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Assessment of the diagnostic accuracy of home blood pressure monitoring by patients

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ABSTRACT

Introduction: According to available guidelines, home blood pressure monitoring (HBPM) can be used to diagnose hypertension and monitor its treatment; however, its effectiveness has rarely been studied in developing countries, including Iran.**Objectives:** This study aimed to evaluate the diagnostic accuracy of HBPM, as compared with that of 24-hour ambulatory blood pressure monitoring (ABPM) and office blood pressure measurement (OBPM).**Patients and Methods:** This study was conducted on 28 patients suspected of having primary hypertension. The blood pressure of the patients was measured by four methods. Initially, blood pressure was measured by a non-physician using a digital sphygmomanometer in a clinic (OBPM-Digital). After about 1 hour, blood pressure was measured by a physician at the clinic using a mercury sphygmomanometer (OBPM-Mercury). In the third stage, the patient's blood pressure was monitored for 24 hours by the ABPM method. In the fourth stage, each subject used a digital sphygmomanometer to measure HBPM for seven consecutive days.**Results:** The blood pressure values measured through the ABPM method were significantly lower than those measured by other methods ($P < 0.05$). The prevalence of hypertension diagnosed by OBPM-Mercury, OBPM-Digital, HBPM, and ABPM method was 82%, 54%, 50%, and 21%, respectively. As compared with ABPM as the gold standard, the diagnostic accuracy of HBPM, OBPM-Digital, and OBPM-Mercury was 64%, 61%, and 32%, respectively. The frequency of white coat hypertension (WCH) diagnosed by HBPM and ABPM methods was 39% and 64%, respectively, and the frequency of masked hypertension (MH) diagnosed was 7% and 4%, respectively. The sensitivity, specificity, and diagnostic accuracy of HBPM, as compared with ABPM, in detecting MH were 100%, 96%, and 97%, respectively; in addition, as compared with WCH, they were 56%, 90%, and 68%, respectively.**Conclusion:** The findings of the present study showed that HBPM had higher diagnostic accuracy than OBPM in diagnosing hypertension. Also, HBPM was able to detect MH with a high level of diagnostic accuracy, and in more than two-thirds of cases, it was also able to detect WCH and diagnose patients with sustained hypertension.

Implication for health policy/practice/research/medical education:

Our study showed that home blood pressure monitoring can be used with high diagnostic accuracy in hypertension detection, determining its phenotypes, and monitoring its treatment.

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Introduction

Hypertension is one of the most important and well-known risk factors for cardiovascular diseases, chronic kidney disease, and cerebrovascular accidents. Based on World Health Organization (WHO) estimates, high blood pressure is 25% prevalent among the world's population

and is projected to reach 60% by 2025 (1).

Although office blood pressure measurement (OBPM) is primarily the usual method of diagnosing and treating hypertension, there may be significant differences between OBPM and out-of-clinic blood pressure measurements (2). There are two common methods of out-of-clinic

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blood pressure measurements, including automatic and outpatient ambulatory 24-hour blood pressure monitoring (ABPM) and home blood pressure monitoring (HBPM). As the main advantage of measuring blood pressure outside a clinic, it provides more natural and real values for patients' blood pressure, when they are away from a clinic environment. The use of these methods has led to the detection of phenotypes in patients with hypertension, including white coat hypertension (WCH) and masked hypertension (MH) (3). WCH occurs when a patient is diagnosed with hypertension when undergoing OBPM, though he/she has normal blood pressure outside a clinic. Conversely, when a patient's blood pressure is normal in the clinic but is high outside the clinic, this condition is called MH. These two phenotypes are very common in both treated and untreated patients, and it is not possible to detect them when measurements are performed only in a clinic (3,4).

It is of great importance to recognize hypertensive phenotypes because WCH is associated with a slight or no increase in cardiovascular events and mortality, as compared with normotensive people (5). In contrast, uncontrolled MH is associated with increased cardiovascular events and mortality (6). In practice, however, patients with WCH who are often treated are exposed to multiple side effects of drugs; besides, the disease can also impose high costs on patients and the health care system due to the widespread prevalence of hypertension. On the other hand, patients with MH who need to be treated are often undiagnosed and therefore, not treated. In general, the prevalence of WCH is estimated to be 40-30%, and the prevalence of MH is estimated to be 10%-30% (7).

