Hypertension Research (2014) 37, 741–745
www.nature.com/hr

ORIGINAL ARTICLE

Is home blood pressure reporting in patients with type 2 diabetes reliable?

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The aim of this study was to evaluate the reliability of self-reported home blood pressure (HBP) in patients with type 2 diabetes by comparing the self-reported values with HBP measurements stored in the memory of the blood pressure (BP) monitor. We also examined what factors affect the reliability of HBP measurements. A cross-sectional study was conducted in 280 patients with type 2 diabetes. Patients were requested to perform triplicate morning and evening measurements over a span of 2 weeks and to enter their HBP values into logbooks. Patients were not informed about the memory function of their BP monitoring devices. The concordance rate of HBP reporting was 78.6%. A total of 51.4% of patients ($n=144$) had >90% concordant data, and 15.7% of patients ($n=44$) had $\leqslant$50% concordant data. In general, HBP values from the logbook were significantly lower and less variable than those from the stored memory ($P<0.05$). The most common type of incorrect data was selected data that were reported in the logbooks that were randomly selected from multiple readings by the HBP monitors (55.8%). The concordance rate of HBP reporting significantly correlated with hemoglobin A_{1c} levels ($\beta=-0.156$; $P=0.0149$) and with smoking status (current *vs.* never, $\beta=-0.165$; $P=0.0184$). In conclusion, HBP measurements from the patients' logbooks were lower and less variable than those from the stored memory in the BP monitors of patients with type 2 diabetes, and the reliability of HBP reporting was affected by glycemic control and smoking status. Repeated instructions regarding HBP measurement to the patients or the use of stored BP measurements is recommended to ensure accurate HBP measurements in patients with type 2 diabetes.
Hypertension Research (2014) **37,** 741–745; doi:10.1038/hr.2014.66; published online 10 April 2014

Keywords: logbook blood pressure; memory blood pressure; s.d.; variability

INTRODUCTION

The prevalence of hypertension in individuals with type 2 diabetes is higher than that in the general population.[1–3] In patients with type 2 diabetes, hypertension is considered an important risk factor for cardiovascular and renal disease;[2,4] therefore, it is very important for these patients to strictly control their blood pressure (BP), as well as their blood glucose levels. The intensive lowering of BP in hypertensive patients with type 2 diabetes has been associated with the reduction of cardiovascular events, as reported by the Hypertension Optimal Treatment randomized trial[5] and the United Kingdom Prospective Diabetes Study.[6]

Home BP (HBP) monitoring has been shown to be useful for controlling BP, and some national and international guidelines also recommend HBP monitoring in certain circumstances. In addition, HBP measurement has been found to have a stronger relationship to target organ damage in several population-based studies and prospective clinical studies.[7,8] We have also shown that the average and variability of HBP correlate with albuminuria in patients with type 2 diabetes.[9,10]

However, there are few studies that have assessed the precision of self-measured BP reporting,[11,12] and to our knowledge, no study has evaluated the reliability of HBP monitoring in patients with type 2 diabetes. The aim of this study was to evaluate the reliability of self-reported HBP in patients with type 2 diabetes by comparing the self-reported values with the stored HBP measurements. We also examined what factors affect the reliability of HBP.

METHODS

Patients

HBP measurements were performed by patients with type 2 diabetes (regardless of hypertensive status) who had regularly visited the diabetes outpatient clinic at the Hospital of Kyoto Prefectural University of Medicine, Kyoto, Japan between May 2011 and July 2012. We recruited patients who were able to measure their BP independently. A total of 288 patients with type 2 diabetes agreed to participate in the present study. We excluded patients who did not comply with the study protocol ($n=7$) and who had advanced renal dysfunction (serum creatinine $\geqslant 176.8\,\mu mol\,l^{-1}$; $n=1$). In all, 280 patients met the criteria and comprised the study population. The diagnosis of type 2

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Received 6 September 2013; revised 20 November 2013; accepted 30 December 2013; published online 10 April 2014

diabetes mellitus was based on the American Diabetes Association criteria.[13] The present study was approved by the local Research Ethics Committee and was conducted in accordance with the Declaration of Helsinki; informed consent was obtained from all patients, although the patients were not aware of our aim to compare the BP values in their logbooks with those stored in the memory of the device.

