

Brief Counselling with Self-evaluation Drug Use Sheet To Improve the effectivity of Drug Therapy in Diabetes Mellitus with Hypertension Complication Outpatients

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Abstract—Brief counseling by Pharmacist (BCP) and self-evaluation drug use sheet (SEDUS) may improve patients' behavioral changes, thereby improve blood pressure levels. The study aims to determine the effect of BCP and self-SEDUS on blood pressure and blood glucose level of outpatients with diabetes mellitus and hypertension complication (DMHC) with standard therapy at Polyclinic of Internal Medicine in Public Hospital, Bantul, Yogyakarta. We conducted a quasi-experimental study with prospective data collection during March-May 2017. A total of 99 DMHC who met the eligibility criteria were divided into three groups, 33 patients each group, respectively. The control group received standard therapy with routine drug information from hospital Pharmacist. The treatment group 1, received standard therapy and BC from the pharmacist (BCP) counselor. The treatment group 2, received conventional therapy and BCP combination with SEDUS. We presented demographic and clinical characteristic, descriptively. We analyzed the mean difference of blood pressure and blood glucose level between the group with one way-ANOVA and multiple comparisons. Result: The Post-treatment systolic blood pressure (PTSBP) in the treatment groups I and II were lower than PTSBP in the control group ($p < 0.05$). The post-treatment blood sugar levels (PTBGL) in the treatment groups were lower than PTBGL in the control group ($p < 0.05$). BCP combination with SEDUS intervention for one month reduced SBP and blood sugar levels ($p < 0.05$). Conclusion: brief Counselling and SEDUS in patients DMHC at Public Hospital, Bantul, Yogyakarta improved effectivity of anti-hypertension and anti-diabetes Mellitus drug.

Keywords—diabetes mellitus and hypertension complications, brief counseling, self-evaluation drug use, medication behavior change

I. INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder, characterized by chronic hyperglycemia caused by insulin secretion abnormalities, insulin work, or both [1]-[3]. DM is one of the public health problems in Indonesia [4]. DM patients routinely and for a long time, need hypoglycemic drugs to control blood sugar levels. The incidence of non-compliance with DM patients undergoing therapy with hypoglycemic drugs is still high [5]-[6]. DM patient

compliance treatment related to quality of life and prevention of complications. The determinants factors of determining the compliance of DM patients in undergoing treatment are the amount of drug and the level of knowledge [7]. One of the benefits of pharmacists in pharmaceutical care is the provision of education and counseling to patients to improve therapeutic success and motivate patients to follow established therapeutic regimens [8]-[10]. In addition to the verbal, counseling can also be done with written materials such as leaflets and self-evaluation drug use sheet (SEDUS) that serves as a reminder to increase knowledge and strengthen what is conveyed by pharmacists during counseling [11]-[12].

Health promotion in the form of health education by pharmacists is an essential factor in increasing patient knowledge [13]-[15]. One of the factors that affect understanding is information.. This information can be obtained through brief counseling given by pharmacists. PBC methods have been developed by pharmacists to apply to pharmaceutical care in patients with chronic diseases such as hypertension, DM or asthma [9], [10], [16], [17]. Based on research conducted by Saputri, it is known that brief counseling increases the success of antihypertensive drug therapy [17]. A study by Saputri (2016) showed that 5A brief counseling and a motivational SMS could improve compliance and control of blood pressure with treatment group. The Saputri study is in line with previous research, which found that pharmaceutical interventions enhance compliance and quality of life [17]-[20]. Brief counseling by pharmacists significantly alters physical activity habits ($p < 0.05$) in the treatment group of hypertensive outpatients in the Internal Medicine Polyclinic [21], [22].

Patient-centered DM management becomes one of the effective models in increasing the success of DM therapy [23]. Transforming medical behavior to the DM Patient requires media and methods that are easy and practical. Health promotion oriented behavior change is not enough to provide information. Self-evaluation drug use sheet is patients' ability to assess therapy success through behavioral changes. Self-evaluation drug use sheet is done by the patient independently

with an assisted pharmacist as a counselor, to achieve understanding and compliance in drug therapy [12], [24].

