Sources of Variability in Blood Pressure Measurement using the Dinamap PRO 100 Automated Oscillometric Device

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The Dinamap automated oscillometric device (GE Medical Systems Information Technologies, Inc., Milwaukee, Wisconsin) for blood pressure measurement is widely employed in epidemiologic studies because it is easy to use and because it eliminates observer variability. In this study, the authors assessed the variability in observed blood pressures associated with use of the Dinamap monitor and estimated the contributions of various factors to that variability. In 60 volunteers (30 aged 23–35 years and 30 aged 54–82 years) from New York, New York, the authors obtained 30 simultaneous paired blood pressure measurements in both arms at 1-minute intervals, using three separate Dinamap PRO 100 devices allocated to arm and subject according to a balanced incomplete block design. Variability, defined as the between-arm difference in blood pressure measurements, was analyzed using a mixed-effects linear regression model. A total of 1,800 paired blood pressure measurements were obtained between September 2001 and June 2002. The mean ages of the two groups were 28.3 years (standard deviation, 4.0) and 71.7 years (standard deviation, 8.0). A diagnosis of hypertension was present in 53% of the older subjects and none of the younger subjects. Fifty percent of paired simultaneous blood pressure measurements obtained were in agreement within 4 mmHg for systolic blood pressure or within 3 mmHg for diastolic blood pressure. Residual variability, attributable to the intrinsic inaccuracy of the device, accounted for 64–82% of the total systolic and diastolic blood pressure variability. The majority of variability in blood pressure measurement was due to the device as used under the study conditions.

blood pressure; epidemiologic methods; equipment and supplies; observer variation; oscillometry; research design

Abbreviation: MESA, Multi-Ethnic Study of Atherosclerosis.

The Dinamap automated oscillometric device (GE Medical Systems Information Technologies, Inc., Milwaukee, Wisconsin) is a device for measuring resting blood pressure. It is easy to use, requires less training than manual mercury sphygmomanometers, and intuitively appears to eliminate or reduce interrater variability as a source of error in blood pressure measurement. These features have led to the use of Dinamap devices in several epidemiologic studies, including the Multi-Ethnic Study of Atherosclerosis (MESA) (1), the Atherosclerosis Risk in Communities Study (2), the National Heart, Lung, and Blood Institute Family Heart Study (3), and the Hypertension Genetic Epidemiology Network study (4). These uses have included measurement of resting blood pressure and blood pressure response to stressors. In several published papers (5–20), investigators have assessed the accuracy of Dinamap devices by comparing Dinamap blood pressure measurements with those obtained by intraarterial recording or auscultation and manual sphygmomanometry. No published data of which we are aware have directly assessed the variability in measured blood pressures obtained with an automated oscillometric blood pressure device.

There are at least two ways in which inaccuracy might contribute to measurement variability. First, a deflation rate of 2 mmHg per second in a subject with a heart rate of 60 beats per minute means that one cardiac cycle is sampled per
2 mmHg, which sets this as the limit of resolution of the device under these conditions. Second, the device works by measuring the arterial pressure oscillation during the cardiac cycle, identifying the pressure level at which the rate of rise is maximal (designated mean arterial pressure), and using a proprietary algorithm to estimate systolic and diastolic blood pressure (e.g., systolic blood pressure = 1.5 × mean arterial pressure). Therefore, the imprecision with which the maximal rate of rise is identified is a second intrinsic source of error. In addition, the algorithm used to estimate systolic and diastolic blood pressure from mean arterial pressure is empirically derived and approximate. However, if all else were completely accurate, this would not create variability in observed blood pressure measurements.

Other factors may also contribute to variability in observed blood pressure values and/or modify the contribution to variability of the intrinsic inaccuracy of the device. These factors include blood pressure level, systematic differences in blood pressure between the left arm and the right arm, subject-specific variation in these differences, differences in measurement by different devices, differences in the order in which the devices are assigned to a particular arm, and sequence effects (i.e., earlier blood pressure measurements versus later measurements). It has also long been recognized that the physical conditions under which blood pressure is measured may affect the observed blood pressure level. These include cuff size relative to arm size, cuff position relative to the heart, posture, physical activity, the state of relaxation of the subject, and ambient temperature (21–25).

The purpose of this study was to quantify the variability in observed blood pressure associated with use of the Dinamap PRO 100 and to estimate the contributions of various factors to that variability under standardized conditions comparable to those achievable in epidemiologic research.

