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Research Article

THE EFFECT OF THE BLOOD PRESSURE FEEDBACK INTERVENTION TO PHYSICIANS ON THE IMPROVEMENT OF THE BLOOD PRESSURE CONTROL

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ABSTRACT

The study aimed to assess the effect of the blood pressure (BP) feedback intervention to physicians on the improvement of the blood pressure control of hypertension subjects. The study was done with controlled repeated intervention design. The adult hypertensive non-hemodialysis subjects from 4 Indonesian hospitals were included as intervention and control subjects. Outcomes were measured as the improvement of systolic BP (SBP). The subjects in intervention (n=385) vs. non-intervention (n=271) groups had similar age and proportion of males ($p>0.05$); proportion of cardiovascular comorbid 78.7% vs. 91.5% ($p<0.01$) and the baseline SBP at 144.1±15.8 vs. 139.6±13.8mmHg ($p<0.01$). The final SBP 138.2±17.2 vs.140.6±15.4mmHg (adjusted $p<0.01$); the difference between (Δ) final-baseline SBP: 5.9±20.3 vs. (-)0.9±20.0mmHg (adjusted $p<0.01$); Δfinal-target SBP: (-)6.1±17.3 vs. (-)9.6±15.5 (adjusted $p<0.01$). There were more intervention subjects with good controlled final SBP; odds ratio (OR) 1.4(CI95%:1.0-1.9, adjusted $p<0.05$). Based on the Δfinal-baseline SBP, the Δfinal-target SBP, and OR SBP reached the target; theintervention subjects had significant SBP improvement.

Key words: blood pressure feedback intervention, blood pressure control

INTRODUCTION

Hypertension is a risk factor of cardiovascular disease (CVD) and CVD was the number one cause of mortality globally (WHO, 2009). Hypertension is a manageable risk (Chobanian *et al*., 2003) but a large proportion of the hypertensive patients failed to reach the blood pressure target (Wu *et al*., 2009). Regardless of the availability of the hypertensive medicine, the hypertension therapy was inadequate. The patients received fewer anti-hypertensive medicines than they needed (Setiati and Sutrisna, 2005). Therapy intensification (TI) by physicians was known to be the most influential factor in the BP control (Maddox *et al*., 2010; Vigen *et al*., 2012). Lack of TI was a single barrier in the BP control in routine visit subjects (Samuels *et al*., 2008) and independent to adherence (Rose *et al*., 2009a). The evidence from the clinical survey, there was only 13% of the eligible patients received the therapy intensification during their primary care visits (Bolen *et al*., 2008).

Among the various existed methods of non-pharmacology intervention, the BP feedback intervention to physicians to improve the TI score and BP control was selected as the intervention procedure. The five-month preliminary study done in the research hospitals gave result that the subjects BP 145/87mmHg and TI score of -0.43, regardless the excellent subjects' adherence and the physician factor is the most important factor in BP control.

Therapy intervention to the patients' care includes the pharmacology and non-pharmacology strategies. Generally non-pharmacology intervention is done to improve the behavior of patient and health care professional (Serlacius and Sutton, 2009). The studies showed the favorable effects of intervention (Atthobari *et al*., 2004; Contreras *et al*., 2005; Ziemer *et al*., 2006; Goldberg *et al*., 2007). The non-pharmacological intervention has inconsistent effect, ranged from mild to moderate, and not predictably effective. The pharmacology intervention should be added

when the non-pharmacology failed to improve the outcome (McDonald *et al*., 2002; Doggrell, 2010; Glynn *et al*., 2010).

This study aimed at assessing the effect of the blood pressure (BP) feedback intervention to physicians on the improvement of the blood pressure control of hypertension subjects in Indonesian hospitals.

MATERIAL AND METHODS

Study design

This study was done with the controlled repeated intervention design. The study done in four hospitals in Indonesia and every two hospitals were involved into intervention and non-intervention groups. The physicians in intervention hospitals received four-time BP feedback intervention, meanwhile the non-intervention physicians went on natural practice.

Subjects

The subjects criteria included ≥18 years old, covered with "Askes" insurance, out-patients of the hospital clinic, four or more visits in the intervention period with one or more uncontrolled BP and/or received hypertensive medicines. The subjects in hemodialysis procedure were excluded. "Askes insurance" is the Indonesian government-owned insurance eligible only for the government employees.

The research hospitals were selected according to the recommendation by the regional Askes management because the hospitals had long experience with the "Askes" service and had about 2000 or more "Askes" subjects monthly. The intervention and non-intervention subjects came from the different hospitals. The BP feedback to physician intervention was a non-pharmacological study; both physicians and subjects in the intervention and non-intervention group should be totally separated. The hospitals comprised two B-class hospitals and two C-class hospitals based on the Indonesian hospital classification. Each B-class and C-class hospitals were divided into Intervention and non-Intervention groups. All physicians with ≥15 subjects in intervention group were selected to participate in the study. The total of 10 (intervention) and 15 (non-intervention) physicians were participated in the study.

