

## **Home blood pressure monitoring is a useful measurement for patients with hypertension: a long-term follow-up study.**

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### **Abstract**

**Objective:** To evaluate the long-term effects of Home Blood Pressure (HBP) monitoring, in order to make an efficacy control on hypertensive patients.

**Methods:** In a prospective, double-blind, randomized study, we enrolled 1183 hypertensive patients registered in the hypertension management center of the community between July 2011 and December 2015. The patients were randomly divided into the control group (n=596) and the self-observation group (587). HBP monitoring was performed each day for 5 years in the self-observation group. Blood Pressure (BP) was performed in the hypertension management center of the community each week for 5 years in the control group. BP data were collected by community, and physicians would adjust the therapeutic regimen according to the data during the follow-up period.

**Results:** 533 subjects in the self-observation group and 499 subjects in the control group completed the entire follow-up. The systolic pressure of patients in the self-observation group decreased by (4.3 ± 3.2) mmHg (P<0.05), the diastolic pressure decreased by (3.5 ± 2.5) mmHg (P<0.05). The systolic pressure of patients in the control group decreased by (3.9 ± 3.1) mmHg (P<0.05), the diastolic pressure decreased by (3.0 ± 2.5) mmHg (P<0.05).

**Conclusions:** HBP monitoring could be an effective method to improve hypertension control; it could be incorporated into the usual care of hypertensive patients in the hypertension management center of the community.

**Keywords:** Blood pressure (BP), Home blood pressure (HBP) monitoring, Hypertension, The diastolic pressure, The systolic pressure.

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### **Introduction**

Hypertension is a widespread disease and an important risk factor for many diseases, such as cardiovascular diseases [1], kidney diseases [2]. Most clinical managements dependent on Blood Pressure (BP) which is based on BP readings in the hospital [3,4]. Although the widely publicized acknowledgment of high prevalence, associated morbidity and mortality, diverse anti-hypertensive medications to prevent, only approximately half of patients with hypertension have achieved the goal BP (BP<140/90 mmHg) [5,6]. In recent years, Home Blood Pressure (HBP) monitoring was endorsed by international guidelines, because it overcomes many of the limitations of traditional BP measurement [7,8]. HBP monitoring is cheaper and easier to perform than clinical BP monitoring [9,10]. It not only provides multiple measurements of BP more accurately reflects a person's BP, also provides information on day-by-day BP variability under relatively well-controlled conditions [11,12].

In this study, we addressed the question whether HBP is operable in the society with its known convention and reduction of BP which might also affect the community measurements of hypertension patients [8].

### **Method**

#### ***Study design and patients***

**Inclusion criteria:** 1) all patients with a physician-reported diagnosis of essential hypertension were registered in the hypertension management center of the community; 2) age over 18 years; 3) stable condition with/without antihypertensive drug in maximum tolerable doses of different classes.

**Exclusion criteria:** 1) substantial valvular heart disease; 2) pregnancy or planned pregnancy during the study; 3) history of myocardial infarction, unstable angina/cerebral vascular event

in the previous six months; 3) renal artery stenosis and/or previous renal artery intervention; 4) secondary hypertension.

### Procedure and follow-up

The study was performed between July 2010 and December 2015. It was approved by the ethic committee of Zhuji Central Hospital. Before enrolment each patient provided written informed consent. The patients were randomly divided into control group (n=596) and self-observation group (587). Data were collected through face-to-face interviews, clinical examinations, and testing by our research center. The general condition of patients was listed in Table 1.

The patients in the self-observation group owned a validated and approved electronic device for measuring BP at home and recorded their morning BP and malaise BP each day. Morning BP were made within 1 h of awakening, malaise BP were made after seated and rested for at least 5 min. BP measurements were performed using an automatic device, HEM-7121 (Omron Healthcare Co. Ltd., Kyoto, Japan).

The patients in the control group were measured and recorded BP in the community at the morning each month. BP were made before breakfast or taking any drugs, with the patient seated and rested for at least 5 min.

All patients' serum total cholesterol, education, smoking and alcohol drinking considered as covariates were determined by standard laboratory measurements each month. Clinical characteristics of Body Mass Index (BMI) and use of antihypertensive medication were inquired and measured each month either.

### Statistical analysis

Data are presented as mean  $\pm$  SD, paired t test was used to determine significant difference between two groups. ANOVA on Ranks (RANOVA) was applied where applicable comparing both groups. Missing data were excluded from the statistical analyses. Two-tailed values of  $P < 0.05$  were considered to indicate statistical significance. All statistical analyses were performed with SPSS statistical software (SPSS 20 Inc., Chicago, USA).

## Result

### Baseline characteristics

There were 1183 patients participated in this study, 1032 patients completed 5 years' follow-up. With regard to the concordance between self-observation group and control group, 22 patients in self-observation group and 14 patients in control group dropped out for moving to another community, 22 patients in the self-observation group and 76 patients in the control group dropped out for refusing to complete the follow-up, 10 in self-observation group and 7 in control group were dead. These patients' data were excluded from statistical analysis for this time point. Baseline characteristics for self-observation group as well as Control Group (CG) are shown in

Table 1. There were no statistical differences for number of characteristics between the two groups at baseline ( $P < 0.05$ ).