MATERIALS AND METHODS

Subjects

We conducted the study among 60 volunteers from New York, New York, between September 2001 and June 2002. The study was performed in two parts: first in a volunteer group of 30 healthy younger persons (ages 23–35 years) who were not using any medication for a chronic health condition, other than treatment for allergies or birth control, and then in a group of 30 older subjects (ages 54–82 years) enrolled in MESA at the Columbia University MESA Field Center. The presence of chronic medical conditions, use of medications, and the presence of hypertension were ascertained during a brief initial interview. The presence of hypertension was based on self-report of a physician’s diagnosis or current use of antihypertensive medication. None of the younger participants had measured blood pressure levels above 140/90 mmHg. Atrial fibrillation, as determined at baseline interview or by electrocardiogram, was an exclusion criterion for MESA (1). None of the subjects had atrial fibrillation, which can interfere with oscillometric measurement of blood pressure. The Institutional Review Board of the Columbia-Presbyterian Medical Center approved the study, and all subjects gave written informed consent.

Procedure

Thirty paired simultaneous blood pressure measurements were obtained at 1-minute intervals in each participant, in three sequences of 10 each. We used three different Dinamap PRO 100 devices. Participants were allocated to one of 12 configurations of assignment of the three devices to the left or right arm using a balanced incomplete block design:

\[
\begin{array}{cccccc}
1,2 & 2,3 & 3,1 & 1,2 & 2,3 & 3,1 \\
2,3 & 1,2 & 2,3 & 3,1 & 3,1 & 1,2 \\
3,1 & 3,1 & 1,2 & 2,3 & 1,2 & 2,3 \\
2,1 & 3,2 & 1,3 & 2,1 & 3,2 & 1,3 \\
3,2 & 2,1 & 3,2 & 1,3 & 1,3 & 2,1 \\
1,3 & 1,3 & 2,1 & 3,2 & 2,1 & 3,1 \\
\end{array}
\]

The numbers in this table refer to the three devices. A participant assigned to one of the 12 configurations had the three devices used on the left and right arms, as shown, in three pairings such that 10 pairs of blood pressure measurements were made in each pairing.

Blood pressure measurements were obtained with the subject in the seated position with 5 minutes’ rest before the first sequence and between sequences, under standardized conditions corresponding to consensus recommendations for blood pressure measurement (23–25). The measurements were taken in a quiet room with an ambient temperature between 70°F and 76°F. Subjects were seated in a chair with back support, with both feet resting comfortably on the floor and both forearms supported on a level surface. Subjects were asked not to talk during the procedure. Cuff size was selected on the basis of a table of cuff sizes and arm circumferences to avoid artifacts arising from selection of an inappropriate-size cuff. The cuff was placed on the arm at the level of the heart. All blood pressure measurements were obtained by a single investigator (J. J. C.).

Statistical analysis

Bland-Altman plots of differences between each systolic and diastolic pair of measurements were used to examine whether the variability of the difference in paired measurements was related to the level of blood pressure. Mean blood pressure levels by age group were calculated by dividing the sum of the subject-specific means by the number of subjects in the group. Mixed-effects linear models were used to examine the data on blood pressure measurement differences. The analyses proceeded from exploratory model fitting and model checking to the development of a final model. Among the factors considered in the exploratory models were population and subject-specific differences between average blood pressure measurements in the right and left arms, differences between average blood pressure measurements, differences in blood pressure measurement variability in the three different machines, and the covariance structure of the serial blood pressure measurements.
The preponderance of right-handed subjects precluded simultaneous examination of differences between the right and left arms and differences between the dominant and nondominant arms.

The final model took the form

\[ D_{ijk} = \mu + \alpha_i + \beta_j + \gamma_{r(i,j)} + \gamma_{l(i,j)} + \epsilon_{ijk}, \]

where \( D_{ijk} \) denotes the \( k \)th difference between the right- and left-hand measurements taken during the \( j \)th block of measurements from the \( i \)th subject, \( \mu \) is the population difference in average measurements from the right and left arms, \( \alpha_i \) is a random subject-specific variance component representing the deviation of the \( i \)th subject’s right-arm versus left-arm difference from the population right-arm versus left-arm difference, \( \beta_j \) denotes the block-specific variance components representing the expected deviations of within-block difference from the expected subject-specific difference, \( r(i,j) \) and \( l(i,j) \) denote the machines used on the right and left arms, respectively, in the \( j \)th block of measurements from the \( i \)th subject, the \( \gamma \)'s are fixed-effects terms representing the differences in the expected measurements between machines, and \( \epsilon_{ijk} \) is a random effect representing residual variability in the \( k \)th measurement in the \( j \)th block from the \( i \)th subject. The random effects are defined to be independent.