Procedure

The study protocol was approved by the Medical and Health Research Ethics Committee (MHREC), Faculty of Medicine Sardjito Hospital *Universitas Gadjah Mada*. The study protocol was also submitted to the management board of hospitals prior to the intervention period.

The preliminary prospective observational study was done in the duration of six months to obtain the subject BP and therapy intensification score. The intervention material was prepared based on the preliminary result in the power-point printing format. The feedback intervention comprised the subjects' BP profile and the BP target. The intervention was done in the out-patient clinic in the research hospitals. The BP feedback was done with the face-to-face method to the physicians in the intervention group for four times by a pharmacist researcher, i.e. in the first month together with the informed-consent and in month 2, 4, and 6 in the intervention period. Meanwhile non-intervention subjects were treated by the physicians who went on natural practice.

Subjects' BP and medication profiles were observed monthly since the approval of informed-consent and continued up to 8 months. Medication profiles were collected from the hospital claims to "Askes", meanwhile the monthly BP profiles, comorbidity, and visiting date were obtained from the medical record. Data were recorded in case report form (CRF), after that the data was entered and stored in Excel Program.

Outcomes Measurement

The subjects' adherence was determined with medication possession ratio (MPR), i.e. the ratio of the total days' supply with the hypertension medicine divided by the numbers of days filled plus the days' supply for the final visit (Robertson *et al*., 2008). The therapy intensification (TI) was defined as the physician's behavior to add hypertensive medicine up to 4 items and/or to add the dosage when the patient's BP is ≥10mmHg

above the target (Maddox *et al*., 2010). The TI score and MPR were calculated based on the formulae with

Excel Program

The systolic BP targets for the comorbid and without comorbid subjects were 130 and 140mmHg respectively. The TI score was measured with standard-based method, i.e. the ratio of the observed medication increase minus numbers of predicted medication increases divided with number of clinic visits (Rose *et al*., 2009b). The TI score in this study had the range from -1 (no TI in all visits) to 0 (maximum TI). Unintended aggressive TI and TI done in normal BP was not considered as TI. Most subjects in this study were hypertensive with cardiovascular (CVD) comorbid patients. In the normal BP, the hypertensive medication increase was probably indicated for the CVD comorbid. The study outcome was measured as the final SBP, the difference between (Δ) pre-intervention and intervention periods, the odds ratio SBP reached the target, Δ mean-target SBP and Δ final-target SBP.

Statistical analyses

Data normality was done with Q-Q plot graph. Comparison between groups was analyzed with Student t-test or chi-square test for subjects' proportion, or paired t-test for the profile changes between periods within group. Some baseline variables were significantly-different between groups i.e. comorbid, SBP, MPR, and numbers of CVD medicine (Table 1). In the order to minimize the subjects' characteristic differences, the results in the intervention period were adjusted with those variables.

Monthly SBP between groups was presented in line-graphs; added with trend lines, equations, and coefficient determination (R^2); and analyzed with repeated measurement Anova. Comparison of the SBP reached the BP target was done with odds ratio analysis.

Weakness of study

Some variables contributed to the SBP outcome including the physician, nurse, patient, and environment factors and could not be controlled in this non-randomized intervention study. However, the study design with control group and the existence of pre-intervention profiles minimized with the effects of above mentioned variables.

RESULTS AND DISCUSSION

The subjects comprised of intervention (n=385) and non-intervention (n=271) groups. Both groups had similar age and proportion of males ($p>0.05$). Intervention subjects had lower proportion of subjects with comorbid ($p<0.01$), higher SBP, but similar mean SBP in pre-intervention period (Table I). The significantly different baseline variables were used for statistical adjustment in the intervention period.

Most of subjects in both groups (>78%) were prescribed with once daily dose of hypertensive medicines. These dosage forms were the appropriate hypertensive medicine selection according to JNCVII guideline (Chobanian *et al*., 2003). Valsartan and amlodipine were the most frequently prescribed hypertensive medicine. The TI consisted of the number and/or dosage hypertensive medicine increase. The number of hypertensive medicine was similar between groups. The result showed that the intervention subjects used more the higher dose-strength medicine at 53.2% (Intervention) compared to 48.3% (non-Intervention) $p>0.05$ including higher dose strength of calcium channel blockers (CCBs) at 19.0% (Intervention) compared to. 3.1% (non-Intervention) $p<0.05$ (Table II).