Based on this, the authors are interested in conducting further research on BCP and SEDUS. We expected that PBC combination with SEDUS could improve the effectivity of hypoglycemic and anti-hypertension drug therapy so that patients' blood sugar and blood pressure can be controlled.

II. METHOD

A. Design, Subject, and Instrument

The study was conducted using a quasi-experimental design with a before and after with control design. Patients' data were taken prospectively at Polyclinic of Internal Medicine, Public Hospital, Bantul from March-May 2017.

The sample size calculation in this study was calculated based on the OpenEpi, statistical formula obtained at least each group of ± 30 patients with 10% non-compliance and 90% power. The inclusion criteria were cooperative male and female patients and available for interview, aged 18-99 with bodyweight category of obesity, based on BMI calculation, and receiving at least one kind of antihyperglycemic and antihypertensives drug. The exclusion criteria were deafness, illiteracy, pregnancy, heart and kidney problems, under hormonal medications and routine other medicines such as TB drugs, HIV and AIDS and history of stroke and hemodialysis.

We used questionnaires and SEDUS for collecting data. Before the instrument used in the research, validation test of the questionnaires and SEDUS form has been done for the diabetes mellitus with hypertension complication patients at PKU Muhammadiyah Hospital and Gading Clinic. The preliminary test has also been done to avoid bias and ambiguity [25], [26].

The research protocol was reviewed and obtained ethical clearance by the research ethics committee of Ahmad Dahlan University.

B. Intervention and Data Analysis

The eligible subjects were divided into three groups. There were 33 patients as the control group. The control group received advice routine care from the pharmacy installation. In the treatment group I, the 33 patients received PBC from the pharmacist counselor and in the treatment group 2, the 33 patients received PBC combination with SEDUS.

The PBC was given on the first visit (pre) by the professional trained-Pharmacist, and SEDUS was completed by the subjects every day until the second visit (post). The data were collected with behavioral changes questionnaires, while blood pressure and blood sugar were taken from subjects' medical records and verified directly with patients. Blood pressure control refers to JNC 8, that is for <60 years the blood pressure level of <140/90 mmHg is categorized as controlled, but >140 or > 90 mmHg is uncontrolled

Statistical analysis to determine the correlation between behavioral change and blood pressure was done using the chi-square test, one way ANOVA and post hoc.

III. RESULT AND DISCUSSION

A. Demographic and Clinical Characteristic

A total of 99 eligible subjects were divided into control group (n=33), treatment group 1 (n=33) and treatment group 2 (n=33). Table I shown the demographic characteristics of subjects in each group.

TABLE I. DEMOGRAPHIC CHARACTERISTICS OF DMH SUBJECTS IN PUBLIC HOSPITAL, BANTUL

Patient Characteri- stics	Control (n=33)	The treatment I (n=33)	The treatment 2(n=33)+	Total (n =99)	P
	N (%)	N (%)	N (%)	N (%)	
Sex					
Male	16(15,9)	9(8,9)	8(7,9)	33 (32,7)	0,0 75
Female	17 (16,8)	24(23,8)	25(24,8)	66(65,4)	
Status					
Married	30(29,7)	33(32,7)	33(32,7)	96 (95,1)	0,0 45*
Single	3 (3,0)	0	0(0)	3(3,0)	
BMI (kg/m2)					
<18,5	3(3,0)	1(1,0)	0(0)	4(4,0)	0,1 07
18,5-24,9	18 (17,8)	17(16,8)	20(19,8)	55(54,5)	
25,0-29,9	11(10,9)	9(8,9)	12(11,9)	32(31,7)	
30,0-34,9	1(1)	6(5,9)	1(1,0)	8(7,9)	
Age (years)					
18-65	24(23,8)	23(22,8)	25(24,8)	72(71,4)	0,4 15
66-79	9 (8,9)	7(6,9)	7(6,9)	23(22,7)	
80-99	0 (0)	3(3,0)	1(1,0)	4(4,0)	
Education					
0-9 years	13(12,9)	17(16,8)	14(13,9)	44(43,6)	0,8 56
10-12 years	10(9,9)	7	10(9,9)	27(26,7)	
>12 years	10(9,9)	9(8,9)	9(8,9)	28(27,7)	
Occupation					
Civil Servant	3(3)	6(5,9)	2(2,0)	11(10,9)	0,1 82
Entreprene- ur	6(5,9)	0(0)	2(2,0)	8(7,9)	
Farmer	0 (0)	0(0)	1(1,0)	1(1,0)	
Unemploye- d	21(20,8)	25(24,8)	25(24,8)	71(70,4)	
Private sector	1(1)	1(1,0)	0(0)	2(2,0)	
Labor	2 (2)	1(1,0)	3(3,0)	6(6,0)	
Fisherman	0 (0)	0 (0)	0(0)	0(0)	
Notes: Notes:Treatment 1=brief counselling; treatment =combination brief counselling+ Self-evaluation drug use P is the significance value. There is a significant difference (p <0.05) between treatment and control using the Chi-Square test for the category variables					