The estimable fixed-effect parameters in this model are \( \mu \) and the differences, \( \gamma_1 - \gamma_2 \) and \( \gamma_2 - \gamma_3 \). The estimable random-effects parameters are the variance of the subject-specific and block-specific components, \( \sigma_\alpha \) and \( \sigma_\beta \), and the variance of the residual terms, \( \sigma_\epsilon \). The estimates presented in the table are based on untransformed data; however, log- and square-root-transformed data revealed qualitatively similar results. Tests of significance were made for the presence of a handedness effect, an overall machine effect (with 2 df), the subject-specific and block-specific variance components, and the residual variability. Model checking was carried out through a combination of examining the significance and magnitude of effect of parameter estimates and examining graphical displays of residuals and covariance structure parameter estimates. All analyses were conducted separately for systolic and diastolic blood pressure measurements. Estimation and significance level checking were carried out using SAS PROC MIXED (SAS Institute, Inc., Cary, North Carolina) (26).

Quantiles were calculated for the observed distributions of the absolute values of the between-arm differences in blood pressure, both unadjusted and adjusted for blood pressure level, arm, subject, block, device, and sequence. For assessment of sequential measurement variability rather than simultaneous variability, the corresponding quantiles were calculated for unadjusted paired blood pressure measurements, where the pairs were defined as the \( i \)th measurement and the \( (i + 1) \)th measurement in the same arm for each subject using a single Dinamap device (a single block of 10 measurements).

**RESULTS**

The mean age of the younger group was 28.3 years (standard deviation, 4.0), while that of the older group was 71.7 years (standard deviation, 8.0). Of the 30 younger subjects, 22 (73.3 percent) were female, as compared with 12 (40 percent) of the 30 older subjects. None of the younger subjects had hypertension, as compared with 16 (53.3 percent) of the older subjects. In both groups, 28 of the 30 subjects were right-handed.

A total of 1,800 paired blood pressure measurements were obtained. Table 1 shows the mean blood pressure levels for the right and left arms in each group. As expected, the younger group had lower mean systolic and diastolic blood pressures than the older group. Figures 1, 2, 3, and 4 represent the Bland–Altman plots of the differences in each systolic and diastolic pair for the younger and older groups. No apparent relation between variability in the differences in paired blood pressure measurements and level of blood pressure was noted. Linear regressions of the squared differences on the average systolic and diastolic blood pressure values indicated no significant relation, which was consistent with the visual impression. The multivariate models for variability did not include terms for systolic or diastolic blood pressure level, because these terms did not contribute significantly to variability in these models.

Table 2 shows the parameter estimates from the mixed-effects models for each group. There was ambiguous evidence of a systematic difference in the average blood pressure measurement between the right arm and the left arm. There was no statistically significant difference among the three machines in average blood pressure measurements. There was evidence of significant subject-specific variability (variance of \( \alpha \)). This variance estimate represents the vari-

**TABLE 1. Mean blood pressure levels and differences, by age group, in a study of variability in blood pressure measurements, New York, New York, 2001–2002**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Younger group (n = 30)</th>
<th>Older group (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left arm</td>
<td>Right arm</td>
</tr>
<tr>
<td>Systolic pressure</td>
<td>115.0 (12.3)†</td>
<td>116.7 (12.8)</td>
</tr>
<tr>
<td>Diastolic pressure</td>
<td>68.9 (7.4)</td>
<td>69.0 (8.0)</td>
</tr>
</tbody>
</table>

* Mean values were computed from the total of 3,600 blood pressure observations (30 in each arm in each subject).
† Numbers in parentheses, standard deviation.
ance of the deviation of the $i$th subject’s right-arm versus left-arm difference from the population average right-arm versus left-arm difference. There was also evidence of block-specific variability (variance of $\beta$). This variance estimate represents the variance of the deviation of a block of 10 blood pressure measurements’ right- versus left-arm difference from the population average right- versus left-arm difference. This contribution may represent cuff repositioning or changes in posture. The variance of the random error ($\epsilon$) is the residual variability. The interpretation of the residual variability is variability due to the intrinsic inaccuracy of the blood pressure device as used under the conditions of the study. We cannot be sure that, in addition, a component of variability due to rapidly fluctuating differ-

FIGURE 1. Bland-Altman plot of between-arm differences in systolic blood pressure (S_DIFF) (mmHg) and mean systolic blood pressure (S_AVG) (mmHg) in the younger age group, New York, New York, 2001–2002.

