Reliability of Self-reported Blood Pressure Measurements

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Background: Home blood pressure (BP) monitoring improves BP control, but it is unknown whether patients accurately report home BP readings to their physician. This study compared self-reported with electronically stored home BP and heart rate (HR) readings and evaluated this agreement in patients with controlled vs uncontrolled hypertension.

Methods: A single-blind, randomized clinical trial was conducted in an ambulatory managed care population. Subjects were identified by hypertension-related codes from the International Classification of Diseases, Ninth Revision (401.0, 401.1, and 401.9). Subjects recorded systolic BP (SBP), diastolic BP (DBP), and HR 3 times daily for 1 week by means of a digital BP monitor. Subjects were unaware that the monitor electronically stored results.

Results: Thirty subjects were enrolled (29 complete data sets); their mean age (±SD) was 56 ± 9 years, and 15 (52%) were women. Sixty-eight percent of subject-recorded SBP, DBP, and HR measurements were identical to electronically stored results. Twenty percent of recorded SBPs and 17% of recorded DBPs differed from stored SBP and DBP by more than 10 mm Hg. Erroneous reporting was evident in 9% of uncontrolled vs 4% of controlled SBPs (P<.001). Similarly, 21% of uncontrolled and 4% of controlled DBPs were erroneously reported (P<.001). In cases where the stored HR exceeded 100 beats/min, 43% of HR readings were recorded as 100 beats/min or less (P<.001).

Conclusions: Most self-reported BP and HR readings were identical to electronically stored measurements. However, erroneous reporting occurred significantly more often in cases of uncontrolled BP and HR, which may misguide physicians in the optimal treatment of their patients with hypertension.

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As many as 50 million adult Americans have hypertension. In 73% of patients receiving treatment for high blood pressure (BP), the BP is not controlled (BP ≥140/90 mm Hg), and 46% are still not being treated. Uncontrolled and untreated high BP increases the risk of cardiovascular morbidity and mortality. Home BP monitoring has been shown to improve BP control and thereby reduce the risk of cardiovascular events in patients who perform self-monitoring. To improve clinical outcomes, patient self-monitoring programs are now commonly incorporated into clinical practice to assist primary care physicians in treating their patients. These programs help patients to measure and control their own disease state. Patient-collected data can be incorporated into medical management, as evidenced by sliding-scale insulin regimens for patients with diabetes, adjusted loop diuretic dosing in patients with congestive heart failure, and titrated corticosteroid use for patients with asthma.

In a recent survey conducted in Germany, 70% of all responders in 1994 stated that they practiced self-BP measurement. There are many devices available to measure home BP, including aneroid and digital monitors, which provide real-time data to both subjects and physicians. While many patients may measure and record their home BP, it remains unknown whether they accurately report the home BP readings to their primary care physician. Studies in other patient populations have reported inaccuracies in self-monitoring. Mazze et al 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 actuations. Therefore, we chose to (1) evaluate the agreement between self-reported
SUBJECTS AND METHODS

This was a single-blind, randomized clinical trial in ambulatory patients with hypertension, enrolled in a large managed care plan.

EQUIPMENT

Seven new home BP monitors (Omron HEM-725CIC; Omron HealthCare, Inc, Vernon Hills, Ill) were purchased for the study. This digital automatic BP monitor is capable of electronically storing up to 350 BP measurements and uses the same technology as the validated HEM-507 CP BP monitor (Omron HealthCare, Inc). The monitor consisted of rubber tubing, cuff, inflatable bladder, and digital display. Two cuff sizes were available; the standard adult cuff was appropriate for arm circumferences measuring 22 to 32 cm, and the large adult cuff was appropriate for circumferences of 32 to 40 cm.

DATA COLLECTION

Participants were members of a large managed care organization in western Pennsylvania and were randomly selected from the automated medical claims database by means of hypertension-related codes from the International Classification of Diseases, Ninth Revision (401.0, 401.1, and 401.9). Subjects were contacted by written request and telephone. The study was approved by the institution's investigational review board, and all subjects provided informed consent. The home BP monitors were programmed with the participant's name and identification number before the first visit. The arm circumferences were measured in centimeters and fitted with an appropriate-sized cuff.

