Potential Problems With the Random-Zero Sphygmomanometer

Nicholas J. Birkett

Abstract The random-zero sphygmomanometer is frequently used in epidemiologic and clinical research to increase the reliability and validity of blood pressure readings. However, recent reports have suggested that there is a correlation between the zero values of a random-zero sphygmomanometer and the zero-corrected blood pressure readings obtained. The design of the random-zero sphygmomanometer would suggest that the zero values and zero-corrected blood pressures should be uncorrelated. Hence, residual correlation might be of importance in determining the utility of this device. We have explored this relation in the Middlesex County Blood Pressure Survey, which collected data on 2725 randomly selected adults. Each person had three blood pressure readings taken with a random-zero sphygmomanometer operated by trained interviewers. There was a very weak but statistically significant correlation between the zero values and zero-corrected systolic blood pressure (r = -0.034, regression slope = -0.10), but there was no statistically significant relation with zero-corrected diastolic blood pressure (r = 0.0003, slope = 0.0006). Both the correlations and regression slopes were higher for subjects over age 65 years. These data fail to confirm the observed correlations found by Kronmal et al. This discrepancy might be explained by differences in measurement technique, which could introduce a blood pressure-dependent skewing of the range of zero values. If confirmed, this effect would have no effect on the validity of the final blood pressure readings and hence would not need to be considered in decisions about the use of the random-zero sphygmomanometer. (Hypertension. 1994;23:254-257.)

Key Words • blood pressure monitors • blood pressure determination • reproducibility of results

Obtaining accurate readings of blood pressure is important for studies of cardiovascular disease, both for epidemiologic and etiologic research and clinical trials. Research in the 1960s and 1970s established that the standard mercury sphygmomanometer can be subject to serious problems of bias and end-digit preference. Several approaches have been explored to overcome these problems, including standardized observer training, semiautomatic or automatic measuring of blood pressure, and the use of modified sphygmomanometers such as the London School of Hygiene sphygmomanometer and the random-zero sphygmomanometer. Of these approaches, the random-zero sphygmomanometer seems to have acquired the most popularity, although recently considerable interest has centered around improved automatic sphygmomanometers and 24-hour blood pressure monitoring.

The original studies of the random-zero sphygmomanometer demonstrated that it reduced expectation bias and end-digit preference. The standard mercury sphygmomanometer is designed so that at equilibrium the mercury column lies at 0 mm Hg. The random-zero device overfills the column so that the equilibrium point is around 40 mm Hg. Before inflation, a wheel is spun to randomize the position of a cam. This cam acts as a stop point for a second, flexible mercury reservoir. During the process of cuff inflation, the reservoir is connected to the mercury column with the result that as the mercury column rises a portion of the mercury is pushed into the reservoir. When one is ready to measure the blood pressure, a valve is turned to isolate the column from the reservoir. By altering the amount of mercury in the column, the zero point of the sphygmomanometer is varied in such a way that the observer is unaware of the actual zero reading until after the cuff has been completely deflated. The blood pressure is measured in the usual way with the equilibrium level of the deflated column (the zero reading) being subtracted from the observed systolic blood pressure (SBP) and diastolic blood pressure (DBP) to produce the actual blood pressure levels. The machine is designed so that the zero level varies from 0 to approximately 20 mm Hg. To ensure that the machine functions correctly, it is necessary to inflate the cuff to a higher level than usual and wait for between 5 and 10 seconds before deflation is begun so that the mercury reservoir has been properly filled. Failure to comply with these instructions will tend to reduce the range of zero levels but should not bias the blood pressure readings. This issue will be discussed again below.