FIGURE 2. Bland-Altman plot of between-arm differences in diastolic blood pressure (D_DIFF) (mmHg) and mean diastolic blood pressure (D_AVG) (mmHg) in the younger age group, New York, New York, 2001–2002.
ences between arms in the true underlying blood pressure is not also contributing to the estimated residual variability, but to our knowledge this has not been described.

In additional analyses, we found no significant evidence of serial correlation in the measurement differences beyond that which could be accounted for by the between-subject and between-block variance components. There was also no strong evidence for changes in the variability of the blood pressure measurements with sequential measurements or for differences in the variability of measurements taken from different machines. However, these aspects of the analysis had low statistical power.

As is shown in table 2, residual variability was the largest component of the three variance components that contributed to the variability of the paired differences in blood pressure measurements. After removal of the fixed effects, which were small, the residual variability accounted for 64–82 percent of the total variability in systolic and diastolic blood pressure differences between arms in the younger and older groups, respectively. It is interesting to compare the
proportion of variability due to the residual terms and the subject- and block-specific components of variability. The ratios for systolic and diastolic pressure and for the two groups ranged from approximately 2:5 to 1:2. The estimated contribution of systematic differences in the machines and between the right and left arms was on the order of only one tenth of the contribution of the random-effects components.

While some aspects of the parameter estimates differed between the older and younger subjects, these differences, when considered in light of the large number of possible comparisons, did not appear to be statistically significant.

Table 3 shows the absolute values for between-arm differences in blood pressure among 60 subjects, New York, New York, 2001–2002

**DISCUSSION**

Our analysis of 1,800 simultaneous paired blood pressure measurements from 60 adults, obtained using the Dinamap PRO 100 oscillometric device, showed that the largest component of variability of between-arm differences in blood pressure was residual variability. Residual variability may be viewed as corresponding to a combination of random

**TABLE 2. Parameter estimates from a mixed-effects model predicting variability in between-arm differences in blood pressure among 60 subjects, New York, New York, 2001–2002**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Systolic blood pressure</th>
<th>Diastolic blood pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Younger group (n = 30)</td>
<td>Older group (n = 30)</td>
</tr>
<tr>
<td>Fixed effects (mmHg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right arm vs. left arm (µ)</td>
<td>1.93 (0.71)**,†</td>
<td>0.35 (0.61)</td>
</tr>
<tr>
<td>Differences between machine 1 and machine 3 (γ₁ − γ₃)</td>
<td>0.31 (0.49)</td>
<td>0.12 (0.40)</td>
</tr>
<tr>
<td>Differences between machine 2 and machine 3 (γ₂ − γ₃)</td>
<td>−0.40 (0.49)</td>
<td>−0.77 (0.40)</td>
</tr>
<tr>
<td>Random effects (mmHg²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject-specific variability (variance of α)</td>
<td>10.48 (3.75)**</td>
<td>7.98 (2.76)*</td>
</tr>
<tr>
<td>Block-specific variability (variance of β)</td>
<td>7.49 (1.99)**</td>
<td>2.40 (1.35)**</td>
</tr>
<tr>
<td>Variance of the random error (variance of ε)</td>
<td>31.89 (1.59)**</td>
<td>47.68 (2.37)**</td>
</tr>
</tbody>
</table>

* p < 0.05; ** p < 0.01; *** p < 0.001.
† Numbers in parentheses, standard error.

**TABLE 3. Absolute values for between-arm differences in blood pressure among 60 subjects, New York, New York, 2001–2002**

<table>
<thead>
<tr>
<th>Age group and percentile</th>
<th>Difference in blood pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Systolic pressure</td>
</tr>
<tr>
<td></td>
<td>Unadjusted</td>
</tr>
<tr>
<td>Younger group</td>
<td></td>
</tr>
<tr>
<td>5th</td>
<td>0</td>
</tr>
<tr>
<td>10th</td>
<td>1.0</td>
</tr>
<tr>
<td>25th</td>
<td>2.0</td>
</tr>
<tr>
<td>50th</td>
<td>4.0</td>
</tr>
<tr>
<td>75th</td>
<td>7.0</td>
</tr>
<tr>
<td>90th</td>
<td>12.0</td>
</tr>
<tr>
<td>95th</td>
<td>15.0</td>
</tr>
<tr>
<td>Older group</td>
<td></td>
</tr>
<tr>
<td>5th</td>
<td>0</td>
</tr>
<tr>
<td>10th</td>
<td>1.0</td>
</tr>
<tr>
<td>25th</td>
<td>2.0</td>
</tr>
<tr>
<td>50th</td>
<td>4.0</td>
</tr>
<tr>
<td>75th</td>
<td>7.0</td>
</tr>
<tr>
<td>90th</td>
<td>12.0</td>
</tr>
<tr>
<td>95th</td>
<td>17.0</td>
</tr>
</tbody>
</table>

