Properties of the Random Zero Sphygmomanometer

Richard A. Kronmal, Gale H. Rutan, Teri A. Manolio, and Nemat O. Borhani

The random zero sphygmomanometer is widely used in studies involving blood pressure measurement because it is believed to eliminate digit preference and reduce measurement error. We performed blood pressure measurements sequentially using random zero and standard sphygmomanometers in random order in 1,356 participants in the Cardiovascular Health Study. Despite adherence to the manufacturer's instructions, we observed a substantially nonuniform distribution of zero levels generated by the random zero sphygmomanometer and a disturbing correlation between the zero level and blood pressures taken with the standard sphygmomanometer. With the random zero device, the pooled estimated slopes for the regression of standard systolic and diastolic pressures on the zero level were −0.71 and −0.17, respectively (both p < 0.0001). The only plausible explanation for this relation between the random zero device and the standard device is that by some unknown mechanism the subject’s blood pressure is influencing the zero level. Systolic and diastolic blood pressures measured with the random zero device were, respectively, 1.65 and 1.84 mm Hg lower (both p < 0.0001) than standard blood pressures. Digit preference was detectable in the uncorrected blood pressure and zero level measured with the random zero device but was eliminated after calculation of the corrected blood pressure. For most epidemiological studies, the random zero sphygmomanometer offers no significant advantage over the standard sphygmomanometer. It may still be useful in those epidemiological studies and clinical trials where blinding is important.

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KEY WORDS • blood pressure monitors • randomized controlled trials • blood pressure determination

Accurate and reliable measurement of blood pressure is an important constituent of epidemiological studies of cardiovascular disease. Because the use of the standard mercury sphygmomanometer may be associated with bias, digit preference, or both, numerous investigations of alternatives to the standard device have been conducted. To date, the only device considered a satisfactory alternative is the Hawksley Random Zero sphygmomanometer (R-Z), which seems to reduce the potential for digit preference. Thus, the R-Z has become the sphygmomanometer of choice in epidemiological studies and clinical trials.

The R-Z produces a variable baseline (zero level) set by the spinning of a wheel; this value is subtracted from the measured blood pressure to obtain a corrected blood pressure. This random zero figure is not visible at the time that the uncorrected blood pressure is taken. Therefore, the observer cannot tell while reading the uncorrected blood pressure what the measured blood pressure reading would be. Systolic and diastolic blood pressures measured with the R-Z have been demonstrated to be lower than the readings obtained by the standard device (1.2–3.3 mm Hg for systolic and 2.2–6.2 mm Hg for diastolic pressures) and their variation slightly greater than those taken with a standard device.

As part of our routine quality control of blood pressure measurements taken during the baseline examination in the Cardiovascular Health Study (CHS), we noted some peculiarities in the distribution of the random zero levels and their correlation with the corrected blood pressures. We recently reported that the slopes relating the zero level to the systolic and diastolic blood pressures were −0.869 and −0.218, respectively (both p < 0.0001). In theory, if the R-Z had produced a truly random zero level, there should be no correlation between the zero level and blood pressure levels. One would expect, however, a small negative correlation between the random zero and the blood pressure levels due to measurement error, including measurement error resulting from digit preference, in determining the zero level. However, such a correlation should be quite small unless the measurement error itself is large.

We were concerned about these findings because of the possibility that the zero level might be influencing the blood pressure measurement, thereby adding error or bias to the measurement. Alternatively, it was possible that the “true” blood pressure was inducing a change in the observed random zero level. In the CHS baseline examination, repeated seated blood pressures were taken only with the R-Z; therefore, an adequate evaluation was not possible. As a result of observing this problem, however, we measured blood pressure in the first year follow-up of the CHS cohort using both an R-Z and a standard mercury sphygmomanometer.

Our objectives were 1) to estimate the distributions of the random zero level and its associations with blood pressure, and 2) to determine the blood pressure levels associated with the zero level.
pressure level, 2) to assess the magnitude of digit preference using the R-Z and the standard device, and 3) to compare the means and variances of the blood pressure measurements in elderly individuals made with these devices. The results are reported in the present communication.

