To What Extent Can We Trust Home Blood Pressure Measurement? A Randomized, Controlled Trial

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Increasingly, patients measure and record their home blood pressure. However, the accuracy with which they report their readings to their physicians is largely unknown. The authors assessed the accuracy and quality of self-reported home blood pressure values in an ambulatory managed care population. Forty-eight hypertensive outpatients were randomly allocated to either receive information about the storage capabilities of a home blood pressure measuring device or not to receive such information. All patients were asked to record the measurement results in a logbook twice daily over a 7-day period. The main outcome measure was the difference in the number of fictional or manipulated reports per group and the difference in missing values. The combined parameter "manipulated or fictional registrations" occurred significantly less frequently in the informed group than in the noninformed group. (10/728 vs. 29/616; relative risk, 0.292; 95% confidence interval, 0.15–0.57; Pearson χ^2=13.15; p<0.0001). Informed patients had fewer missing registrations than the noninformed (13/728 vs. 41/616 measurements; relative risk, 0.27; 95% confidence interval, 0.15–0.47; Pearson χ^2=20.5; p<0.0001). The mean of the fictional data did not differ systematically from the mean of the correctly reported individual blood pressure values. There was no trend to over- or underestimate blood pressure values in the noninformed group. With this study design, it was possible to identify manipulation of home blood pressure values for the first time. Accuracy and interpretation of home blood pressure measurement may be increased by using devices with a memory function. (J Clin Hypertens. 2002;4:405–407, 412)

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Accuracy of home blood pressure monitoring has been widely investigated.[1–5] Nordmann and colleagues[2] identified low educational level as a factor associated with poor accuracy of patients' recorded blood pressure values. We investigated the extent to which nonprovision of specific information about device capabilities affects the accuracy of home reporting of blood pressure monitoring. We used fictional or manipulated logbook entries as the primary outcome measure.

METHODS

Forty-eight consenting hypertensive patients from the practice of one of the investigators (W.V.) in the outpatient clinic of the Department of Internal Medicine at the University of Zurich were randomized. The patients had consecutively been referred for 24-hour ambulatory blood pressure monitoring to diagnose hypertension or had a follow-up visit to reassess antihypertensive therapy between February and June of 1998. The random sequence was generated by drawing lots in a masked fashion. Concealment of randomization was achieved by using sealed, opaque envelopes. The envelopes were opened by a third person (the research nurse), who then informed the patient about the fact that the blood pressure device would store the blood pressure values, or withheld that information, according to the randomization.

The clinical research nurse demonstrated to all patients how to correctly fit the monitor and cuff and instructed them to measure their blood pressure with the monitor (Omron IC, Omron Electronics AG, Steinhausen, Switzerland). The patients' arm circumferences were measured in centimeters and fitted with appropriate-sized cuffs. The patients were asked to measure their blood pressure in a sitting position after some minutes of rest, twice in the morning (between 6 and 8 a.m.) and twice in the evening (between 6 and 8 p.m.) for 1 week. The values displayed by the monitor were required to be entered into a logbook (a total of 28 values per patient).

Patients allocated to the intervention arm were told that the device was equipped with a memory function. The stored information consists of systolic, diastolic, and pulse measurements and the time and date.

We classified logbook records as correct when they matched in terms of retrieved value and time. We classified them as manipulated when the logbook records had incorrect values at a given time. If there was a device value but no logbook record, the value was considered "no registration." Values were considered as missing when there were both no stored records in the device and no entries in the logbook for the particular time event. Fictional data were defined as no record in the device but a registered value in the logbook (Figure). The primary outcome measure was the difference of manipulated and fictional values between the two groups.

Statistical Analysis

Stored values of the Omron IC device were exported as ASCII-data and transmitted to an SPSS statistical software package (version 10.0, SPSS Inc., Chicago, IL) for further analysis. A *t* test was used for the comparison of blood pressure values. Differences between the two groups for missing, fictional, and manipulated logbook entries were analyzed by an χ^2 test. To control for potential confounding, we checked for any association between the non-normally distributed rate of manipulated or missing data and patient characteristics by means of Spearman rank correlations. Also, we assessed the association between patient characteristics and treatment allocation.

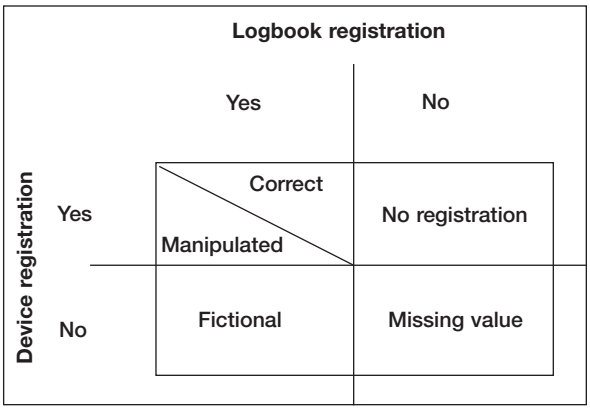

Figure. Description of definitions used for statistical analysis; existence of both a device registration and a logbook entry at the specified time can be correct or manipulated. An existing device record without a time-corresponding logbook entry is defined as no registration. Fictional values are invented logbook entries without a time-related device value. Missing values are a missing device value and a missing logbook entry.

RESULTS

Twenty-two patients were allocated to the noninformed group and 26 patients to the informed group. Hence, the total numbers of measurements for the noninformed and informed groups were 616 and 728, respectively.