Study design

To assess the accuracy of the patient-reported data, we used the following criteria. The logbooks contained the data recorded by the patients after they measured their BP. The stored memory data contained all of the recordings that were retrieved from the memory of the electronic BP device. When values from the logbook matched those of the stored memory, we defined them as concordant data. We examined the rate of concordant data (concordance rate) and compared the BP levels in the logbook and those in the stored memory. For the mismatched values, we classified the data into five categories depending on the error types. First, selected data were data that were reported in the logbooks that were randomly selected from multiple readings (more than three times) by the home BP monitors. Second, fictional data refers to values entered in the logbooks that could not be retrieved from the memory of the HBP monitors. Third, shifted data were defined as the data in the logbooks that were entered into the memory of the BP device on another day but for the same time. Fourth, switched data were defined as data in the logbooks that were entered into the memory of the BP device on another day and at a different time. Fifth, omitted data were defined as data that were found in the memory of the HBP monitors but were not entered into the logbooks. We then examined the rate of these mismatched data. In addition, we classified the patients according to their most common error type and compared the BP levels and variability for the error type (as observed in the logbooks) with the BP levels and variability stored in the memory of the HBP monitor. We used s.d. of BP as an index of day-to-day variability of HBP values in the present study.

To identify the factors that affect the accuracy of HBP measurements, we examined the relationship between the concordance rate of HBP and various factors, including sex, age, duration of diabetes, body mass index, serum cholesterol concentration, hemoglobin A_{1c}, smoking status, alcohol status, presence of microvascular complications or macrovascular complications, memory BP and the use of antihypertensive drugs and insulin.

Data collection

Blood samples for biochemical tests were collected at the hospital. Hemoglobin A_{1c}, low-density lipoprotein cholesterol, triglycerides, high-density lipoprotein cholesterol and other biochemical data were determined using the standard laboratory assays. Information, including age, duration of diabetes, microvascular complications, macrovascular complications, smoking and alcohol drinking status, hypoglycemic medication and antihypertensive medication, were obtained at the time of the BP measurement. Alcohol drinking status (everyday, social, never) and smoking status (current, past or never smokers) were assessed by interview.

HBP measurements were performed using an automatic device (HEM-7080IC, Omron Healthcare Co. Ltd, Kyoto, Japan) that uses the cuff-oscillometric method to generate a digital display of the heart rate and the systolic/diastolic BP (SBP/DBP) values. This monitor is also capable of electronically storing BP measurements. HEM-7080IC uses the identical components and BP-determining algorithm as another device (HEM-705IT) that was previously validated and satisfies the criteria of the British Hypertension Society protocol.[14]

All of the patients used this oscillometer for the first time in this study. They were instructed to perform triplicate morning and evening measurements for 14 consecutive days. Morning BP measurements were made within 1 h of waking, before breakfast or taking any drugs and after the patient had been seated and rested for at least 5 min.[15] Evening BP measurements were obtained in a similar manner just before bedtime. The cuff was placed directly around the non-dominant arm, and the position of the cuff was maintained at the level of the heart.

Statistical analysis

Values are expressed as the mean ± s.d. for continuous variables. A paired *t*-test was used to assess the difference between memory and logbook BP values. Linear regression analyses, Student's *t*-test and one-way analysis of variance were used to assess the relationship between the concordance rate and the factors that affect the accuracy of reporting. We chose the variables significantly related with HBP concordance rate by univariate regression analysis, Student's *t*-test and one-way analysis of variance as covariates in a multivariate analysis. All statistical analyses were performed using the JMP software (JMP; SAS Institute Inc., Cary, NC, USA).