* Adjusted for blood pressure level, arm, subject, block, device, and sequence.
measurement error inherent in the action of the machines, random rapidly fluctuating differences between blood pressure values in the right and left arms, and possibly also transient effects of posture. The subject-specific and block-specific components of variability were estimated to be of smaller magnitude than the residual variability. The subject-specific components of variability may be viewed as corresponding to a combination of true subject-specific differences between average blood pressures in the right and left arms or systematic differences in posture or placement of the cuffs on the right and left arms. The block-specific components of variability may be viewed as a combination of fairly slowly changing differences in actual blood pressure between the right and left arms and changes between blocks of measurement in posture or position of the cuffs on the right and left arms.

Subject-specific variability, which made the largest contribution to variability for systolic and diastolic pressure in both groups after residual variability, represents differences among subjects in cuff placement, posture, state of relaxation, and other aspects of the subject’s state at the time of measurement or of the interaction between the subject and the device. The persistence of subject-specific variability, despite careful standardization of the conditions and procedures for measuring the blood pressure, suggests that even more meticulous standardization may have the potential to reduce variability somewhat.

We did not find the variability of simultaneous blood pressure measurements and sequential blood pressure measurements obtained in the same arm 1 minute apart to be very different. This suggests that short-term biologic variation in blood pressure is small compared with other sources of variability.

Our findings on between-arm differences in blood pressure measurements using the Dinamap device are comparable to those from other studies of simultaneous measurements using different devices. In 1960, using aneroid sphygmomanometers, Harrison et al. (27) performed three simultaneous blood pressure measurements on both arms at 1-minute intervals in 447 patients. Fifty percent of these subjects had between-arm differences in systolic blood pressure greater than or equal to 5 mmHg (versus 45 percent in our study), and 44 percent had differences in diastolic blood pressure of at least 5 mmHg (versus 34 percent in our study). Harrison et al. also obtained simultaneous intraarterial pressure measurements of the brachial artery in both arms in a subsample of 53 subjects. In this subgroup, 29 percent of the subjects were noted to have between-arm differences in systolic blood pressure of at least 5 mmHg. Similarly, in 1985, Gould et al. (28) published results from a study of eight simultaneous paired blood pressure measurements made on both arms using a random-zero mercury sphygmomanometer in 91 hypertensive subjects. They reported that only 8 percent of the between-arm differences in systolic pressure and 3 percent of differences in diastolic pressure exceeded 10 mmHg, as compared with 15 percent and 8 percent for systolic and diastolic pressure differences in our study. Kaufman et al. (29) analyzed paired arm blood pressure measurements obtained with three different oscillometric devices, one of which was an earlier model of the Dinamap, in 25 anesthetized patients. On the basis of evaluation of Bland-Altman data plots, these investigators concluded that there was no important relation between level of blood pressure and variability. In addition, they concluded that different devices have different degrees of variability and that therefore measurements obtained by different devices are not interchangeable (29).

Several limitations of our study may be considered in interpreting these findings. Biologic and nonbiologic factors other than those considered in the analyses may contribute to blood pressure variability. However, it seems less likely that such factors would affect between-arm differences in simultaneous blood pressure measurements. Our data also do not address the reliability of data obtained with Dinamap models other than the PRO 100 or with automated oscillometric devices sold by other manufacturers. An earlier model of the Dinamap, the 1846-SX, was used in the Atherosclerosis Risk in Communities Study (2) and the Hypertension Genetic Epidemiology Network study (4), while the PRO 100 model is being used in MESA (1) and was used in this study. Observed variability may be different for measurements obtained under conditions that differ from those in our study.

Our study did not address the accuracy of blood pressure measurements taken with the Dinamap PRO 100 device. Other investigators have examined the accuracy of oscillometric devices compared with intraarterial blood pressure recordings or mercury sphygmomanometry (5–20). A recent review summarized findings on the accuracy of a number of blood pressure devices (13). The Dinamap 8100 device was
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