Although ABPM is considered to be the gold standard for measuring blood pressure (8), its use is associated with a high cost. Moreover, ABPM is not available to all patients and in all centers. It is a good method for measuring blood pressure in certain cases, but it is not good for long-term monitoring of blood pressure. HBPM, on the other hand, allows the patient to measure and monitor blood pressure at every desired time and is associated with a high level of patient acceptance. In addition, the use of HBPM for monitoring patients undergoing treatment is associated with better control of blood pressure (9). However, it is necessary to train patients to use this method properly (10).

Objectives

Common guidelines for measuring blood pressure recommend using ABPM and HBPM to diagnose patients and monitor the process of treatment (7). However, the effectiveness of this method has rarely been studied in low-income and developing countries, including Iran. Also, the rate of the acceptance of blood pressure monitoring methods may vary among different races; hence, it is

necessary to consider clinical needs, patients' preferences, and cultural barriers in choosing an appropriate method for monitoring high blood pressure (11). Therefore, this study aimed to determine the diagnostic accuracy of HBPM, as compared with that of ABPM (as the gold standard method of measuring blood pressure), and OBPM.

Patients and Methods

Study design

This study was conducted on patients over 18 years of age suspected of having hypertension, which referred to a clinic. They either had a blood pressure of above 135/85 mm Hg at home or blood pressure of above 140/90 mm Hg in an office, or as diagnosed by a physician, had symptoms of hypertension, and needed further examination. Exclusion criteria were chronic hypertension, secondary hypertension, and unwillingness to participate in the study. The patients without access to the necessary items required for assessing blood pressure at home were excluded from the study. A total of 28 patients were non-randomly selected based on the order of admission. Written consent was obtained from all the patients.

After explaining the objectives and the method of measurements to each patient, the data on age, gender, weight, and height of the patients were recorded using a form. Then, the blood pressure of the patients was measured by four methods. First, using a digital sphygmomanometer and under appropriate conditions, systolic and diastolic blood pressures of the patients were measured twice by a non-physician by Omron digital sphygmomanometer (model: M3 HEM-7131-E, Omron healthcare Co., Japan), and the mean values were recorded as the values obtained from digital clinic blood pressure measurement (OBPM-Digital). Then, after about an hour, systolic and diastolic blood pressures of the patients were measured twice by a physician using a mercury sphygmomanometer. The mean values were recorded as office blood pressure measurements with a mercury sphygmomanometer (OBPM-Mercury).

In the third stage, using an ABPM device (Cardio Pro ABPM System device, ACT Co., Iran), the blood pressure of the patients was measured for 24 hours. The mean systolic and diastolic blood pressures during the phase of awakening, throughout the day, and during sleep time were measured every 20 minutes, and the total mean systolic and diastolic blood pressures were recorded. During the sleep phase, a 10%-20% reduction of systolic or diastolic blood pressure was considered as dipping, and an increase was considered as reverse hypertension. Moreover, if blood pressure was higher than 130/85 mmHg immediately after waking up, it was considered an increase in morning blood pressure (morning surge). The mean heart rate was also measured by ABPM. In the fourth stage, patients were trained to perform HBPM by Omron

digital sphygmomanometer (Model: M3 HEM-7131-E, Omron healthcare Co., Japan). To assess blood pressure at home, each patient was required to measure his/her blood pressure at home twice a day for seven consecutive days in the morning and evening and recorded it in a chart. When reviewing the charts, the measurements performed on the first day were excluded from the calculation, and the mean value of measurements performed in the next six days was considered the patient's blood pressure measured at home.

Systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg measured by OBPM (digital or mercury), systolic blood pressure ≥ 130 mm Hg, and diastolic blood pressure ≥ 80 mm Hg measured by ABPM, and systolic blood pressure ≥ 135 mm Hg and diastolic blood pressure ≥ 85 mmHg measured by HBPM were considered as hypertension. Besides, the presence of systolic or diastolic hypertension in each method was considered as the presence of hypertension in that method (7).

The phenotype of patients' blood pressure status was determined in OBPM measurements and compared with HBPM and ABPM. If the patient's blood pressure was normal in both methods, it was considered as a normotensive condition, and if hypertension was observed in both methods, it was considered as sustained hypertension. WCH was considered when the first method showed hypertension, and the second method indicated normal blood pressure. In the opposite case, the condition was considered as MH.

Statistical analysis

SPSS 25 statistical software was used for data entry and analysis. Frequency (percentage) was used to describe variables, and a paired *t* test was used to compare blood pressures measured by different methods. ABPM was considered the gold standard, and the diagnostic efficiency (sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy) of other methods was calculated. The diagnostic efficiency of HBPM in detecting each hypertensive phenotype was also assessed, as compared with ABPM. A $P < 0.05$ was set as the level of significance.

Results

Of all the participants, 18 patients (64%) were female, and ten people (36%) were male. The mean (SD) of the patients' age was 49 ± 10 years. The mean (SD) of peoples' height, weight, and body mass index (BMI) were 167 ± 11 cm, 75 ± 12 kg, and 27.1 ± 4.7 kg/m², respectively.

Table 1 and Figure 1 show the mean systolic and diastolic blood pressure measured by different methods, and they are compared with the values measured by ABPM. The mean (SD) of heart rate recorded by ABPM was 76 ± 10 beats per minute. In addition, 21 people (75%) had hypotension during the sleep phase, and 14 people

(50%) had morning hypertension. The highest levels of blood pressure were observed in cases measured by OBPM-Mercury. The values of blood pressure measured by OBPM-Digital, OBPM-Mercury, and HBPM were significantly higher than the values measured through ABPM ($P < 0.05$).

Table 2 and Figure 2 show the frequency of hypertension in different methods based on criteria defined in the methods section. The prevalence of hypertension had a decreasing trend in cases monitored by OBPM-Mercury, OBPM-Digital, HBPM, and ABPM methods, respectively. The frequency of hypertension measured by the OBPM-Mercury method was almost four times. The frequency of hypertension measured by OBPM-Digital and HBPM was more than twice higher than the frequency of hypertension measured by the ABPM method.

Table 3 shows the diagnostic efficiency (sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy) of different methods of measuring blood pressure compared to ABPM as the gold standard. HBPM had the highest diagnostic accuracy, while OBPM-Mercury blood pressure measurement had

Table 1. Mean systolic and diastolic blood pressure measured in different methods

Method		Mean (SD)	P value*
ABPM	Systolic, mm Hg	121 \pm 19	-
	Diastolic, mm Hg	72 \pm 13	-
OBPM-Mercury	Systolic, mm Hg	143 \pm 19	<0.001
	Diastolic, mm Hg	91 \pm 15	<0.001
OBPM-Digital	Systolic, mm Hg	135 \pm 24	0.001
	Diastolic, mm Hg	84 \pm 15	<0.001
HBPM	Systolic, mm Hg	130 \pm 16	0.005
	Diastolic, mm Hg	83 \pm 8	<0.001

* Comparison of different methods with ABPM mean, paired *t* test. ABPM: Ambulatory blood pressure monitoring, OBPM-Mercury: office blood pressure measurement with mercury sphygmomanometer, OBPM-Digital: office blood pressure measurement with digital sphygmomanometer, HBPM: home blood pressure monitoring.