RESULTS

The clinical characteristics of the patients are shown in Table 1. A total of 55.4% of the patients ($n=155$) took antihypertensive medications during the study. We collected an average (s.d.) of 79.9 ± 7.8 HBP measurements and 6.3 ± 7.3 erroneous data points from each patient. The concordance rate between the BP values from the stored memory and those from the logbooks was 78.6%. A total of 23.2% of patients ($n=65$) had 100% concordant measurements, and 51.4% of patients ($n=144$) had >90% concordance. A total of 15.7% of the patients ($n=44$) had ⩽50% concordant measurements (Figure 1).

The mean of the morning SBP and DBP retrieved from the stored memory were 130.6 ± 16.2 mm Hg and 72.6 ± 9.7 mm Hg, respectively. The mean of the morning SBP and DBP from the logbooks were 129.8 ± 15.8 mm Hg and 72.2 ± 9.5 mm Hg, respectively (Table 2). Morning and evening BP values from the logbooks were significantly lower than those from the stored memory. The s.d. of the BP values from the logbooks was also lower than that of the BP values from the stored memory.

The most common error was selected data (55.8%), but fictional data were present for 23.3% of the patients. Shifted data, switched data and omitted data were found in 11.6%, 6.0% and 3.3% of the patients, respectively. The mean of the morning SBP and DBP measurements that were retrieved from the stored memory were not significantly different among the five error types. However, for selected and shifted data, the mean of the morning SBP and DBP

Table 1 Characteristics of the patients with type 2 diabetes

Number	280
Sex (male/female)	160/120
Age (years)	65.9 ± 9.9
Duration of diabetes (year)	12.7 ± 10.0
BMI (kg m^{-2})	23.5 ± 3.5
Hemoglobin A_{1c} (%)	7.2 ± 1.1
LDL cholesterol (mmol l^{-1})	2.69 ± 0.78
HDL cholesterol (mmol l^{-1})	1.53 ± 0.44
Triglycerides (mmol l^{-1})	1.46 ± 0.81
Morning systolic memory BP (mm Hg)	130.6 ± 16.2
Morning diastolic memory BP (mm Hg)	72.6 ± 9.7
Evening systolic memory BP (mm Hg)	126.1 ± 15.3
Evening diastolic memory BP (mm Hg)	67.8 ± 9.4
Retinopathy (−/+)	219/61
Neuropathy (−/+)	201/79
Nephropathy (−/+)	134/146
Cardiovascular disease (−/+)	229/51
Number of antihypertensive drugs (0/1/2/3/4/5)	125/69/59/18/6/3
Treatment of diabetes (Diet/OHA/insulin/insulin + OHA)	34/193/17/36
Smoking (never/past/current)	126/97/57
Alcohol (never/social/everyday)	165/49/66

Abbreviations: BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; OHA, oral hypoglycemic agent.
Data are mean ± s.d. or number of patients.

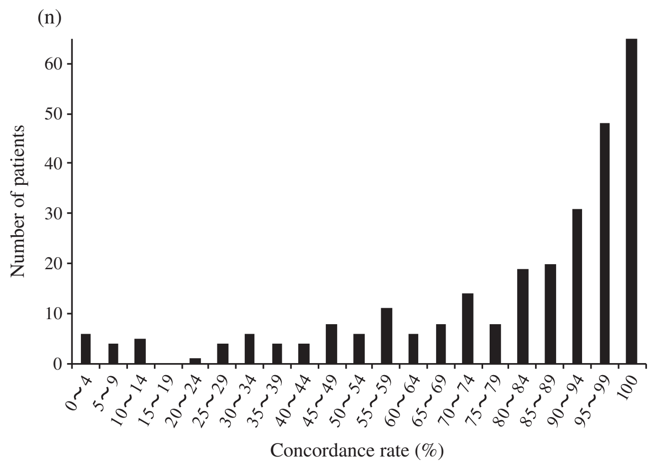

Figure 1 Patient numbers by concordance rate of home blood pressure reporting.