Methods

The CHS cohort consists of 5,201 participants 65 years of age and older. The details of the study have been described elsewhere. The Hawksley R-Z (model 7076, Hawksley and Sons Limited, Sussex, England) was the only blood pressure device used in the baseline examination; both the R-Z and the standard device (W.A. Baum Co., Inc., Copiague, N.Y.) were used in the first follow-up examination. After 6 months of follow-up, 22 technicians had measured the blood pressure of 2,616 participants using both devices. We present in detail the data from six technicians who each measured blood pressure on more than 199 participants. These six represent all four Field Centers and performed blood pressure measurements on a total of 1,365 participants. The results for the remaining 16 technicians are included in the pooled data used in the regression analysis only because the number of measurements made by any one of these technicians was insufficient to justify intensive analysis. Analysis of the data from the 16 excluded technicians yielded findings similar to those from the six technicians examined in detail.

Only one R-Z device was used at two of the Field Centers. Two devices were used at the other two Field Centers, although the technicians examined tended to use one of the two predominantly. For those centers having only one device, it is impossible to separate the effect of the device from technician effects. Similarly, the almost exclusive use of one of the devices at the centers having two also precluded any separation of these effects. The fact that the findings are consistent across 22 technicians using eight different R-Z devices makes it extremely likely, however, that the effects observed are primarily due to the properties of all of the devices rather than to technician effects.

The protocol used for the R-Z blood pressure measurement in CHS was based on the most current recommendations from the American Heart Association and adaptations for R-Z usage from the Systolic Hypertension in the Elderly Program. Blood pressure observers in our study were centrally trained using the standardized protocol and were tested for reproducibility of technique before certification. The standardized protocol included 1) measurement of arm circumference for appropriate cuff size; 2) palpation of the mid-height of the cuff at heart level; 3) palpation of the systolic blood pressure with the standard manometer before the 5-minute rest to determine the maximal inflation level for the R-Z when the blood pressure is subsequently auscultated; 4) allowance of a full 5-minute rest in the seated position with the cuff in place and the bellows valve open on the R-Z before obtaining the blood pressure; 5) support of the elbow and forearm on a standard-size table with the participant seated upright, legs uncrossed; 6) definition of the diastolic blood pressure as phase V; and 7) frequent assessment of quality and reproducibility of blood pressure measurements by a variety of quality control procedures. The standard mercury sphygmomanometer was used following the American Heart Association recommendations. The last digit of the participant ID number (odd or even) was used to determine whether the random zero or standard device was used first. The order in which the devices were used was thus essentially random with respect to time of day and day of week of the clinic visit.

Regression analysis was used to determine the relationship between the zero level and the random zero blood pressures. Differences between the blood pressures taken with the R-Z and with the standard device were compared using the paired t test. Analysis of variance procedures were used to estimate the slopes relating the R-Z blood pressures or the standard blood pressures to the zero level after adjustment for technician and to test the hypothesis that the slopes were the same for all technicians. All of the analyses reported here were obtained using the spss/rc statistical package. All participants in CHS signed an informed consent form approved by the human subjects review boards of the institutions involved.

Results

Figure 1 shows the distributions of the random zero levels obtained by each of the six technicians who participated in this study. The distributions of the random zero level values were nonuniform, and in several instances large peaks occurred at specific values. The distributions were also statistically significantly different from each other (p<0.0001).

Figures 2 and 3 show the distributions of the systolic (Figure 2) and diastolic (Figure 3) blood pressures for the entire sample as measured by both devices. Note that for the interval sizes shown (deliberately chosen to mask any digit preference), no major differences between the distributions appear. However, considerable digit preference with the standard device is illustrated in Figure 4, which shows the distribution of diastolic blood pressure for both devices as used by Technician 6. All of the other technicians show digit preference with the standard device, but the pattern varies (Figures 5A and 5B). Little digit preference is seen with the R-Z for any of the technicians (Figures 6A and 6B).
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Table 1 shows the means and variances and the mean differences between the blood pressures from the R-Z and those from the standard device. Note that these differences are highly statistically significant ($p<0.00001$): the means for the R-Z were smaller than those for the standard device. The magnitude of these differences is similar for both the systolic and diastolic blood pressures ($-1.65$ and $-1.84$ mm Hg, respectively). The variances for the blood pressure measurements taken by the two devices are similar.