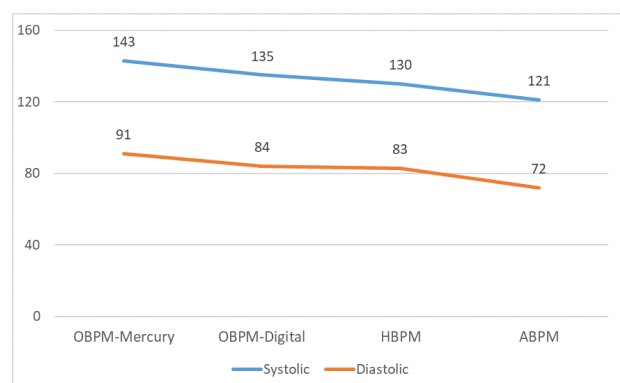


Figure 1. Mean systolic and diastolic blood pressure in different methods.

Table 2. Frequency of hypertension in various measurement methods*

Method		Hypertension, No (%) (n=28)
ABPM	Systolic	6 (21%)
	Diastolic	6 (21%)
	Overall	6 (21%)
OBPM-Mercury	Systolic	18 (64%)
	Diastolic	20 (71%)
	Overall	23 (82%)
OBPM-Digital	Systolic	11 (39%)
	Diastolic	13 (46%)
	Overall	15 (54%)
HBPM	Systolic	12 (43%)
	Diastolic	10 (36%)
	Overall	14 (50%)

* Definition of hypertension level in each method according to Patients and Methods section.

ABPM: Ambulatory blood pressure monitoring, OBPM-Mercury: office blood pressure measurement with mercury sphygmomanometer, OBPM-Digital: office blood pressure measurement with digital sphygmomanometer, HBPM: home blood pressure monitoring.

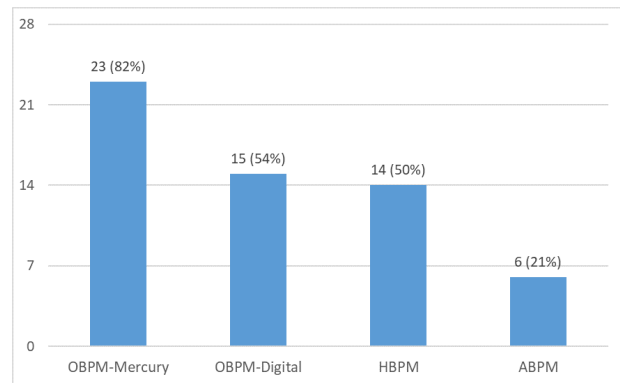
the lowest diagnostic accuracy. In all the three methods, the positive predictive value was equal to, or less than 36%, and the negative predictive value was more than 80%.

Table 4 and Figure 3 show the status of OBPMs, compared with those measured by ABPM and HBPM. Table 5 shows the diagnostic efficacy of HBPM over ABPM in detecting hypertensive phenotypes (both are compared with OBPM-Mercury). The results presented in this table indicate that HBPM can detect MH with high diagnostic accuracy, and it is also able to detect WCH and diagnose patients with sustained hypertension in more than two-thirds of cases.

Discussion

The findings of the present study showed that the mean blood pressure measured by ABPM was lower than the values measured through other methods. Following ABPM, HBPM showed the lowest frequency of hypertension and had the highest diagnostic accuracy, as compared with OBPM-Mercury or OBPM-Digital. HBPM was also highly sensitive and more specific than the other two methods. In addition, HBPM was able to detect MH with high diagnostic accuracy. In more than two-thirds of cases, it was also able to detect WCH and diagnose patients with sustained hypertension.

Various studies have assessed the diagnostic efficacy of

**Figure 2.** Frequency of hypertension based on different methods.

HBPM versus ABPM in different groups of patients, such as treated or untreated patients, diabetic patients, etc (12). According to the results of a review study by Stergiou and Bliziotis, the sensitivity and specificity of diagnosis of hypertension using HBPM in untreated patients were 48%-100% and 44%-93%, respectively. In comparison, in treated patients, they were 52%-97%, and is 84-63%, respectively (12). Based on the results of Kang and colleagues' study, HBPM had low sensitivity (47%-74%) but high specificity (86%-95%), positive predictive value (41%-87%), and negative predictive value (82%-94%) as compared with ABPM (13). In our study, as compared with ABPM, the sensitivity of all the three methods, including HBPM, OBPM-Mercury, and OBPM-Digital, was the same and equal to 83%. However, the specificity of HBPM was 59% that was more than three times higher than that of OBPM-Mercury. Overall, HBPM had higher diagnostic accuracy than the two OBPM methods. The negative predictive value in all three methods was higher than 80%, indicating that in observing normal blood pressure in these methods, it can be concluded, with a very high probability, that the patient does not have hypertension. However, considering the positive predictive value of these methods (less than 36%), when hypertension is detected by these methods, it is necessary to confirm the diagnosis by repeated measurements or using ABPM.

