Self-Monitoring of Blood Pressure for Improving Adherence to Antihypertensive Medicines and Blood Pressure Control: A Randomized Controlled Trial

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BACKGROUND
Self-monitoring is reported to have limited efficacy for hypertension management in high-income countries. In this study, we aimed to evaluate the effect of self-monitoring on blood pressure (BP) control in an Iranian population.

METHODS
A randomized controlled trial was conducted on 196 mild to moderate hypertensive patients in an outpatient cardiovascular clinic. Patients in the intervention group received a wrist self-monitoring device and were educated to measure and document their BP daily during the study period (24 weeks). Patients in the control group received usual care. Three follow-up visits with the physician were scheduled for all patients (weeks 4, 12, and 24), and the investigator assessed adherence to medications after each visit (pill counting). The primary outcome (BP) was compared between groups using repeated-measure analysis of variance.

RESULTS
One hundred ninety patients completed the study. Systolic BP (144.4 ± 7.4 vs 145.9 ± 6.4 mm Hg) and diastolic BP (85.5 ± 6.9 vs. 85.1 ± 7.7 mm Hg) were similar between groups at baseline. The trend of BP was not significantly different between groups during the study period. Systolic and diastolic BP decreased significantly in both groups at the first follow-up visit (systolic BP: 132.6 vs. 133.4 mm Hg; diastolic BP: 77.4 vs. 77.2 mm Hg). In the intervention group, we observed a small continued decrease in diastolic BP up to week 24 BP ($P = 0.01$). Both groups showed adherence rates >95% during the study period.

CONCLUSIONS
Our study could not confirm that self-monitoring can improve BP control in patients with frequent medical visits.

Keywords: adherence to medication; antihypertensive medication; blood pressure; compliance; hypertension; pill counting; self-monitoring.

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Hypertension is a major risk factor for development of cardiovascular disease, which is the principal cause of death worldwide.[1] Evidence shows that appropriate management of hypertension could reduce mortality rate of stroke and coronary heart disease.[2] Nevertheless, several studies have revealed that most patients with hypertension cannot achieve treatment goals.[2–5] One of the major causes of uncontrolled hypertension is patients' inadequate adherence to therapeutic regimen.[6–8]

Adherence is defined as the extent to which individuals' behavior complies with healthcare professional advice about lifestyle and prescribed medications.[9] Adherence to medications consists of following the provider's advice with respect to timing, dosage, and frequency of consuming medicines in a defined period. In most chronic medical conditions, particularly hypertension, a growing body of evidence shows that nonadherence is often observed among patients and is associated with adverse outcomes and higher healthcare costs.[10] Adherence rate in hypertensive patients is estimated to be 50%–70%.[11] In a recent systematic review of national literature, our findings showed that Iranian patients with cardiovascular diseases do not have sufficient adherence to medications (40%–60%).[12] Several factors may affect

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medication adherence, including adverse drug reactions, forgetfulness, and absence of physical signs of blood pressure improvement that motivate medication adherence.[13] Some interventions aiming to improve adherence to antihypertensive medications include simplified dosing regimens, patient education, motivational/supportive programs, and reminder systems.[11] One of these supportive interventions is the self-monitoring of blood pressure, and several studies have reported its beneficial effects in improving adherence to prescribed medications.[1,6,14] Self-monitoring has been proposed as an adjunct method for blood pressure management because it can increase the patients' awareness of their blood pressure fluctuations and facilitate their participation in the treatment plan. Moreover, self-monitoring can provide further information about the effectiveness of the treatment plan for healthcare providers.[1,15] Despite the advantages mentioned, there are some studies that have failed to show significant benefits from self-monitoring in adherence improvement or hypertension control.[13,16] In addition, few studies have evaluated the effect of self-monitoring in low- and middle-income countries where the hypertension care standards may be different from those in high-income countries.[17]

Therefore, we investigated the efficacy of self-monitoring on blood pressure control and adherence to antihypertensive medications in patients with mild to moderate hypertension in an Iranian population.