The TI score and MPR were the important factors in the subjects' BP control. The baseline MPR of the intervention subjects was lower than the non-intervention subjects but both groups had >0.80 baseline MPR that considered as high (Robertson *et al*., 2008). In the intervention period MPR was not different between groups ($p>0.05$). Based on the MPR, the BP feedback intervention did not decrease the subjects' adherence.

Intervention in this study was done to the physicians because the physician factor particularly TI was the most important factor in blood pressure control (Samuels *et al*., 2008, Vigen *et al*., 2012). Regardless the excellent subjects' adherence, the large proportion of the subjects failed to reach the BP target.

Table I. Baseline and pre-intervention period profiles of the intervention and non-intervention subjects

Characteristics	Intervention (n=385)	Non-intervention (n=271)	p-value
Male (%)*	41.6	44.2	0.43
Comorbid (%)*	78.7	91.5	<0.01**
Age (years)	64.1±10.1	64.2±8.8	0.94
Baseline SBP (mmHg)	144.1±15.8	139.6±13.8	<0.01**
Mean SBP (mmHg)	141.6±12.2	142.0±12.9	0.69
Visit Frequency	4.8±1.4	4.6±1.4	0.11
TI-Score	-0.40±0.29	-0.36±0.27	0.10
MPR	0.82±0.22	0.86±0.17	0.03**
Antihypertensive Medicine	1.6±0.8	1.6±0.7	0.69
Cardiovascular Medicine	3.5±1.5	3.2±1.4	<0.01**

* = chi-square test for categorical variables (continuous variables used Student T-test);
** = significantly different between groups

Table II. Profile and proportion of the antihypertensive medicine between intervention and non-intervention subjects

Antihypertensive	Intervention		Non-intervention	
	Unit	%	Unit	%
Amlodipine	958	22.1	1022	31.4
Valsartan	1103	25.4	486	14.9
Bisoprolol	460	10.6	280	8.6
Diltiazem	567	13.1	41	1.3
HCT	172	4.0	252	7.7
Irbesartan	168	3.9	238	7.3
Candesartan	30	0.7	324	10.0
Nifedipine (controlled-release)	255	5.9	60	1.8
Lisinopril	76	1.8	195	6.0
Clonidine	220	5.1	13	0.4
Others	331	7.6	345	10.6
once daily antihypertensive	3420	78.8	2563	78.7
higher dose strength (p=0.22)**	2309	53.2	1573	48.3
**controlled release CCB (p=0.02)	825	19.0	101	3.1

* proportion comparison analyzed with chi-square test
** higher dose strength medicine included controlled-release CCB (diltiazem or nifedipin)

This finding was intensely related to the relatively low TI score. The TI was the stronger factor than MPR in BP control (Rose *et al.*, 2009, Maddox *et al.*, 2010). The TI score in the intervention group was not significantly better than the control group (Table III). From the interview with the intervention physicians, four physicians stated that they did not rely on the clinic BP data for the treatment adjustment due to higher BP measured in the clinic.

Though the TI score of the intervention group was not significantly different from the non-Intervention group, the intervention group had the improvement of the TI score from-0.40 in baseline (Table I) to -0.36 in the final follow up (Table III). The increase of TI score in intervention group improved the subjects' BP control significantly (Table IV).

Table III. Post-intervention profile and the reduction of blood pressure between intervention vs. non-intervention subjects

Characteristics	Intervention (n=385)	Non-intervention (n=271)	p-value	** adjusted p-value
Final SBP (mmHg)*	138.2±17.2	140.6±15.4	0.07	<0.01
Mean SBP (mmHg)	140.4±10.8	140.6±10.0	0.79	0.07
TI-Score	-0.36±0.24	-0.40±0.24	0.03	0.08
MPR	0.83±0.22	0.85±0.16	0.15	0.83
Antihypertensive Medicine*	1.6±0.80	1.7±0.7	0.09	<0.01
Cardiovascular Med.	3.9±1.4	3.4±1.6	<0.01	0.61
ΔFinal–Target SBP (mmHg)*	-6.1±17.3	-9.6±15.5	<0.01	<0.01
ΔMean–Target SBP (mmHg)	-8.3±11.5	-9.7±10.4	0.12	0.10
ΔFinal–Baseline SBP (mmHg)*	5.9±20.3	-0.9±20.0	<0.01	<0.01

* significantly different between groups;
**adjusted with significantly different variables in baseline/period 1.