In general, the prevalence of WCH is 30-40%, and the prevalence of MH is estimated to be 10%-30% (7,14). In the study by Nasothimiou et al, the prevalence of WCH in HBPM and ABPM was 14% and 15%, respectively, and accordingly, the prevalence of MH was 16% and 15%,

Table 3. Diagnostic efficiency of different blood pressure measurement methods compared to ABPM

Method	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Diagnostic accuracy
OBPM-Mercury	83%	18%	22%	80%	32%
OBPM-Digital	83%	55%	33%	92%	61%
HBPM	83%	59%	36%	93%	64%

ABPM: Ambulatory blood pressure monitoring, OBPM-Mercury: office blood pressure measurement with mercury sphygmomanometer, OBPM-Digital: office blood pressure measurement with digital sphygmomanometer, HBPM: home blood pressure monitoring.

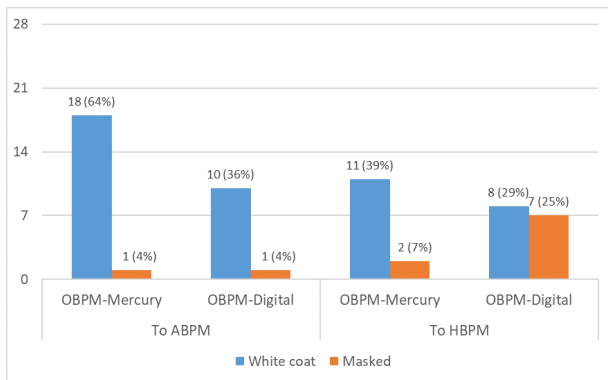


Figure 3. Frequency of hypertension phenotypes (white coat and masked).

respectively (15). In our study, the frequency of WCH in HBPM and ABPM was 39% and 64%, respectively, and the frequency of MH was 7% and 4%, respectively. Differences in the prevalence of MH and WCH in different centers, and studies can be attributed to differences in sample sizes, characteristics of patients, and study centers.

In Nasothimiou et al study, compared with ABPM, the sensitivity and specificity of HBPM in the diagnosis of sustained hypertension were 90% and 89%, respectively. While there were 61% and 94% in the diagnosis of WCH, respectively, and were 60% and 93% in the diagnosis of MH, respectively (15). In our study, compared with ABPM, the sensitivity, specificity, and diagnostic accuracy of HBPM in the diagnosis of MH were 100%, 96%, and 97%, respectively, and in the diagnosis of WCH were 56%, 90%, and 68%, respectively. It indicates that HBPM had high sensitivity and specificity in the diagnosis of MH. However, it has low sensitivity and specificity in the

diagnosis of WCH.

Evidence suggests that HBPM or ABPM methods should be used to confirm the diagnosis of hypertension and monitor its long-term process of management. There is strong evidence that the mentioned methods are superior to the routine methods of blood pressure measurement in a clinic and are more effective in predicting the damage in a target organ caused by hypertension and the occurrence of cardiovascular events (7,16,17). As compared with routine methods of blood pressure monitoring, HBPM is associated with an improved level of blood pressure control (18). Besides that, the measurement of blood pressure levels at home are more repeatable than the measurements performed in a clinic and have a better predictive value (19) and may reduce the burden of hypertension (7). However, there is still controversy about whether HBPM can act as an alternative to ABPM or not. In some cases, it has been reported that because of the moderate agreement between the two methods, they may not be considered as alternatives to each other (13,20). Although, in some guidelines, ABPM is mentioned as the preferred method of evaluation (2), it is still considered as an expensive method, unaffordable for some patients, and it can only be used in specialized centers. Therefore, HBPM is considered an important component of hypertension management and is utilized to evaluate and treat hypertension. In the case of the appropriate application of protocols, HBPM can be used instead of ABPM when it is not available (8). Thus, HBPM is increasingly used in many countries (21) and today guidelines, developed in the United States, Canada, and Europe for the management of hypertension emphasized the importance of out-of-clinic blood pressure monitoring for the daily management of patients with hypertension. (7). However, in low- and middle-income