**Table 1.** Baseline characteristics of both groups at baseline.

Characteristics	Self-observation group (n=533)	Control group (n=499)	p-value
Gender			
Male	290	276	>0.05
Female	243	223	>0.05
Age(years)	63.5 $\pm$ 11.4	64.5 $\pm$ 10.2	>0.05
Diabetes mellitus	23%	32%	>0.05
Adiposities	64%	72%	>0.05
Smoking	32%	34%	>0.05
BMI at the baseline (kg/m <sup>2</sup> )	28.1 $\pm$ 3.4	27.5 $\pm$ 3.7	>0.05
Weight at the baseline (kg)	76.5 $\pm$ 19.4	78.5 $\pm$ 18.8	>0.05
Serum total cholesterol (mmol/l)	6.1 $\pm$ 0.7	5.9 $\pm$ 0.6	>0.05
Education			
Middle school	239	217	>0.05
High school	172	142	>0.05
University	122	140	>0.05
Alcohol drinking	218	187	>0.05

Throughout the BP variance of five years, significant reductions were noted baseline/5 years for mean systolic BP/mean diastolic BP in both groups ( $< 0.05$ ). The proportion of patients improved at goal BP ( $< 140/90$  mmHg) in the follow-up period were 85.37% to 79.96% compared self-observation group to control group. A 2-tailed t test was used to compare the sample means in each group. The systolic pressure of patients in self-observation group decreased by (4.3  $\pm$  3.2) mmHg ( $P < 0.05$ ), the diastolic pressure decreased by (3.5  $\pm$  2.5) mmHg ( $P < 0.05$ ). The systolic pressure of patients in control group decreased by (3.9  $\pm$  3.1) mmHg ( $P < 0.05$ ), the diastolic pressure decreased by (3.0  $\pm$  2.5) mmHg ( $P < 0.05$ ). A decrease in mean systolic BP was statistically significant in self-observation group and control group ( $P < 0.05$ ). An increase in mean diastolic BP was also statistically significant in self-observation group and control group ( $P < 0.05$ ).

**Table 2.** The BP variance of both groups in the follow-up period.

		Self-observation group (n=533)	Control group (n=499)	p-value
Baseline	Mean systolic BP	138	142	>0.05
	Mean diastolic BP	91	94	>0.05
1 year	Mean systolic BP	135	135	>0.05
	Mean diastolic BP	88	89	>0.05

2 years	Mean systolic BP	128	132	>0.05
	Mean diastolic BP	83	87	>0.05
3 years	Mean systolic BP	126	122	>0.05
	Mean diastolic BP	75	76	>0.05
4 years	Mean systolic BP	126	124	>0.05
	Mean diastolic BP	78	77	>0.05
5 years	Mean systolic BP	121	127	<0.05
	Mean diastolic BP	76	79	>0.05

In the follow-up period, 78 patients in self-observation group and 105 in the control group could not control BP under the normal range. Overview all patients in the follow-up, 79 patients have stroke, 7 patients developed into hypertensive heart disease and needed hospitalization and treatment. Analysing the patients' BP records, we found out that most of the patients could not strictly accordance with the method we have mentioned. The patients did not record every day in the morning and their BP records did not show any change or even higher along with time. Consider total cholesterol as risk factors of stroke, we further analysed the relationship between serum total cholesterol and stroke. It showed that there was no significant difference between self-observation group and control group (P<0.05). We further divided each group into stroke group and non-stroke group based on the occurrence of stroke. It showed that was significant difference between stroke group and non-stroke group in both self-observation group and control group (Table 3, p<0.05).

**Table 3.** The serum total cholesterol of both groups in the follow-up period.

	Self-observation group (n=533)		Control group (n=499)	
	Stroke group (n=34)	Non-stroke group (n=499)	Stroke group (n=45)	Non-stroke group (n=454)
Baseline	6.4 ± 0.9	5.5 ± 0.7	5.9 ± 0.8	5.7 ± 0.7
1 year	6.2 ± 0.7	5.6 ± 0.6	6.1 ± 0.5	5.6 ± 0.6
2 years	6.2 ± 0.6	5.5 ± 0.8	6.2 ± 0.6	5.5 ± 0.7
3 years	6.3 ± 0.7	5.4 ± 0.5	6.2 ± 0.7	5.4 ± 0.8
4 years	6.2 ± 0.8	5.4 ± 0.4	6.1 ± 0.6	5.4 ± 0.8
5 years	6.2 ± 0.6	5.5 ± 0.5	6.1 ± 0.5	5.4 ± 0.6

### Discussion

Recently reports have a review demonstrating that HBP monitoring has a small but clinically significant effect on the reduction of BP [13,14]. In this study it showed that HBP monitoring can be an effective method to improve hypertension control [15]. The results indicate that self-management of monitoring BP is as good as monitoring by doctors in the hospital [16]. Daily regular monitoring is critical to successful management of hypertension and other associated

chronic conditions [9,17]. In this study patients in self-observation group became more engaged in their hypertension care, which improved efficacious control of hypertension [9,18]. In consideration of the availability and efficacy of HBP monitoring, it could be incorporated into the usual care of hypertensive patients in the hypertension management center of the community [4,19,20]. Day-by-day BP monitoring at home could intuitive reaction the BP variance which is associated with the severity of target organ damage and cardiovascular outcomes [21-23]. BP variance is influenced by many pathological conditions, such as neural, and humoral factors as previous reports have mentioned [24-26]. The morning surge of BP in Asians is more associated with the incidence of cardiovascular events than that in whites [27,28]. Thus, BP monitoring including at night and in the morning is especially important for Asian patients away from organ damage [29].

In this study, we found that total cholesterol is associated with stroke. We found that patients with high total cholesterol had a higher rate of poor outcomes as many reports have mentioned [30,31]. Consider the BP' records of those patients with organ damage or stroke, we thought that the perseverance of keeping healthy life style is the most advantageous factors of hypertension patients.

Patients who were inconvenient to the hospital for monitoring their BP could be provided more measurements which is relatively easy to accomplish, is cost-effective, and has been shown to have an increasing role in the management of BP to regularly control BP.

### Conclusion

HBP monitoring was an effective method to improve hypertension control and would be incorporated into the usual care of hypertensive patients in the hypertension management center of the community.

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