Based on Table 1, it is known that the majority of subjects were women (67.3%), married (95.1%), young, i.e. less than 65 years (71.4%) and educated more than junior high schools (54%). Demographic characteristics of subjects (sex (P = 0.075), age (P = 0.415), education (P = 0.856), and occupation (P = 0.182)) are similar between treatment and control group.

B. Clinical characteristics

Clinical characteristics and lifestyle of the subjects are presented in Table II.

TABLE II. LIFESTYLE AND CLINICAL CHARACTERISTICS OF DMH SUBJECTS IN PUBLIC HOSPITAL, BANTUL

Patient Characteristics	Control group (n=33)		The treatment group I (n=33)		the treatment group II (n=33)		Total (n=99)		P
	n	%	n	%	n	%	n	%	
Smoking Status									0,357
Yes	2	2,0	1	1,0	0	0,0	3	3,0	
No	31	30,7	32	31,7	33	32,7	96	95,1	
Physical exercise									0,474
1x/ day	15	14,8	15	14,9	11	10,9	41	40,6	
1x/ week	9	8,9	12	11,8	17	16,8	38	37,5	
1x/ month	4	4,0	4	4,0	2	2,0	10	10,0	
No	5	5,0	2	2,0	3	3,0	10	10,0	
Diet									0,604
Salt	0	0	2	2,0	0	0	2	2,0	
Sugar	1	1,0	0	0	0	0	1	1,0	
Cholesterol	0	0	0	0	0	0	0	0	
Salt + Sugar	12	11,9	13	12,9	15	14,9	40	39,7	
Salt+ Sugar + Cholesterol	19	18,8	19	18,8	18	17,8	56	55,4	
Health Cost									0,364
Personal	1	1,0	0	0	0	0	1	1,0	
BPJS	32	31,7	33	32,7	33	32,7	98	97,1	
Other Insurance	0	0	0	0	0	0	0	0	
DM duration									0,234
< 10 years	20	19,8	13	12,9	14	13,9	47	46,6	
10-20 years	11	10,9	16	15,8	18	17,8	45	44,5	
>20 years	2	2,0	4	4,0	1	1,0	7	7,0	
DM+HT History									0,294
Yes	14	13,9	15	14,9	10	9,9	39	38,7	
No	19	18,8	17	16,8	24	23,8	60	59,4	
Drug amount									0,339
2 drugs	7	6,9	4	4,0	3	3,0	14	13,9	
>2 drug	26	25,7	29	28,8	30	29,7	85	84,2	

Notes: Notes: Treatment 1=brief counselling; treatment =combination brief counselling+ Self-evaluation drug use
P is the significance value. There is a significant difference (p <0.05) between treatment and control using the Chi-Square test for the category variables

Based on Table II, most of the Subjects were non-smokers, regular exercise every day, carbohydrate and salt diet, health financing by BPJS and taking the drug more than two drugs.

Statistically, the duration of illness, diagnosis of the disease, the number of drugs, and the payment types of the three groups were the same (p > 0.05).

C. Filling Self-Evaluation Drug Use sheet (SEDUS)

Therapy success can be achieved by ensuring that patients understand the information given by pharmacists during the brief counseling. If they do, they will be able to change their treatment behavior by complying with medication and maintaining a healthy lifestyle. The SEDUS form can improve the success of treatment for patients with diabetes mellitus and hypertensive complications because the patients must complete the form every day. It is expected that SEDUS can improve patients' compliance in taking medication. The patients' response to the SEDUS is shown in Table III.