Table IV. Proportion of mean sbp and final follow-up sbp compared to sbp target in intervention vs. non-intervention subjects

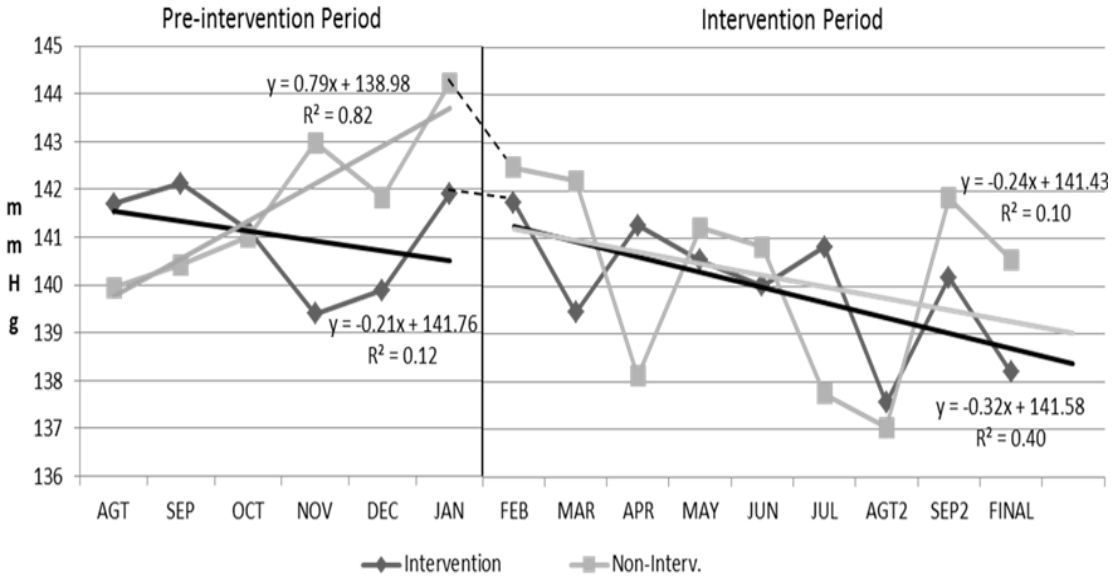
	Mean SBP			Final SBP		
	Intervention (%)	Non-interv. (%)	p-value	Intervention (%)	Non-interv. (%)	p-value
Not reached SBP target	75.3	82.7	0.04	51.2	59.4	0.16
Reached SBP target	24.7	17.3		48.8	40.6	
Odds Ratio Reached BP Target	OR:1.5 (CI95%:1.0-2.2) p-value:0.027 adjusted p-value: 0.208			OR:1.4 (CI95%:1.0-1.9) p-value:0.022 adjusted p-value: 0.023		

Reach SBP target = SBP was equal to or lower than SBP target ;
p-value was analyzed with chi-square test.

The final SBP in both groups was higher than the target and the proportion of the subjects with the mean SBP reached target was low. The intervention subjects had better SBP parameters significantly than the non-intervention group including final SBP, Δfinal-baseline SBP, Δfinal-target SBP ($p<0.01$) (Table III), and the proportion of subjects with the final follow up SBP and mean SBP reached the SBP target with OR 1.4(CI95%:1.0-1.9, adjusted $p<0.02$) and OR 1.5(CI95%:1.0-2.2, adjusted $p<0.21$) respectively (Table IV).

The line graphs described the monthly SBP in pre and intervention periods. In the intervention period monthly SBP of both groups had negative linear trend lines which indicated the SBP improvement in the final follow-up. The intervention group in the intervention period had better equation of the trend line and higher coefficient determination (R^2) vs. the non-intervention subjects (Figure 1).

The monthly SBP with the repeated measurement Anova was similar in the test within-subjects effects and the test between-subjects. This result was probably invalid due to relatively few subjects 29.6% in the intervention vs. 21.8% in non-intervention groups with 14 visits (100% persistence during the study). The repeated measurement analysis was applicable only in the subjects with 100% persistence.



Repeated measurement Anova: test within-subject effects p=0.48; test between-subjects effects p=0.50

Figure 1. Monthly Systolic Blood Pressure, Trend line, and Equation of Intervention vs. Non-Intervention Subjects

The intervention subjects had the significantly better SBP profiles with the following variables: the final SBP, the difference between (Δ) final–target SBP and Δfinal-baseline SBP, the proportion of subjects with mean SBP reached the target, OR the final SBP reached the target, the equation and the coefficient determination (R^2) of the monthly SBP trend line.

The feedback intervention was recommended to be continued in the future by the pharmacists in the hospitals. The feedback intervention might be possible conducted with the computer-based medical information as reminder information e.g. the data of BP would be high-lighted when it was higher than the target. During the study and the interview with the physicians, it was known that generally the physicians were not recognized the uncontrolled BP in the previous visits and did not refer the BP data to intensify the therapy. The reminder information aimed at supporting the physicians to intensify the therapy of uncontrolled BP. This feedback is also applicable in hyperlipidemic and diabetic patients.

CONCLUSION

The blood pressure feedback intervention to physicians improved of the blood pressure control of hypertension subjects in Indonesian Hospitals.

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