Table 2 Comparison between memory and logbook blood pressure

	Memory BP	*Logbook BP*	P-*value*
Mean of morning SBP (mm Hg)	130.6 ± 16.2	129.8 ± 15.8	<0.0001
Mean of morning DBP (mm Hg)	72.6 ± 9.7	72.2 ± 9.5	0.0005
Mean of evening SBP (mm Hg)	126.1 ± 15.3	125.7 ± 14.7	0.0050
Mean of evening DBP (mm Hg)	67.8 ± 9.4	67.6 ± 9.4	0.0150
S.d. of morning SBP (mm Hg)	9.8 ± 3.5	7.9 ± 3.2	<0.0001
S.d. of morning DBP (mm Hg)	5.6 ± 2.7	4.4 ± 1.8	<0.0001
S.d. of evening SBP (mm Hg)	10.2 ± 3.6	8.4 ± 3.6	<0.0001
S.d. of evening DBP (mm Hg)	5.9 ± 2.5	4.8 ± 1.9	<0.0001

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure. Data are mean ± s.d.

values that were retrieved from the logbooks were significantly lower than those retrieved from the stored memory (Supplementary Table S1). The s.d. of the morning SBP values retrieved from the logbooks were significantly lower than those from the stored memory in selected, fictional and shifted data. The s.d. of the morning DBP measurements that were retrieved from the logbooks were also significantly lower than those from the stored memory in selected and shifted data.

Hemoglobin A_{1c}, high-density lipoprotein cholesterol, triglycerides, mean of the morning SBP, mean of the evening DBP and the morning SBP s.d. from the stored memory were significantly correlated with the HBP concordance rate (Table 3). In addition, the HBP concordance rate was significantly lower in current smokers than that in non-smokers (Table 4). Multivariate linear regression analysis indicated that the independent explanatory variables concerning the HBP concordance rate were hemoglobin A_{1c} and smoking status (Table 5).

DISCUSSION

This study revealed that the mean and the s.d. of HBP values from the logbooks were significantly lower and smaller, respectively, than those from the stored memory and that the main HBP reporting error was data selection by patients. In addition, we found that hemoglobin A_{1c} and smoking status significantly correlated with the inaccuracy of HBP reporting. The accuracy of HBP was decreased in patients with poorly controlled glycemia and in those who smoked. Possible explanations for this decrease in accuracy are that the patients were concerned about increasing their antihypertensive medication or that their health consciousness might have been poor.

Table 3 Univariate regression analysis on factors affecting concordance rate between memory and logbook blood pressure

	Concordance rate	
	r	P-*value*
Age	0.035	0.5567
Duration of diabetes mellitus	−0.053	0.3838
BMI	−0.091	0.1338
Hemoglobin A_{1C}	−0.127	0.0333
LDL cholesterol	−0.059	0.3738
HDL cholesterol	0.131	0.0286
Triglycerides	−0.121	0.0429
Mean of morning SBP (memory)	−0.121	0.0443
Mean of morning DBP (memory)	−0.095	0.1144
Mean of evening SBP (memory)	−0.110	0.0742
Mean of evening DBP (memory)	−0.127	0.0386
S.d. of morning SBP (memory)	−0.129	0.0310
S.d. of morning DBP (memory)	−0.112	0.0620
S.d. of evening SBP (memory)	−0.014	0.8106
S.d. of evening DBP (memory)	0.038	0.6281