Simple linear regression slopes and intercepts of systolic and diastolic blood pressures as predicted by the random zero level are shown in Table 2. The slopes for the systolic and diastolic blood pressures range, respectively, from $-1.15$ to $-0.43$ and from $-0.34$ to $0.066$. The test of hypothesis for equality of slopes among technicians is rejected ($p=0.046$) for systolic blood pressure and is nonsignificant for diastolic blood pressure. The similarity of the relation between the zero level and the measurements made by both devices is remarkable and is evident in the results from the data for the 16 excluded technicians as well as the six selected technicians. The pooled estimated slope is $-0.71$ for the systolic blood pressure and $-0.17$ for the diastolic blood pressure, both statistically significant ($p<0.001$).

To determine whether the random zero level was affected by the true underlying blood pressure or was related to the measured corrected blood pressure, we used a multiple linear regression analysis to predict the R-Z blood pressure from both the random zero level and the blood pressure determined by the standard mercury sphygmomanometer (used as a surrogate for the "true" blood pressure). Even after adjustment for the systolic blood pressure taken by the standard device, the zero level was still significantly correlated to the corrected R-Z systolic blood pressure. The coefficient, however, was small, only $-0.08$ ($p<0.05$). The random zero level was not significantly associated with the diastolic blood pressure measured by the R-Z, after adjustment for the diastolic blood pressure from the standard device ($p>0.8$).

Figure 7 illustrates our finding that the zero level is related to the true blood pressure. The mean systolic blood pressure measured with the standard device is plotted against the zero level from the R-Z for the four technicians whose measurements show a significant linear relation between the zero level and the R-Z systolic blood pressure. We use the measurement taken with the standard device as a surrogate for the unobserved "true" blood pressure. As expected from the analyses presented in Table 2, these plots also show that the zero level is negatively related to the systolic blood pressure, with a more pronounced effect for small values of the zero level. Because it is not possible for the zero level read from the R-Z to influence the blood pressure measured on the standard device, the only plausible explanation for this finding is that the zero level is partially determined by the "true" level of the participant's blood pressure.

**Discussion**

The R-Z accomplishes the desirable result of removing much of the digit preference observed with the standard sphygmomanometer. However, a price is paid for this improvement. Not only does any tendency for digit preference evidenced by the individual technician carry over to the measurement of the uncorrected blood pressures using the R-Z, but the R-Z also adds a new
source of error: digit preference or other error that may occur in the recording of the random zero level. Although the subtraction of these two imperfectly measured quantities results in a blood pressure measurement that is less subject to digit preference, it is not totally eliminated, since the digit preferences in the individual components of the measurement will be reflected in the computed difference. Furthermore, the price paid for partially removing the digit preference is often an increase in variance since the R-Z blood pressure measurement is the difference between two measurements that are both subject to error. The standard sphygmomanometer avoids this potential weakness because only a single reading is taken for each blood pressure. Most studies comparing the R-Z with the standard device have shown such an increase in variance.2,3,8,9 The CHS technicians were highly trained and had a full year of experience in using the R-Z during the first year clinic examinations. This added experience may explain the lack of difference in variance between the two devices seen during the follow-up exam. It is also possible that the technicians did not use the same care in performing the standard device measurement during the follow-up exam because it was an
add-on to the measurements they were required to do during the first year of the study.

The fact that the random zero level is correlated to the corrected blood pressure taken by the R-Z is troubling. However, we have shown here that this relation is due to the correlation of the zero level to the "true" blood pressure. Thus, it appears that the zero level is not influencing the blood pressure measurement taken with the R-Z. It is unclear why a residual correlation still remains between the zero level and the R-Z systolic blood pressure after adjustment for the standard systolic blood pressure. Although it is possible that the unobserved "true" blood pressure been used in the regression, the corrected blood pressure taken by the R-Z is not predicting the random zero level as well as the true blood pressure. Had the unobserved "true" blood pressure been used in the regression, the small residual correlation might have disappeared.