Comparison of blood pressures obtained using the random-zero sphygmomanometer with simultaneously obtained readings from a normal mercury sphygmomanometer reveals that the random-zero readings tend to be slightly lower (around 2 mm Hg for SBP and 4 mm Hg for DBP). These studies also found a slight increase in the variance of readings taken using the random-zero sphygmomanometer. On the other hand, random-zero readings demonstrate less end-digit preference and are less susceptible to expectation bias.
Recently, Kronmal et al.12,13 have published data suggesting a further problem with the random-zero sphygmomanometer: they found highly significant correlations between the zero values and both the SBP and DBP after subtracting the zero values from the observed blood pressure values (regression slopes = -.57 and -.22 for SBP and DBP, respectively). These correlations persisted when the zero values were corrected with independently obtained blood pressure values from standard mercury sphygmomanometers (slopes = -.71 and -.17, respectively). They suggest that the actual blood pressure may be affecting the zero level.

Concern over the implications of these observed correlations has led us to reanalyze data collected from more than 2700 randomly selected subjects in a community blood pressure survey. We present here our empirical findings and a hypothesis to explain the results.

Methods

The Middlesex County Blood Pressure Survey was conducted from 1982 to 1983 in Middlesex County, Ontario, Canada. The methods of this survey have been published elsewhere.14 Briefly, before the start of any field work, the protocol was reviewed and approved by the Ethics Review Committee of the University of Western Ontario. All subjects were contacted using approved consent procedures, and all study methods were in accordance with institutional guidelines and were approved by this committee. A three-stage stratified probability sample of 1500 households containing 3067 people was selected. Personal interviews were conducted in the respondent’s home. The interviews included a 15-minute questionnaire and three blood pressure measurements. All observers were trained using the Rose Korotkoff phases being recorded to the nearest even digit. The cuff was inflated at a rate of 2 mm Hg/s with the first and fifth Korotkoff phases being recorded to the nearest even digit. After complete deflation, the zero point was read to the nearest digit. Observed blood pressures were converted to actual pressures by subtracting the zero value from the observed readings. All observers were trained using the Rose technique.4 In total, nine interviewers conducted the interviews, obtaining a minimum of 393 readings each with a mean of 908 readings per interviewer. All interviewers had their own sphygmomanometer, making it impossible to separate interviewer from machine effects.

Pearson correlation coefficients were calculated to relate the observed zero values to the zero-corrected blood pressures. Linear regression was used to obtain the slope of this relation. Comparability of the slopes across the three measurements was performed using ANOVA techniques.

Results

Interviews were obtained from 2735 people (response rate, 89.2%) with three blood pressure readings obtained in 2725 subjects and two readings in 1 additional subject. The mean blood pressures at the three readings were 124.1/76.9, 122.9/76.7, and 122.2/76.5 mm Hg, respectively. The mean subject age was 42 years; 47% of the sample was male. Separate correlation and regression analyses were obtained on the readings from the first, second, and third measurements. A standard test for equality of correlation coefficients16 showed that there were no significant differences among the correlations for SBP (χ²=3.4, P=.18) or DBP (χ²=3.5, P=.17). ANOVA testing also revealed no difference in the regression slopes from the three sets of measurements (P>.2). Therefore, all measurements were combined in the remaining analyses.

Tables 1 and 2 present the correlations and regression slopes relating the observed zero values to the zero-corrected SBP and DBP for each interviewer separately and for the pooled data set. For SBP, the correlations and slopes were significant for only three of the nine interviewers. The pooled estimate of the correlation was only -.034, with a regression slope of -.10. These both achieved statistical significance because of the large sample size but were markedly smaller than the corresponding values from Kronmal et al (correlation =-.20, slope =-.71).13 For DBP, values for only one interviewer were significant, and the pooled estimates of correlation (.00032) and slope (.0006) were

<table>
<thead>
<tr>
<th>Interviewer</th>
<th>Correlation</th>
<th>Slope</th>
<th>P*</th>
<th>n</th>
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<td>-.0338</td>
<td>-.100</td>
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<tr>
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<td>-.301</td>
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<td>-.111</td>
<td>.31</td>
<td>1044</td>
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</table>

*Test for slope=0.
Table 3. Correlations and Regression Slopes Relating Random-Zero Level and Corrected Systolic and Diastolic Blood Pressures: Effect of Age

<table>
<thead>
<tr>
<th>Factor</th>
<th>Age &lt; 65</th>
<th>Age ≥ 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero SBP, correlation</td>
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<td>-0.088*</td>
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<tr>
<td>Zero DBP, correlation</td>
<td>0.009</td>
<td>-0.054</td>
</tr>
<tr>
<td>Zero SBP, slope</td>
<td>-0.053</td>
<td>-0.319*</td>
</tr>
<tr>
<td>Zero DBP, slope</td>
<td>0.016</td>
<td>-0.107</td>
</tr>
</tbody>
</table>

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

*P < 0.05.