METHODS

Study design

A randomized, controlled trial (clinical trial registration number: NCT01525108) was conducted at an outpatient cardiovascular clinic from February 2012 to March 2013. The medical care was provided by a team that included a cardiologist, a general practitioner, and a staff nurse. The study protocol was approved by the Research Ethics Committee of the Tehran University of Medical Sciences, Tehran, Iran. All study participants provided written informed consent. During the study period, no concurrent studies or interventions were carried out at the clinic to improve patients' lifestyle.

Inclusion criteria

The following inclusion criteria were used: patients aged >18 years; new cases with a diagnosis of mild to moderate hypertension (stage I: 140/90–159/99 mm Hg) or those already on antihypertensive treatment but not controlled according to Joint National Committee 7 (JNC 7) guideline; patients who did not have an electronic device for measuring blood pressure at home.

Exclusion criteria

The following exclusion criteria were applied: patients with secondary hypertension, severe cardiovascular comorbidities, contraindication for antihypertensive drugs, or serum creatinine >1.5 mg/dl. Patients were withdrawn from the study if adverse drug reactions caused cessation of medication therapy.

Sample size and randomization

Study sample size was calculated based on the assumptions of an expected difference of 5 mm Hg, SD of 10 mm Hg, significance level of 0.05, and power of 90% (n = 170 participants). However, we assumed a 15% loss to follow-up and planned to recruit 196 patients. Balanced block randomization was used to allocate patients to the study groups. Two of the authors (A.S. and Z.J.) had access to the randomization list, and they were not involved in the recruitment process at the clinic. The author who recruited patients (M.H.) used telephone calls to ask for an allocation order after a patient signed the informed consent.

Study groups

Intervention group. Patients received a wrist blood pressure measurement device (SHB-200w, P/N 323101356; Samsung C&T, Seoul, Korea). They were instructed how to use the device and document their measurements in a logbook. They were advised to measure their blood pressure once daily at a specific time every day. The logbook was checked at each visit by the investigator and was collected at the final visit for data analysis.

Control group. Patients received usual care as suggested by the physician.

At the recruitment day, the following 3 steps were carried out: (i) confirmation of the inclusion and exclusion criteria; (ii) informing of the patient about the study and signing of the written consent; and (iii) obtainment of a demographic and clinical history. The investigator contacted each patient before scheduled follow-up visits. During the study period, patients were asked about possible side effects of their medications, and the drug therapy regimen was modified by the physician if necessary to control blood pressure. Each patient was provided with a prescription for the required amount of antihypertensive drugs until the next visit. Three follow-up visits were scheduled for all patients at 4, 12, and 24 weeks during the study; these visits consisted of consultation with the medical care team and outcomes assessment by the investigator.

Study outcomes

Blood pressure. The primary outcome of the study was office-based blood pressure, which was measured by a digital upper arm device (BM 16, Item no. 4211125/652.02/9; Beurer, Ulm, Germany). At baseline and each follow-up visit, blood pressure was measured twice with a 10-minute interval in resting position. The mean of the 2 measurements was documented. For the intervention group, the average of self-monitoring figures during the last week before each follow-up visit was documented for analysis.

Drug use at the baseline. We used pill counting to assess patients' drug use at the baseline, as per the study protocol.

After trying the pill counting on several recruited patients, we realized that the method was inaccurate and unreliable because the number of prescribed and consumed pills before recruitment could not be evaluated by the investigator. Hence we discontinued the pill counting at the baseline. To have an indication of drug use at the baseline, we used a translated version of the Morisky Medication Adherence Scale 8 (Morisky scale) on a random subsample of remaining patients (the translation had not been validated).