TABLE III. DATA ON SEDUS OF DMH PATIENTS IN PUBLIC HOSPITAL, BANTUL

A		B		C		Total
Σ	%	Σ	%	Σ	%	
18	54,54	10	30,30	5	15,15	33

From Table III, it is known that of the 33 DMH patients in the treatment group II who completed the self-evaluation sheet for drug use there were 18 (54.54%) patients (A group). As many as 10 (30.30%) DMH patients fill out SEDUS but are incomplete (B group) and the remaining 5 (15.15%) do not or very minimal fill out the SEDUS (C group).

D. Effect of brief counseling and SEDUS on Blood Pressure and Blood glucose level

Table IV shown the impact of brief counseling and brief counseling combined with SEDUS on clinical outcomes. There was a significant difference in systolic and diastolic blood pressure at pre and post-treatment in the treatment group 2 (p <0.05). In the treatment group 1, post-treatment systolic blood pressure (PTSBP) was lower than pre-treatment. Post-treatment systolic blood pressure (PTSBP) in the treatment group I or II were lower than the PTSB in control group (p <0.05). There was no significant difference in diastolic blood pressure between the treatment and control groups (p > 0.05).

From Table IV it was found that the provision of short counseling or SEDUS increased the efficacy of antihypertensive drug therapy, indicated by systolic blood pressure after treatment lower than the systolic blood pressure before treatment (p <0.05). From Table IV, it was found that the provision of short counseling or SEDUS may increase the effectiveness of antihyperglycemic drug therapy, although it is not statistically significant. (p > 0.05). This study is different from the results of previous research; the time factor of treatment seems to play a role in this [27].

Pharmaceutical care practice is intended to meet a need in the health care system that has arisen due to the increase in complexity of drug therapy and the significant level of drug-related morbidity and mortality associated with drug use. Pharmaceutical care using BCP combined with SEDUS has a better effect than using one of them. Pharmaceutical care is an important aspect in realizing therapeutic goals for patients with chronic illness [12], [27], [28].

TABLE IV. THE MEAN VALUES OF BLOOD PRESSURE AND BLOOD GLUCOSE LEVEL IN CONTROL AND TREATMENT GROUPS, PRE AND POST-TREATMENT, OUTPATIENTS DMH OF INTERNAL DISEASE POLICLINIC, PUBLIC HOSPITAL, BANTUL, YOGYAKARTA

Variable	Treatment group			p
	Control	The I Treatment	The II Treatment	
Blood Pressure				
Sistolic:pre	139,24±15,53	135,30±13,46	139,55±16,22	>0.05
post	132,88±12,81	126,94±8,86*	129,55±9,55*	<0.05
p	>0.05	<0.05	<0.05	
Diastolic:pre	84,70±8,27	83,64±8,22	87,12±9,27	>0.05
post	83,64±10,40	81,21±8,29	83,68±9,16*	>0.05
p	>0.05	>0.05	<0.05	
Blood Sugar				
Pre	203.48±68.55	200,24±17.98	189.76±13.08	>0.05
Post	187.36±60.45	175,55±11.29	153.73±9.35	<0.05
p	>0.05	<0.05	<0.05	

Notes: Treatment 1=brief counselling; treatment =combination brief counselling+ Self-evaluation drug use; * = There was a significant difference (p <0.05) between the pre and post-treatment

The current findings suggest the need for hospital-pharmacists to improve their pharmaceutical care skill and knowledge base in pharmacotherapeutics with appropriate training to facilitate clinical problem-solving. Their participation in educational programs on communication will allow them to develop stronger communication skills to interact effectively with patients.

This study has limitations. The research method is limited to the study period so that treatment is only given once, namely at the first visit. Similar research by giving treatment more than 2 times can still be developed again. The number of samples was limited in the study period, March - May 2017, so that only 96 patients were included in the inclusion criteria. Research needs to be done with more subjects with longer interventions so that the results are better

IV. CONCLUSION

Brief counseling and self-evaluation drug use sheet as controlling measures of medication compliance can positively improve clinical outcome of diabetes mellitus with hypertension outpatient clinic of Public Hospital, Bantul, Yogyakarta.

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Declare: no conflict of interest.

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