Table 4. Hypertension phenotypes status measured in the clinic compared to outside the clinic

	Normotensive	Sustained Hypertension	White coat hypertension	Masked hypertension
OBPM-Mercury to ABPM	4 (14%)	5 (18%)	18 (64%)	1 (4%)
OBPM-Digital to ABPM	12 (43%)	5 (18%)	10 (36%)	1 (4%)
OBPM-Mercury to HBPM	4 (11%)	12 (43%)	11 (39%)	2 (7%)
OBPM-Digital to HBPM	6 (21%)	7 (25%)	8 (29%)	7 (25%)

Normotensive: Normal blood pressure in both methods, Sustained hypertension: Hypertension in both methods, White coat hypertension: Hypertension in first method but normal blood pressure in second one, Masked hypertension: Normal blood pressure in first method but hypertension in second one.

ABPM: Ambulatory blood pressure monitoring, OBPM-Mercury: office blood pressure measurement with mercury sphygmomanometer, OBPM-Digital: office blood pressure measurement with digital sphygmomanometer, HBPM: home blood pressure monitoring.

Table 5. Diagnostic efficacy of HBPM over ABPM in hypertension phenotypes detection

Hypertension phenotypes	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Diagnostic accuracy
Sustained	80%	65%	33%	94%	68%
White coat	56%	90%	91%	53%	68%
Masked	100%	96%	50%	100%	97%

ABPM: Ambulatory blood pressure monitoring, HBPM: home blood pressure monitoring.

countries, one of the most important limitations in using out-of-clinic blood pressure measurement methods is the limited access to such methods attributed to economic problems and health systems' lack of coverage. Therefore, to overcome these problems, it is necessary to consider the likelihood of purchasing appropriate equipment, which can increase their utilization. Strong support from the health systems is also needed to increase the utilization of HBPM and allow physicians and healthcare professionals to spend more time educating patients. However, it is worth noting that HBPM results can be misleading when measurement devices are not properly calibrated, or the cuff is not properly set on the right site. In addition, HBPM may cause anxiety and lead to multiple monitoring of blood pressure in patients. There is a risk of change in the process of treatment by the patient without consulting a physician (10,22).

Conclusion

The findings of the present study showed the frequency of hypertension diagnosed by HBPM was higher than that diagnosed by ABPM; HBPM method had a higher level of diagnostic accuracy than OBPM in diagnosing hypertension. HBPM was able to detect MH with high diagnostic accuracy. In addition, in more than two-thirds of cases, it was also able to detect WCH and diagnose patients with sustained hypertension.

Limitations of the study

Our study had some limitations including, a small sample size and single-center study. Therefore, we suggest that to make general use of HBPM, more studies should be conducted with larger sample size, in multiple centers, and different ethnicities and cultures of our country. Finally, following patient acceptance, our guidelines for diagnosis and treatment of hypertension need to be revised.

Authors' contribution

All authors passed four criteria for authorship contribution based on recommendations of the International Committee of Medical Journal Editors. SH and NR designed the protocol of the study. NR and SJ developed the protocol and performed it. Analysis of data performed by NR. All authors performed critical revision of the manuscript for important intellectual content, and all of them read and approved the final paper.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The study was also approved by the ethics committee of Qazvin University of Medical Sciences (#IR.QUMS.REC.1397.134). The institutional ethical committee at Qazvin University of Medical Sciences

approved all study protocols. Accordingly, written informed consent was taken from all participants before any intervention. Moreover, ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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