The clinical research nurse showed each subject how to fit the monitor and cuff and instructed the subjects to measure their BP and HR with the monitor 3 times a day at specified time intervals: morning (approximately 8 AM), afternoon (between noon and 5 PM), and evening (between 7 and 11 PM). Subjects were instructed to record the systolic BP (SBPr), diastolic BP (DBPr), and HR (HRr) in their diary for 1 week for a total of 21 measurements. After the 1-week study period, subjects were asked to answer 2 questions in their diary regarding satisfaction with the monitor by checking the appropriate response. The first question stated, "How easy or difficult did you find this monitor to use?" Five options were available, ranging from "easy" to "difficult." The second question stated, "If this monitor was available, would you use it again?" Five responses were available, ranging from "definitely yes" to "definitely no."

Pharmacy claims data from June 1996 through July 1998 were collected for all study participants taking prescription medications. Subjects obtaining refills for long-term prescribed medications were deemed adherent if they had medication for 80% or more for the study year (10 or more of 12 months of refills). Adherence was calculated for the 12 months after study enrollment.

STUDY POPULATION

Men and women 18 years of age or older with stage 1, 2, or 3 hypertension were offered the opportunity to participate. Participants were excluded if they had atrial fibrillation, were illiterate, or were unable to speak English. Subjects were unaware that the home BP monitor electronically stored the BP and HR results (SBPe, DBPe, and HRe).

STATISTICS

It was calculated that 29 subjects were required to determine a 2-mm Hg and 2-beat/min subject rounding error, at an α of .05 with greater than 95% power, assuming a 3-mm Hg SD in instrument measurements. The general linear models procedure (SAS; SAS Institute Inc, Cary, NC) compared least-squares means to determine that there was no interaction between time and recorder. A Student paired t test was used to assess the agreement between self-reported and electronically stored home BP and HR readings. The χ2 test was used to evaluate this agreement in controlled vs uncontrolled BP and HR measurements. Controlled BP was defined as a measurement of less than 140/90 mm Hg and uncontrolled as a measurement of 140/90 mm Hg or greater. Controlled HR was defined as a measurement of 100 beats/min or less and uncontrolled as a measurement of greater than 100 beats/min. Differences resulting in P<.05 were deemed significant. Data are presented as mean ± SD. The term case refers to 1 reading. Erroneous reporting is defined as a difference between the BP or HR measurement documented in the subject diary (SBPr, DBPr, and HRr) and measurements electronically stored on the monitor (SBPe, DBPe, and HRe).

and electronically stored home BP and heart rate (HR) readings in patients with hypertension, (2) compare this agreement in subjects with controlled vs uncontrolled hypertension, (3) compare compliance with recording BP measurements with medication adherence, and (4) assess the ease and subject willingness to continue home monitoring.

RESULTS

Seventy-three subjects were randomly identified and mailed introductory letters describing the study. Forty-three members were excluded: 21 refused to participate, 17 were unable to be contacted by telephone, 3 failed to attend the scheduled appointment and declined to reschedule, 1 had atrial fibrillation, and 1 had moved. Thirty subjects were enrolled into the study. One participant was excluded for failure to comply with the study protocol. Complete data were available for 29 participants. The mean age was 56 ± 9 years, the mean weight was 86.4 ± 17.6 kg, and 52% were women. Twenty-four participants (83%) were white and 5 (17%) were African Americans.

Sixty-nine percent of the subjects (n = 20) reported taking between 1 and 3 daily medications, 24% (n = 7) reported taking between 4 and 6 daily medications, and 1 subject reported taking 8 medications daily. One subject denied taking any daily medications. Ninety-six percent of the subjects (n = 28) were prescribed at least 1 antihypertensive medication: 79% (n = 23) of these participants were receiving monotherapy and 21% (n = 6) were prescribed 2 antihypertensive drugs.
Table 1. Trends for Reporting Multiple Blood Pressure Readings per Interval*

<table>
<thead>
<tr>
<th>SBP Repeated per Interval, No. (%)</th>
<th>DBP Repeated per Interval, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest pressure</td>
<td>26 (36)</td>
</tr>
<tr>
<td>Middle pressure</td>
<td>27 (37)</td>
</tr>
<tr>
<td>Lowest pressure</td>
<td>20 (27)</td>
</tr>
</tbody>
</table>

*SBP indicates systolic blood pressure; DBP, diastolic blood pressure.

Only 1 subject adhered to the protocol by measuring and recording SBPr, DBPr, and HRR at each of 3 time intervals. Twenty-three of 29 subjects deviated from the protocol and repeated BP and HR measurements more than once (greater than 2 readings per interval) and self-selected which pressure to record. The number of BP measurements per week ranged from 30 to 83. When systolic BP measurements were repeated during an interval, there was an unequal distribution between reporting the highest SBPe, the lowest SBPe, and the SBPe that was in between the highest and lowest in the interval (Table 1). When DBPs were repeated, the reading between the highest and lowest DBPe during the interval was most frequently reported (41%, 30/73).