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

Moreover, we analyzed HBP measurement accuracy in patients who were taking or not taking antihypertensive drugs. The HBP concordance rates between the two groups was similar (76.7 ± 23.3%, 80.9 ± 24.8%, $P = 0.1852$), and the mean and the s.d. of HBP values from the logbooks were significantly lower and smaller, respectively, than those from the stored memory in each group. The mean of the morning SBP from the logbooks was significantly lower than that from the stored memory from patients with (132.7 ± 15.4 *vs.* 133.7 ± 16.0 mm Hg, $P = 0.0002$) or without (126.1 ± 15.5 *vs.* 126.7 ± 15.7 mm Hg, $P = 0.0031$) antihypertensive drugs. The s.d. of the morning SBP from the logbooks was significantly less than that from the stored memory from patients with (8.2 ± 3.2 *vs.* 10.1 ± 3.6, $P < 0.0001$) or without (7.4 ± 3.2 *vs.* 9.4 ± 3.3, $P < 0.0001$) antihypertensive drugs. The HBP concordance rate was negatively correlated with the mean HBP and smoking status and was significantly lower in current smokers than in past or non-smokers taking antihypertensive drugs. This result was not observed in patients who did not take antihypertensive drugs (Supplementary Tables S2 and S3). We should pay more attention to the accuracy of HBP in patients who take antihypertensive drugs, who have poor control of their HBP or who smoke.

In this study, the HBP concordance rate between the logbooks and the stored memory was similar to previous studies in non-diabetic patients.[11,12] Our findings were also similar to the results of a study by Mazze *et al.*,[16] who evaluated the reliability of self-reported capillary glucose measurements in logbooks (74%). Their study found that the mean blood glucose values from the logbooks were significantly lower than those from the stored memory in many cases, primarily because blood glucose measurements $>13.9\,mmol\,l^{-1}$ ($250\,mg\,dl^{-1}$) were omitted from their logbooks. Patients had a tendency to select their HBP measurements; therefore, the logbook BP values were significantly lower and less variable than memory BP values in this study. It seems that patients omitted the measurements when the measurements were higher or lower than expected in HBP reporting. Therefore, the differences in the mean BP between the stored memory

Table 4 Factors affecting concordance rate between memory and logbook blood pressure among the groups

	Concordance rate (%)	P-value
Sex		*0.7095*
Male	78 ± 26	
Female	79 ± 27	
Smoking		*0.0055*
Never	80 ± 25	
Past	80 ± 24	
Current	67 ± 32	
Alcohol		*0.7480*
Never	77 ± 28	
Social	75 ± 30	
Everyday	79 ± 22	
Retinopathy		*0.5121*
−	78 ± 26	
+	81 ± 27	
Neuropathy		*0.2351*
−	80 ± 26	
+	76 ± 26	
Nephropathy		*0.3858*
−	80 ± 25	
+	77 ± 27	
Past history of cardiovascular disease		*0.4405*
−	78 ± 27	
+	81 ± 21	
Antihypertensive drugs		*0.1776*
−	81 ± 25	
+	77 ± 27	
Hypoglycemic drugs		*0.4065*
−	81 ± 25	
+	78 ± 27	
Insulin treatment		*0.3800*
−	78 ± 26	
+	82 ± 29	
Self-monitoring of blood glucose		*0.9782*
−	79 ± 26	
+	79 ± 30	

Data are mean ± s.d.

Table 5 Multivariate regression analysis on factors affecting concordance rate between memory and logbook blood pressure

	β	P-value
Hemoglobin A_{1c}	−0.156	0.0149
HDL cholesterol	0.071	0.2742
Smoking status (current *vs.* never)	−0.165	0.0184
Smoking status (past *vs.* never)	0.019	0.7775
Mean of morning SBP (memory)	−0.089	0.1843
S.d. of morning SBP (memory)	−0.095	0.1540

Abbreviations: HDL, high-density lipoprotein; SBP, systolic blood pressure.
β indicates multiple linear regression coefficient. Adjusted for all variables in this table.

and the logbooks were small in our study. However, a previous study has shown that even slight differences in SBP significantly decrease cardiovascular events;[17] therefore, the findings of our study may be valuable in this regard. Moreover, we analyzed the relationship between the BP level and the difference between the BP measurements retrieved from the logbooks and from the stored memory (Supplementary Figure S1). Linear regression analysis showed that there was a significant relationship between the absolute value of the difference in the morning SBP and the mean of the morning SBP ($P=0.0015$). Therefore, we should consider the possibility of differences between the values in the logbooks and the actual BP in patients with poorly controlled hypertension.