Medication adherence. Pill counting was the main method to calculate patients' adherence to antihypertensive medications during the study period (the 3 follow-up visits). The investigator asked each patient to bring the leftover medications to the clinic. To reduce pill dumping, the investigator tried to convince patients not to hide actual consumption by stating that the physician will not be informed about their performance. The pill counting was carried out in a separate room not exposed to the medial care team. Number of consumed pills was calculated and divided by the number of total prescribed pills for each antihypertensive drug. The adherence rate for each drug was calculated separately at each follow-up visit. An average of the adherence rates to all antihypertensive medications was computed as the final adherence rate at each time point.[18] An arbitrary cutoff threshold of 80% was considered an acceptable adherence rate.

Statistical analysis

Baseline characteristics were compared between groups using χ^2 or Student t test according to type of the variables. Primary outcome was analyzed by repeated-measure analysis of variance. Within-group comparisons of the primary outcome were carried out using paired t test, and adherence to medication was analyzed using independent sample t test. P values <0.05 were considered significant.

RESULTS

A total of 196 patients met the inclusion criteria and were recruited in the study (98 patients in each group). At the end of the trial period, 94 patients in the intervention group and 96 patients in the control group completed the study. One patient in each group refused to continue after recruitment. Three patients in the intervention group did not follow the self-monitoring protocol and were excluded. In the control group, 1 patient was hospitalized during the study period for psychiatric disorders and was not able to continue the study. The baseline characteristics of the study population are summarized in Table 1. The number of office visits was the same for all patients in our study; however, some patients might have had delays in attending the appointments.

Blood pressure

No significant difference was observed between study groups regarding baseline systolic blood pressure (144.4 ± 7.4 vs 145.9 ± 6.4 mm Hg; P = 0.11) and diastolic blood pressure (85.5 ± 6.9 vs 85.0 ± 7.7; P = 0.66). Results of the repeated-measure analysis of variance revealed no significant interaction between study groups and systolic or diastolic blood pressure during the study (sphericity not met, Greenhouse-Geisser correction was used; P = 0.36 and 0.65, respectively) (Figure 1). Moreover, test of within-subject contrasts comparing the fluctuations of systolic or diastolic blood pressure in consecutive measurement times (baseline and 4 weeks, 4 and 12 weeks, 12 and 24 weeks) did not show any significant differences between groups (all P > 0.05).

However, within-group comparisons revealed notable trends in the study groups: systolic blood pressure at the first follow-up visit (week 4) was significantly lower than that at the baseline in both intervention and control groups (mean difference: 11.6 ± 8.6 vs. 12.5 ± 8.2 mm Hg; P < 0.001). Diastolic blood pressure was also significantly lower in comparison with the baseline in both intervention and control groups (mean difference: 8.1 ± 6.7 vs. 7.9 ± 8.6 mm Hg; P < 0.001). The trend of blood pressure was slightly different at 12- and 24-week follow-ups. The systolic blood pressure did not alter in any of the study groups (P > 0.05). On the other hand, the diastolic blood pressure significantly decreased in the intervention group comparing 4- and 24-week follow-ups (mean difference: 1.3 ± 4.8 mm Hg; P = 0.01).

Analysis of self-monitoring figures in the intervention group revealed no significant difference among 4-, 12-, and 24-week follow-up visits (120.4 ± 11.7 mm Hg, 121.9 ± 11.5 mm Hg, and 122.2 ± 11.5 mm Hg, respectively; P = 0.12). In addition, the corresponding values for diastolic blood pressure were also not significantly different (73.9 ± 7.9 mm Hg, 73.6 ± 7.9 mm Hg, and 74.5 ± 11.1 mm Hg; P = 0.61).

Medication adherence

Because the pill counting proved unreliable for assessing the baseline drug use, the results of applying Morisky scale on a random subsample of patients (n = 87) suggested that 56.3% of the patients had low or moderate adherence to drug use.

At the follow-up visits using the pill counting method, approximately all study patients showed adherence rate >95% which was above the threshold of acceptable adherence (80%). The difference between study groups was statistically significant at all 3 follow-up visits (all P < 0.05). However, the effect size was small, and the differences were within the margin of acceptable adherence rate for hypertensive patients (Table 2). The number of antihypertensive medications was not different between groups at the follow-up visits (Table 2).