Overall, there were no statistically significant differences between SBPe and SBPr (0.43 mm Hg; P = .57). Of the SBPr readings, 67.8% were identical to SBPe (Figure 1). Twenty-four participants (83%) recorded an SBPr at least twice that differed from SBPe by more than 10 mm Hg. Fifteen participants (52%) reported 1 or more readings that were never electronically stored by the monitor at the recorded interval. Three participants completely omitted 1 or more electronically stored readings from their diary.

Similarly, there were no statistically significant differences between DBPe and DBPr (0.2 mm Hg; P = .71). Of the DBPr readings, 67.9% were identical to DBPe (Figure 1). Eighteen participants (62%) recorded a DBPr on 2 or more occasions that differed from the DBPe by more than 10 mm Hg. Fourteen participants (48%) reported 1 or more readings that were never electronically stored by the monitor at the recorded interval. Six participants completely omitted 1 or more electronically stored readings from their diary.

Of the HRR readings, 67.9% were identical to the HRR (Figure 2). No difference was found between HRe and HRR (0.36 beat/min; P = .44). Nineteen participants (65%) recorded at least 2 measurements that differed from the HRe by more than 10 beats/min. Thirteen participants (45%) reported HRr readings that were not stored by the monitor as documented in the diary. Six participants completely omitted 1 or more electronically stored HR readings from their diary.

Our results showed that 46.9% of the SBPe readings and 24.5% of the DBPe readings reflected uncontrolled hypertension. When SBPe was 140 mm Hg or greater, 12 participants recorded their SBP less than 140 mm Hg on at least 1 occasion. Conversely, 3.6% of controlled SBPe readings were recorded by 7 participants as being 140 mm Hg or more (P < .001) (Table 2).

Erroneous reporting was evident in 20.9% of uncontrolled DBPe readings, in which 14 participants recorded a DBPe of 90 mm Hg or more as being less than 90 mm Hg on at least 1 occasion, whereas 3.8% of controlled DBPe readings (<90 mm Hg) taken by 7 participants were recorded as 90 mm Hg or more on at least 1 occasion (P < .001). Of the HRe readings, 4.4% were uncontrolled (>100 beats/min). In these cases, 43.5% of the HR readings recorded by 6 participants were erroneously reported as being less than 100 beats/min (P < .001).

Seventy-six percent of the subjects (n = 22) found the monitor easy to use, and 83% (n = 24) reported that they would definitely or most likely use the monitor again if available. Only 1 subject found the monitor difficult to use.

Only 2 of 28 participants receiving medications had a 12-month medication refill rate of less than 80%. Exactly 75.0% of these participants (n = 21) had medication refill rates of 100% (12 months of medications refilled in 12 calendar months). Three participants who had the highest incidence of erroneous BP reporting had a medication adherence rate of 100%.

**COMMENT**

Encouraging patients to monitor their disease provides objective information to motivate patients to control their health condition. Home monitoring also pro-

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Figure 1. Absolute percentage difference in self-reported from electronically stored blood pressure (BP) readings. SBP indicates systolic BP; DBP, diastolic BP.

Figure 2. Absolute percentage difference in self-reported from electronically stored heart rate readings.
vides documentation of the effects of medications, which may improve patient adherence to prescribed treatments. Additionally, these data are particularly useful for primary care physicians who must assess “true” rather than “office” disease severity and level of control. The value of patient-directed treatment and monitoring programs depends on the reliability of the data collected.

The percentage of recordings that were identical to those values stored electronically in this study (68%) was similar to the accuracy of subject-recorded adherence to metered-dose inhaler therapy in 75 subjects with asthma (67%). Our findings are also consistent with results of a study by Mazze et al, who evaluated the use of glucometer reflectance photometers to compare self-reported capillary glucose measurements vs electronically stored glucose concentrations in 19 insulin-dependent diabetic subjects. Their study found a significant difference between the mean blood glucose values recorded by the memory reflectance meter and the subject. In 74% of the cases, mean blood glucose recordings in the subjects’ logbooks were lower than readings that were electronically stored, primarily because subjects omitted blood glucose concentrations greater than 13.9 mmol/L (250 mg/dL) from their logbooks. In our study, erroneous reporting occurred more frequently in instances where BP was greater than 140/90 mm Hg or when HR exceeded 100 beats/min. In cases where erroneous reporting was evident, subjects were more likely to falsely create and record BPs and HRs that were not measured by the monitor as documented rather than completely omit the measured result from the diary. Although the same percentage of accurate reporting was evident in all measurement categories (SBP, DBP, and HR; Figures 1 and 2), only 1 subject accurately recorded results across all 3 measurement categories. With the exception of this 1 individual, different subjects contributed to the 68% of accurate results in each category.