HBP concordance rates were similar among the studies by Nordmann *et al.*[11] and Johnson *et al.*[12] and ours. However, they assessed the accuracy of HBP in patients with hypertension, and we assessed HBP in patients with type 2 diabetes, which we believe is novel. Moreover, the number of patients was larger in our study than in the other aforementioned studies. Nordmann *et al.*[11] suggested that low education level was the only independent predictor of poor BP measurement accuracy. However, there was no relationship between the educational level and the accuracy of HBP measurement in some of the patients ($n=197$) in our study ($P=0.9437$), and there was no relationship between cognitive function (as measured by mini-cog test)[18,19] and the accuracy of HBP reporting ($P=0.1949$) in most of our patients ($n=263$). This may be because there were no patients in this study with severe cognitive dysfunction who were unable to measure their BP. Johnson *et al.*[12] found that erroneous reporting was evident in patients with uncontrolled BP, which is in accordance with our data. In addition, there was no relationship between the accuracy of HBP measurements and the number of antihypertensive medications or the accuracy of HBP measurements and the timing of the HBP measurements. However, there was a tendency for the concordance rate for the first half of the study (days 1–7) to be higher than that of the second half (days 8–14) (80.5 ± 25.5%; 76.8 ± 30.6%, $P=0.0013$). There might be an experience effect on the accuracy of HBP measurements partly, because the patients paid less attention to HBP measurements as the study progressed.

The present study has some limitations. First, the number of patients was relatively small, because we chose patients who had never borrowed a BP monitor from us. However, this is the first study to evaluate the reliability of HBP in patients with type 2 diabetes and to identify the main errors of HBP reporting and the factors that affect the reliability of HBP reporting. Second, patients might have noticed the memory function, as mentioned on the face of the oscillometer and in the instruction manual. This knowledge might have resulted in reporting bias. However, when we provided the new logbook with the oscillometer to the patients in this study, the patients seemed to believe that we would analyze their new logbook data. Moreover, patients were not aware of our aim to compare their HBP measurements in the logbook with those recorded by the oscillometer; therefore, significantly biased reporting seems unlikely. Third, there might be weekly differences in the accuracy of HBP measurements. However, we did not account for the work day of each patient and could not assess any weekly differences by separating the HBP data into week day and weekend categories. Fourth, unfortunately, we do not have data regarding HBP monitoring experience of the patients before this study. Therefore, there is a possibility that previous experience of HBP monitoring affected the accuracy of HBP reporting.

In conclusion, patients with type 2 diabetes sometimes reported inaccurate HBP measurements and, as a result, HBP control from the logbooks appeared better than that from the stored memory. False reporting of BP may misguide physicians, resulting in inadequate medical treatment of their patients. To obtain the true HBP value, we should instruct patients to record the HBP measurement correctly. Specifically, patients with poorly controlled glycemia or who smoke may need repeated instructions. Furthermore, it may be helpful to use automatic devices that can store BP measurements for the proper assessment of BP control.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

We thank Naoko Higo, Machiko Hasegawa and Terumi Kaneko for teaching the patients how to measure their blood pressure; Sayoko Tanaka, Hiroko Kawamura and Sanae Utena for their secretarial assistance; and Akane Miki for her enormous help with data handling. Each of these individuals is affiliated with Kyoto Prefectural University of Medicine, Kyoto, Japan.

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Supplementary Information accompanies the paper on Hypertension Research website (http://www.nature.com/hr)