, Tegalrejo, Depok, and Sleman primary health centres in 2 districts in Yogyakarta province. A patient had to be aged 45 years or older, be under the universal health coverage (called BPJS), be prescribed antihypertensive medication, did not have any comorbidity, and only patient non-adherent were included in the study. Patients were observed on their systolic blood pressure (SBP) ≥ 160 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg based two intermittent tests within 5 minutes at the primary health centres. Individuals were not eligible if they had comorbid diseases or hypertensive complications, refused to consent to participate, or dropped out during follow-up period. Individuals who met the eligibility criteria were scheduled for a CHP home visit.

A number of 357 eligible participants were identified from the 4 target primary health centres. During baseline assessment, 7% of these individuals could not be found their home address, 3% developed complications and 5% refused to participate. The rest of 304 individuals were scheduled for a home visit and finally 199 subjects were confirmed as eligible and enrolled in the study. One hundred and fifty (75%) of the eligible subjects accomplished the follow up study and were analyzed, consisting 75 patients in the CHP group and 75 patients in the usual care group.

The intervention

The intervention named as Counseling in Home Pharmacy care. The Counseling in Home Pharmacy care (CHP) is a program initiated by Management and Community Pharmacy research group, Faculty of Pharmacy, Gadjah Mada University in collaboration with pharmacists working in primary health centres in Yogyakarta Province. It is a pilot program aimed to provide the additional service provided by pharmacist in community setting. In current practice, CHP was not routinely provided due to pharmacists' workload. Therefore, our study is considered as pilot study in introducing the CHP for hypertensive patients. The study was approved by an ethics committee (UGM Ethical Committee) no KE/FK/237/EC/2015. This study was carried out as per International Conference on Harmonization-Good Clinical Practices Guideline (ICH-GCP).

At intervention period, a trained pharmacist accompanied by pharmacy student (surveyor) confirmed the inclusion criteria and completed baseline measurements including patient's blood pressure using standardized sphygmomanometer. Subsequently, participants were simple randomized to either the CHP or usual care groups using a matched samples method based on their blood pressure level. All participants in CHP group received counseling in home visit for 4 weeks. During the counseling process, patients were advised about 1) their blood pressure status (controlled/uncontrolled), 2) their antihypertensive medication administration (medication names, dosages, and frequency of taking medicine), 3) importance of adherence to the medication prescribed, 4) whether they had unpleasant symptoms (side effects) of their antihypertensive medication and how to deal with it, and 5) the use of medication reminder. Additional measure also performed to explore patients' satisfaction to the CHP. An average CHP program took about 10 minutes per weeks and the length of follow up was 4 weeks visit.

Data collection

Data for analysis was collected during the four home visits, performed 4 weeks apart. Two blood pressure examinations were taken at each home visit by surveyors (pharmacy students) who were trained to follow a standard blood pressure measurement protocol. Antihypertensive medication adherence was assessed

by Morisky Green Levine Scale (MGLS) and validated by home pill count. Structured interviews were delivered at baseline, including questionnaire to ask socio-demographics, comorbidity, health status, and attitudes toward the CHP program. At the final home visit, CHP participants responded to structured questions about their satisfactions to CHP.

Data analysis

We computed the antihypertensive medication adherence as MGLS score. The MGLS was a self-administered questionnaire to detect any potential reasons associated with medication taking behavior to hypertensive treatment. It is a tool with 4 questions (items). The questions were designed to avoid a response bias, a tendency of patients to answer "yes" only, by formulating an unfavorable item. The calculation of adherence is based on the total score, can range from 0, 1-3, and 4 reflecting high, medium, and low adherence, respectively. Medication adherence was validated by pill count measurement, as the total number of tablets dispensed minus the total number counted in the audit, divided by the number that should be been taken by each subject.

SBP and DBP were measured as the average of two blood pressure measurements taken at each home visit. Medication adherence, SBP and DBP, and change scores were calculated for each participant at 4 weeks follow up and subtracting the value at baseline. Initial comparisons of the change scores for the CHP and usual care subjects were made using *Chi-square* test. Change score of MGLS before and after CHP was compared using *Wilcoxon-sign* rank test, and comparison between CHP and usual care group was performed using *Mann-whitney* test.

RESULTS

Participants' characteristics

A total of 150 participants in the study were consisted of 75 in the CHP group and 75 in the usual care. The mean age of study sample was 59 years, 66.7 % were women, 93% was up to senior high school, and 73% were not employed. Table 1 displays the characteristics of the participants at baseline. There was no statistically significant difference in any characteristic between individuals in CHP or usual care.