Pharmacy claims data were used to assess medication adherence and compare subject compliance with medications with the accuracy of self-reported BP measurements. There was no apparent link between compliance with medications and the accuracy of BP reporting. Seventy-five percent of the participants had prescription refill rates of 100%; the 3 participants who had the highest rate of erroneous BP reporting were included in this group.

A limitation of this study was the possibility that subjects more reliably reported results because they knew they were participating in a BP study. Furthermore, the relatively high refusal rate (29%) may indicate a selection bias, leading to the enrollment of subjects more likely to correctly report BPs. Thus, the results of this study likely provide a conservative estimate of the true incidence of erroneous reporting. Another limitation is that the monitor is not physically attached to the subject. It is impossible to rule out the possibility that other people used the monitor and therefore electronically stored results were not representative of the study participant’s BP. This was inevitable in an effort to conceal that the monitor electronically stored the results. However, after analyzing each subjects’ data, there were few recordings that were clear outliers from other subject-specific cases. Additionally, the exact time of each measurement was electronically stored on the monitor, which allowed us to view the frequency of BP measurement. There were several instances where repeated readings were less than 1 minute apart, supporting the use of the machine by 1 individual. The likelihood of spurious reporting being caused by technical difficulties was low, since only 1 subject reported that the monitor was difficult to use.

Although this study found that most self-reported BP and HR readings were identical to the electronically stored

<table>
<thead>
<tr>
<th>Electronic Measurement Type</th>
<th>Reported Measurement</th>
<th>% of Total Measurements</th>
<th>No. of Participants With Reported Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP ≥140 mm Hg (total, 247 measurements)</td>
<td>SBP ≥140 mm Hg</td>
<td>89.5</td>
<td>24</td>
</tr>
<tr>
<td>SBP &lt;140 mm Hg</td>
<td>8.9</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>1.6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>SBP ≥140 mm Hg (total, 280 measurements)</td>
<td>SBP ≥140 mm Hg</td>
<td>3.6</td>
<td>7</td>
</tr>
<tr>
<td>SBP &lt;140 mm Hg</td>
<td>95.0</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>1.4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>DBP ≥90 mm Hg (total, 129 measurements)</td>
<td>DBP ≥90 mm Hg</td>
<td>76.7</td>
<td>22</td>
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<tr>
<td>DBP &lt;90 mm Hg</td>
<td>20.9</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>2.3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>DBP &lt;90 mm Hg (total, 398 measurements)</td>
<td>DBP ≥90 mm Hg</td>
<td>3.8</td>
<td>7</td>
</tr>
<tr>
<td>DBP &lt;90 mm Hg</td>
<td>95.0</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>1.2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>HR &gt;100 beats/min (total, 23 measurements)</td>
<td>HR &gt;100 beats/min</td>
<td>52.2</td>
<td>4</td>
</tr>
<tr>
<td>HR ≤100 beats/min</td>
<td>43.5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>4.3</td>
<td>1</td>
<td></td>
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<tr>
<td>HR &lt;100 beats/min (total, 504 measurements)</td>
<td>HR &gt;100 beats/min</td>
<td>0.2</td>
<td>1</td>
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<tr>
<td>HR ≤100 beats/min</td>
<td>98.4</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Omitted from diary</td>
<td>1.4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

*BP indicates blood pressure; HR, heart rate; SBP, systolic BP; and DBP, diastolic BP.
measurements, erroneous reporting occurred significantly more frequently in cases of elevated BP and HR. Accurate home BP data are crucial in the primary care physician’s evaluation of home BP control. False reporting of uncontrolled pressures may misguide physicians in the optimal medical treatment of their patients with hypertension, which could result in worse patient outcomes. If physicians perceive a disparity between home and office readings, they should initially validate the accuracy of the monitor by calibrating it against a standard mercury sphygmomanometer and consider “white-coat” hypertension and false reporting. If false reporting is suspected, physicians may obtain a 24-hour ambulatory BP monitor or use a BP monitor that electronically stores results.

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REFERENCES