Fifteen patients in the informed group (57.7%) and 14 in the noninformed group (63.6%) were not on antihypertensive treatment before the study. Fifteen of the 26 informed patients (57.7%) and 10 of the 22 noninformed patients (45.5%) were male. The informed patients were older (54.8±14.4 years [SD]) than the noninformed patients (45.5±11.4 years) (Table I).

The mean systolic device values were 136.3±16.8 mm Hg (SD) for the noninformed group and 145.2± 19.6 mm Hg for the informed group ($p<0.001$). The mean diastolic device values were 86.0±12.2 mm Hg for the noninformed group and 85.5±11.8 mm Hg for the informed group ($p=0.46$).

The combined parameter "manipulated or fictional registrations" occurred significantly less frequently in the informed group than in the noninformed group (10/728 vs. 29/616; relative risk, 0.292; 95% confidence interval, 0.15–0.57; Pearson $\chi^2=13.15$; $p<0.0001$). Informed patients had fewer missing registrations than the noninformed (13/728 vs. 41/616 measurements; relative risk, 0.27; 95% confidence interval, 0.15–0.47; Pearson $\chi^2=20.5$; $p<0.0001$). Fictional registrations alone were also less frequent in the noninformed group. (3/728 vs. 20/616 measurements; relative risk 0.13; 95% confidence interval, 0.04–0.35; Pearson $\chi^2=15.9$; $p<0.0001$) (Table II).

Fictional protocol data were not systematically lower or higher than the mean individual blood pressure values. Since the mean age differed between the two groups, we analyzed for potential confounding by age. A significant association between age and the primary outcome measure was excluded ($r=-0.12$; $p>0.12$).

COMMENT

Our results suggest that withholding information about the memory function of home blood pressure

devices affects the accuracy of self-reporting. The combined outcome measure "fictional or manipulated logbook entries" was significantly lower in the group who knew about the storage of blood pressure recordings. Fictional protocol data were not systematically lower or higher than the mean individual blood pressure values. We therefore conclude that the effect of manipulation alone does not influence the mean protocol data. However, analysis of some individual patients in the noninformed group revealed significant effects of manipulation, which did not influence the total group results. Therefore, our findings may not make a difference in the planning of therapy in the majority of cases.

Nevertheless, it is useful to encourage patients to measure blood pressure at home. In clinical practice, home blood pressure values provide valuable information about the effects of medications.[6] Some evidence exists that home blood pressure measurement improves patients' adherence to prescribed treatments[7] and helps to diagnose white coat hypertension.[8] The usefulness of reported measurements, however, depends on the accuracy of the collected data. Studies in other patient populations have disclosed inaccuracies in self-monitoring. Mazze and coworkers[9] found a significant difference between electronically stored and self-reported blood glucose measurements in subjects with diabetes. Similarly, there is a significant difference between self-reported adherence with metered-dose inhalers in subjects with asthma and electronically stored inhaler data.[10–11]

In contrast to the work by Mengden and coworkers,[1] our study design enabled us to differentiate between log entry mistakes that may also occur in an "ideal" setting, where the patient is motivated to make correct log entries (because he knows that the device stores blood pressure values) and the log entry inaccuracies that occur because the patient manipulates or invents values. Mengden et al.[1] assumed that patients who knew about the storage capacity of the device would not make reporting mistakes. We demonstrated that these patients also have inaccuracies in their logbook entries, but to a much smaller extent than noninformed patients.

This study has some limitations. The population size was limited. The mean age of the two groups at baseline differed; however, confounding by age was excluded. It is possible that subjects who are willing to participate in such a study report the results more reliably, and that our findings may have underestimated

Table I. Distribution of Patient Characteristics in the Two Groups

	Informed Group (n=26)	Noninformed Group (n=22)
Sex		
Male	15 (57.7%)	10 (45.5%)
Female	11 (42.3%)	12 (54.5%)
Age (±SD)	54.8±14.4	45.5±11.4
Medical appointment for:		
Diagnosis	15 (57.7%)	14 (63.6%)
Control visit	11 (42.3%)	8 (36.4%)

Patients referred for diagnosis were untreated. Patients referred for a control visit were on antihypertensive treatment.

Table II. Two by Two Tables for the Three Outcome Measures

Outcome		Informed	Noninformed
Fictional or manipulated	No	718	587
	Yes	10	29
Relative risk, 0.292 (95% CI, 0.15–0.57); Pearson chi-square=13.15; $p<0.0001$			
Fictional values	No	725	596
	Yes	3	20
Relative risk, 0.13 (95% CI, 0.04–0.35); Pearson chi-square=15.9; $p<0.0001$			
Missing entries	No	715	575
	Yes	13	41
Relative risk, 0.27 (95% CI, 0.15–0.47); Pearson chi-square=20.5; $p<0.0001$			

Differences between groups are presented as relative risks with 95% confidence intervals (CI) (chi-square test).

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the results that would be obtained in an unselected hypertensive population, because the effect of withholding information on those individuals may be greater. Moreover, because the monitor is not physically attached to the subject, it is impossible to rule out that other people used the monitor. Therefore, electronically stored results may not represent the study participant's own blood pressure values.

CONCLUSIONS

With our study design, it was possible to identify manipulation of home blood pressure values for the first time. Accuracy and interpretation of home blood pressure measurement may be increased by using devices with a memory function.

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