Although it is reassuring that the zero level is not biasing the measurement of the blood pressure on the R-Z by an important amount, the question is whether the reduction in digit preference is worth the extra cost (the price of the R-Z is more than six times that of the standard device), the increased performance time required to measure and record the zero level, the added patient discomfort due to the need to inflate the cuff to a higher pressure, and the increased variability that usually accompanies its use. Although digit preference exists in the use of the standard device, its magnitude among well-trained technicians appears to be quite small. Examination of the distributions of systolic and diastolic blood pressure using the standard device shows that most of the digit preference results in a small change in the blood pressure of at most 2 mm Hg. We believe that this could be reduced further if training and quality control procedures were instituted. It is quite likely that the additional random noise and digit preference involved in measuring the zero level may be of

### Table 2. Regression Slopes and Correlations for Random Zero Sphygmomanometer and Standard Device Systolic and Diastolic Blood Pressure vs. Random Zero Level for Each of the Six Technicians and for the Other 16 Technicians As a Group

<table>
<thead>
<tr>
<th>Technician</th>
<th>Systolic BP</th>
<th>Diastolic BP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coefficient (SD)</td>
<td>Correlation</td>
</tr>
<tr>
<td>1 R-Z</td>
<td>-0.53 (0.21)</td>
<td>-0.15</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.68 (0.20)</td>
<td>-0.20</td>
</tr>
<tr>
<td>2 R-Z</td>
<td>-0.92 (0.28)</td>
<td>-0.22</td>
</tr>
<tr>
<td>Standard</td>
<td>-1.03 (0.29)</td>
<td>-0.24</td>
</tr>
<tr>
<td>3 R-Z</td>
<td>-0.43 (0.22)</td>
<td>-0.13</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.31 (0.22)</td>
<td>-0.10</td>
</tr>
<tr>
<td>4 R-Z</td>
<td>-1.15 (0.22)</td>
<td>-0.31</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.99 (0.22)</td>
<td>-0.27</td>
</tr>
<tr>
<td>5 R-Z</td>
<td>-0.80 (0.26)</td>
<td>-0.21</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.88 (0.25)</td>
<td>-0.24</td>
</tr>
<tr>
<td>6 R-Z</td>
<td>-0.15 (0.24)</td>
<td>-0.04</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.13 (0.24)</td>
<td>-0.04</td>
</tr>
<tr>
<td>Pooled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-Z</td>
<td>-0.71 (0.10)</td>
<td>-0.20</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.68 (0.10)</td>
<td>-0.19</td>
</tr>
<tr>
<td>The other 16 technicians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-Z</td>
<td>-0.61 (0.10)</td>
<td>-0.17</td>
</tr>
<tr>
<td>Standard</td>
<td>-0.59 (0.10)</td>
<td>-0.14</td>
</tr>
</tbody>
</table>

BP, blood pressure; R-Z, random zero sphygmomanometer. Pooled estimates are for all technicians combined assuming equal slopes for all technicians.

*Paired t test.
greater magnitude than the small digit preference that would be present with the standard device in a near optimum setting. Thus, by using the R-Z we may be exchanging the problem of digit preference for an increased variability due to measurement error. Also, it would not be difficult to adjust the blood pressure readings from the standard device during analyses to take into account the digit preference, which can be estimated from the data. If this were done, the disadvantages of using the standard device would be largely eliminated for most observational studies. Even if the digit preference was not accounted for in the analysis, it is unlikely that it would meaningfully affect the usual correlational analyses carried out in epidemiological studies. However, it might affect tabular analysis in which the cut points for the blood pressures are close to the values at which digit preference occurs.

For clinical trials and epidemiological studies where blinding is essential because of the potential for observer bias in recording the blood pressure, the technician, particularly near values that might determine either trial eligibility or mandated treatment changes. Although reduction of the digit preference would argue for the use of the R-Z in the clinical trial setting, the differences in means between the R-Z and the standard mercury sphygmomanometer would be of concern. For this reason, O'Brien et al. have recommended that the R-Z not be used in hypertension research. Although we concur with this recommendation for observational studies, we believe that the R-Z may still be preferable for studies where blinding is essential because of the potential for observer bias in recording the blood pressure.

Given the problems with both the R-Z and the standard device, efforts should be made to develop an affordable blood pressure measuring device that is free of digit preference and potential observer bias. Such a device should not cause additional measurement error and ideally should not require greater cost or effort to complete the measurement.

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The Random Zero Sphygmomanometer

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