DISCUSSION

The use of self-monitoring as an adjunct to office blood pressure evaluations is favored by many international guidelines in hypertension management.[19,20] In a systematic review and meta-analysis in 2011, the magnitude and mechanisms of self-monitoring impact on blood pressure reduction were evaluated. The authors concluded that self-monitoring significantly decreased systolic and diastolic

Table 1. Demographic and clinical characteristics at baseline

Characteristic	Intervention group (n = 97)	Control group (n = 97)
Age, y	59.6 (10.3)	57.8 (11.1)
Female sex	58 (59.8)	61 (62.9)
Smoking history	7 (7.2)	8 (8.2)
Comorbidities		
Diabetes	21 (21.6)	27 (27.8)
Hyperlipidemia	85 (87.6)	78 (80.4)
Cardiovascular disease	50 (51.5)	50 (51.5)
No. of co-medications consumed daily	4.2 (1.9)	4.1 (1.8)
Hypertension duration, y	6.6 (6.9)	6.0 (5.3)
No. of new hypertensive cases	4 (4.1)	6 (6.6)
No. of patients with HTN diagnosis <6 months	14 (14.4)	10 (10.3)
Baseline office BP, mm Hg		
Systolic BP	144.4 (7.4)	145.9 (6.4)
Diastolic BP	85.5 (6.9)	85.0 (7.7)
Antihypertensive medications		
Angiotensin-converting enzyme inhibitors	29 (29.9)	38 (39.2)
Angiotensin II receptor antagonists	48 (49.5)	47 (48.5)
Calcium channel blockers	31 (31.9)	19 (19.6)
β-Blockers	87 (89.7)	84 (86.6)
Diuretics	19 (19.6)	19 (19.6)

Data are reported as mean (SD) for continues variable and No. (%) for categorical variables.
Abbreviations: BP, blood pressure; HTN, hypertension.

blood pressure; however, the effect size seemed to be relatively small (reduction in systolic blood pressure: −2.63 (95% CI, −4.24 to −1.02) mm Hg; diastolic blood pressure: −1.68 (95% CI, −2.58 to −0.79) mm Hg). The effectiveness became more significant if self-monitoring was accompanied by supportive programs such as telemonitoring interventions. Nevertheless, very few studies have evaluated the effect of self-monitoring in low- and middle-income countries.[17]

As seen in our result, blood pressure decreased significantly in both groups through the first month of the study and was consistently maintained in both groups without any significant differences between them. Thus, the results from this study could not support the clinically meaningful effect of self-monitoring on blood pressure control. In line with our findings, Madsen *et al.* concluded that antihypertensive treatment based on self-monitoring was similar to usual monitoring of office blood pressure. They showed that the decrease in systolic blood pressure was not significantly different in self-monitoring group in comparison with the usual-care group in a 6-month follow-up period.[21] In another study conducted by Vetter *et al.* (SVATCH study), it was shown that self-monitoring can lead to a slight improvement of blood pressure control, but they could not demonstrate a significant, clinically important additional benefit of self-monitoring for hypertension control.[22]

In this study, adherence to medications was not adequate according to the Morisky scale at baseline. At the follow-up assessments by pill counting, the adherence rates were revealed to be clinically adequate in both groups, with the average >95%. Although the difference between groups was statistically significant, we prefer not to interpret this finding as a clinically relevant result for 2 reasons: First, the adherence rates were >95% at all 3 follow-up visits in both groups,which were far greater than the arbitrary threshold of 80% generally accepted as adequate adherence in hypertensive patients. Second, the difference between groups was very small (approximately 2%), which might not have any implications for clinical practice. A number of other studies have addressed the impact of self-monitoring on adherence, but controversies exist among their findings. In a randomized clinical trial by van Onzenoort *et al.*, self-monitoring as an adjunct to office blood pressure measurement resulted in higher adherence to treatment, but similar to our results, the difference of adherence rates between 2 groups was not clinically significant.[13] On the contrary, some studies have reported positive effects of self-monitoring on adherence. Result of a descriptive study revealed that patients who measured their blood pressure daily at home missed less drug doses than the patients who did not measure their blood pressure at all.[23] The result of another randomized controlled study by Marquez-Contreras *et al.* also showed an improved adherence rate in patients who carried out self-monitoring in comparison with usual care.[6]