Table 2 shows the personal, social and behavioral characteristics based on the patient's perspective, and affected their drug adherence. The most common discouraging factors related to non-adherent were forgetfulness (46.67%), lack of access to medication (30%), and lack of understanding the need of medication (20%).

Effects on Antihypertensive Medication Adherence

Effectiveness of CHP program in improving medication adherence was demonstrated by the change score of MGLS over the 4 weeks study period among CHP group, as depicted in Table 3. The CHP was associated with improvement in adherence score (score from 3.5 in pre-test to 1.6 at post-test) ($p < 0.05$). In contrast, for usual care, the change in adherence (score from 3.42 at pre-test to 3.50 at post-test) was not statistically significant.

Effects on Blood Pressure

During the CHP of the 4 weeks follow-up, mean of SBP decreased approximately 8 mmHg for CHP group ($p = 0.004$). DBP also decreased significantly 4.67 mmHg on average in CHP group ($p = 0.016$). The SBP and DBP were somewhat higher among usual care participants (5.33 mmHg and 1.33 mmHg respectively). Table 4 shows the effect of intervention, CHP

program, on blood pressure change for 4 weeks study follow up. There was a trend toward a lowering SBP among CHP group than usual care patients. This effect was limited to patients who were non-adherent to their antihypertensive medication regimen at baseline. Among these individuals the mean drop in SBP was 8 mmHg for CHP group and only 4.67 mmHg for usual care group. Hypertensive patients who were non-adherent with their medications at baseline were most influenced by the CHP intervention.

Satisfaction of CHP group about the program intervention

Table 5 shows the responses of CHP group to statements about their satisfaction of the program implementation. In addition, they indicated their overall satisfaction with CHP by percentage of participants agree or disagree, where 0 considered as very dissatisfied, and 100 as very satisfied. Almost participants, 73-93% scored the item in the upper quartile, while only 5-20% scored the items in the lower quartile.

Table 1. Baseline characteristics of patients in CHP and usual care groups

Characteristics		CHP group (75) N (%)	Usual care (75) N (%)	Total (150) N (%)	P value*
Sex					
	Male	25 (33.3)	25 (33.3)	50 (33.33)	1.000
	Female	50 (66.7)	50 (66.7)	100 (66.67)	
Age (years)					
	45-≤ 65	50 (66.7)	45 (60.0)	95 (63.33)	0.705
	> 65	25 (33.3)	30 (40.0)	55 (36.67)	
	Average	59.53±11.66	61.60±13.63		
Education					
	Not pass elementary school	10 (13.3)	5 (6.7)	15 (10)	0.788
	Elementary school	25 (33.3)	30 (40.0)	55 (36.67)	
	Junior high school	25 (33.3)	25 (33.3)	50 (33.33)	
	Senior high school	10 (13.3)	10 (13.3)	20 (13.34)	
	Bachelor degree	5 (6.7)	5 (6.7)	10 (6.66)	
Employed					
	Employed	15 (20)	25 (33.3)	40 (26.67)	0.407
	Not employed	60 (80)	50 (66.7)	110 (73.33)	
Diagnosed of hypertension (years)					
	≤ 3	55 (73.3)	60 (80.0)	115 (76.67)	0.666
	>3	20 (26.7)	15 (20.0)	35 (23.33)	
	Average	2.86±1.51	2.21±1.37		
Antihypertension medication					
	Amlodipine	60 (80)	70 (93)	130 (86)	
	Captopril	15 (20)	5 (7)	20 (14)	

*There were no differences between CHP and usual care groups ($p < 0.05$). CHP: Counseling in Home Pharmacy care

Table 2. Reasons for medication non-adherence

Factor that discouraged patients' medication taking behavior	N (%)
Busy and forgetting with the medication taking schedule	70 (46.67)
Lack of access to medication	45 (30)
Lack of understanding of need of medication	36 (20)
Side effects experience	5 (3.33)

Table 3. Medication adherence score comparison by study group

MGLS score*	CHP	Usual care	Change score	p value
Pre-test	3.517±0.794	3.417±2.037	0.100±0.622	0.204**
Post-test	1.583±0.588	3.500±2.015	-1.851±0.129	≤0.001**
Change score	-1.934±1.432	0.083±4.067		≤0.001**
p value	≤0.001*	0.059*		

*MGLS: Morisky Green Levine scale, range score 0-4, where 0 is high adherence and 4 is low adherence

Table 4. Change in systolic and diastolic blood pressures by study group

Blood pressure		CHP	Usual care	Change score	p value
SBP (mmHg)	Pre-test	147±12.46	136±14.54	8.67±20.31	0.113**
	Post-test	137±7.48	141±8.96	-4.67±13.56	0.121**
	Δ pre-post	-8.00±5.49	5.33±8.12		≤0.001**
	p value	0.004*	0.023*		
DBP (mmHg)	Pre-test	91±8.84	89±9.67	1.67±13.84	0.728**
	Post-test	86±4.71	90±8.96	-4.33±9.61	0.206**
	Δ pre-post	-4.67±6.11	1.33±3.99		0.004**
	p value	0.016*	0.194*		