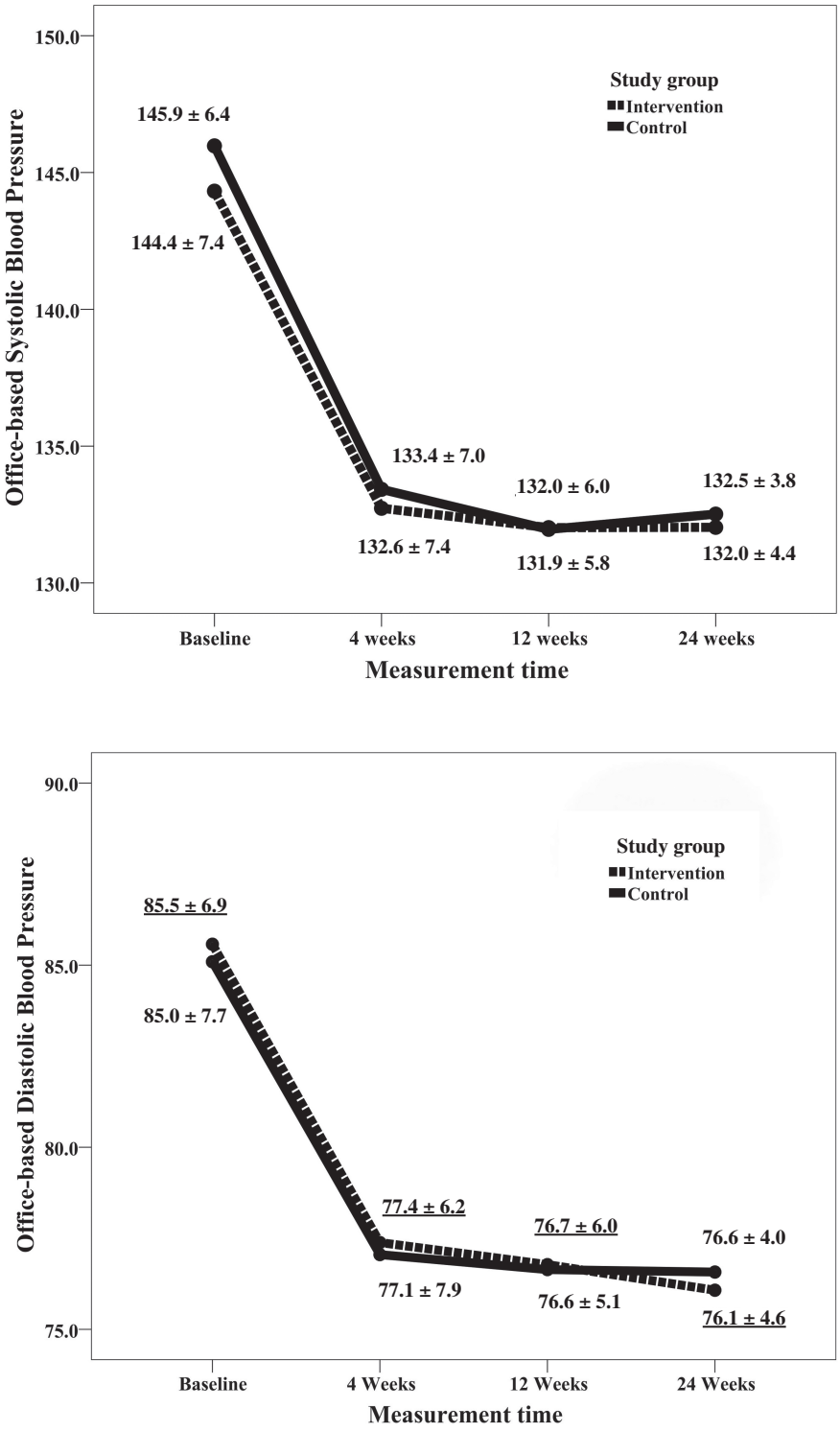

Figure 1. Trends of office-based systolic and diastolic blood pressure. Underlined numbers are related to the "intervention group."