*significant at $p < 0.05$

Table 5. CHP group's satisfaction regarding the program implementation

Statements (n=75)	Agree. N (%)	Disagree. N (%)
CHP program made me aware of my blood pressure	70 (93.33)	5 (6.67)
CHP increase my understanding about the effectiveness of antihypertensive medication	60 (80)	15 (20)
CHP increase my understanding about the need of antihypertensive medication	65 (86.67)	10 (13.33)
CHP relieved my worries about the side effects of antihypertensive medication	55 (73.33)	20 (26.67)
CHP make me adhere on antihypertensive medication	60 (80)	15 (20)

*Agree=1-2. Disagree=3-4 on a 4-point Likert scale where 1= strongly agree and 4= strongly disagree

DISCUSSION

The pharmacist counseling integrated in home visit is commonly used for patient with chronic conditions, includes hypertension in developed nations.^{10, 11} However, in only a few case studies have pharmacists provided counseling as supplement service to care their patients in developing countries like Indonesia.¹² We conducted pilot study in initiating counseling for patients in home care and evaluate the efficacy of the program. Cranor *et.al* demonstrated that pharmacists' intervention and routine follow up of diabetic patients resulted significant differences in health outcome over long term period and lowering health care costs.¹³

In our study, home visit with counseling for hypertensive patients was associated with significantly reduced SBP and possibly lower DBP. Of particular note, the amount of SBP reduction attributable to CHP was similar to that shown in clinical trials of antihypertensive drugs compared to placebo.¹⁴ For CHP group, average SBP dropped 8 mmHg more than it did for control participants. A study showed that measuring SBP is useful to estimate the prediction of cardiovascular complications.¹⁵ A meta-analysis study including 14 clinical interventions of various antihypertensive medication regimens showed a significantly different in mean SBP ranged about 5-6 mmHg.¹⁶ This lowering SBP provided positive impact on 42% less stroke incidence and 14% reduction of coronary heart disease.¹⁶ For CHP group, we also generate comparable reductions in cardiovascular disease risk.

In the study, it is highlighting that CHP program associated with antihypertensive medication adherence, and outcome in blood pressure control. For CHP group, the major improvement in blood pressure outcome was occurred in patient who experienced an elevated adherence to their antihypertensive medication regimen during the period of study. These results suggest that the effectiveness of CHP on blood pressure may be intervened by patient education elaborated in CHP. This finding is in line with the established association between intervention on education, antihypertensive medication adherence and blood pressure level.¹⁷

There may also have been direct impacts of the CHP on blood pressure level. CHP participants reported that CHP program initiated by pharmacists made them more conscious of their blood pressure and increase awareness about their disease. Direct effect of CHP on lowering blood pressure has been theoretically shows, that behavioral interventions have association with lower blood pressure in hypertension.¹⁸

At the baseline, we assessed the factors associated with patient non-adherence. Patients explained several reasons for non-adherence as forgetfulness, lack of access to medication, and lack of understanding the need of medication. This finding can be explained by 2 relevant factors. First, many patients with hypertension have negative experiences toward antihypertensive drugs and lack of understanding on nature of chronic disease. Patients frequently discontinue medication when they did not

have disturbing symptoms. Second, although health care providers provide education and information about the importance of continuing antihypertensive drugs, patients are still not following the advice due to lack of attention to blood pressure control and low intensity of information.^{19, 20}

Finally, it is reasonable that the effect of the intervention was due to family support at home to monitor patient's symptom and control blood pressure. Several studies have demonstrated impact of blood pressure self-monitoring and social support on medication-taking behavior or blood pressure control.²¹ Thus, it appears most likely that CHP exerted its effect on blood pressure by affecting patient medication-taking behavior, and possibly by influencing pharmacist counseling practice.

The study had several limitations. The generalizability of the study findings to other population may be caution. The features of our study designs must be considered. First, the participants included in this study were 45 years old or older, and thus the study findings may different with younger population. Second, the sample size in our study is considered limited. Third, the length of intervention was only 4 weeks which might be not adequate to prove the evidence in lowering blood pressure level.

CONCLUSION

The CHP program was found to be effective to improve medication adherence and blood pressure control in hypertensive patients. This program can be implemented routinely to assist patients with hypertension or with other chronic diseases, is likely to improve clinical outcomes and potentially saving the cost of hypertensive management.

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