Considering our findings on medication adherence and blood pressure, we hypothesize that the study protocol, which consisted of 3 follow-up visits with the medical care team, might have resulted in improving the patients' adherence and blood pressure during the first month of study. There is another observation that strengthens our hypothesis. Our study showed that the patients in the intervention group experienced a consistent decrease in their diastolic blood pressure between the first and the third follow-up visits. Concurrently, the follow-up visits and the adherence monitoring became less intensive during the study as the time interval became wider (4, 12, 24 weeks). This coincidence

Table 2. Number of and adherence to antihypertensive medications in study groups

Adherence score	Intervention group (n = 97)	Control group (n = 97)	*P* value
Adherence 1 (baseline to week 4)	99.6 ± 3%	97.1 ± 9%	0.01
Adherence 2 (week 4 to week 12)	98.9 ± 5%	96.5 ± 7%	0.005
Adherence 3 (week 12 to week 24)	99.0 ± 5%	97.8 ± 3%	0.04
Mean no. of antihypertensive medications			
No. of medications 1 (baseline to week 4)	2.2 ± 0.7	2.1 ± 0.6	0.45
No. of medications 2 (week 4 to week 12)	2.2 ± 0.6	2.1 ± 0.6	0.61
No. of medications 3 (week 12 to week 24)	2.1 ± 0.7	2.1 ± 0.6	0.82

may suggest that self-monitoring might have significant positive effects on BP control for patients with less-intensive medical visits.

There are 2 possible factors that might have resulted in overestimation of adherence rate. First, monitoring of adherence (pill counting) could have motivated patients to adhere to their treatment plan. The effect of adherence monitoring is corroborated in a systematic review, which reported that compliance with antihypertensive medications were higher in clinical randomized trials compared with observational studies.[7] Second, the informed consent procedure might have resulted in a high rate of adherence. Patients who contribute to the pill counting and adherence monitoring process could be more willing to participate in such studies. Thus, overestimation of adherence rate should be considered in interpreting our study results.

From the standpoint of methodology, our study was a robust randomized controlled trial that provides adequate internal validity. The randomization protocol was highly concealed from the investigator by a telephone-based allocation procedure. We did not observe any significant differences at baseline between the study groups as a proof of randomization accuracy. The caregivers were also blind to the patients' allocated study group. However, a few caveats should also be mentioned.

We could not assess baseline adherence by pill counting method, and a translated version of Morisky scale was used in a subsample of patients to document baseline status. However, the translated version has not been validated in an Iranian population. Despite the limitations to the Morisky scale tool, the baseline BP of our study population could also confirm patients' inadequate adherence at the recruitment time (i.e., systolic BP: 144.4 ± 7.4 vs. 145.9 ± 6.4 mm Hg; diastolic BP: 85.5 ± 6.9 vs. 85.1 ± 7.7 mm Hg). We should also mention that the pill-counting method also possesses some intrinsic disadvantages, as mentioned in the previous paragraphs; nevertheless, it remains one of the most common adherence measurement tools.[24]

In conclusion, our study could not confirm that self-monitoring may be able to improve blood pressure control and adherence to antihypertensive medications in patients with a plan of frequent office-based monitoring by physician. Future studies should evaluate the self-monitoring effects on blood pressure control in other medical care plans and also use other adherence measurement tools, including the Medication Event Monitoring System and claims data.

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DISCLOSURE

The authors declared no conflict of interest.

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