Discussion

In a large community blood pressure study, comparison of the zero-corrected blood pressure with the random-zero values failed to confirm the reported correlation between zero levels and blood pressure. There was a small but statistically significant correlation between the zero values and the zero-corrected SBP (r = -0.034).

After insightful comments from a reviewer of this manuscript, a hypothesis can be presented to explain the discrepant observations. There is a noticeable time delay from when the maximal cuff pressure is reached to when the flexible reservoir of the random-zero sphygmomanometer is completely filled. The time required is related to both the randomly determined capacity of the reservoir and the pressure gradient pushing mercury into the reservoir. Examination of a random-zero sphygmomanometer revealed that maximal bladder filling takes less than 2 seconds at a cuff pressure of 200 mm Hg or higher. The time increases as the maximal cuff pressure is lowered until, at a cuff pressure of around 160 mm Hg, maximal bladder filling is never achieved. Because low zero values (0 to 5 mm Hg) require maximal reservoir filling, low cuff inflation pressure would tend to truncate the distribution of zero values. There would also be a tendency to obtain zeros greater than 20 mm Hg.

From published reports, it appears that Kronmal et al. determined the maximum point of cuff inflation based on the blood pressure level at which the radial pulse was obliterated to palpation. There is no clear statement about how long the maximum pressure was maintained before closing the reservoir value, but given the relative low pressure obtained, it is reasonable to assume that the reservoir would be incompletely filled. Under these assumptions, one would expect that subjects with higher SBP would tend to have more complete reservoir filling and thus lower mean zero values. This process would introduce a negative correlation between the true blood pressure and the zero values.

This hypothesis is supported by several observations.

First, the Middlesex survey used a fixed maximal inflation pressure (200 mm Hg) and maintained this pressure for at least 5 seconds. This would produce complete reservoir filling for all subjects, and hence there should be no correlation, as was found. Second, the correlation found by Kronmal et al. remained even when independently obtained blood pressures collected with a standard mercury sphygmomanometer were substituted. Finally, the hypothesis is also compatible with the apparently larger proportion of zero values over 20 mm Hg in the study of Kronmal et al. when compared with the Middlesex survey.
If this explanation of the observed correlations is substantiated, are there significant implications regarding the use of the random-zero sphygmomanometer? In our opinion, the answer would be no. Once the valve has been closed to isolate the reservoir from the mercury column, the random-zero sphygmomanometer functions as a regular mercury sphygmomanometer. The effect of inadequate reservoir filling would be to alter the distribution of zero values, which would not have any effect on the true blood pressure readings. This was found by Kronmal et al.\textsuperscript{12,13} blood pressure readings obtained with the random-zero sphygmomanometer and the standard sphygmomanometer were essentially the same once allowance was made for the reported bias of 2 mm Hg associated with random-zero measurements.

Other explanations for these discrepant results could be considered, but it is unclear which of these other explanations could be seriously entertained. A number of sphygmomanometers were used in each study, making instrument failure an unlikely explanation for the differences. Kronmal et al.\textsuperscript{12,13} studied a sample of people aged 65 and older, whereas the Middlesex study included adults of all ages. Hence, one might hypothesize an age-related effect. Subgroup analysis of the Middlesex County Survey by age indicates that the regression slopes between the zero readings and the zero-corrected blood pressure did increase with age, although the regression slopes found for people over age 65 are still much lower than reported by Kronmal et al. It has been suggested that increased arterial rigidity in the elderly adversely affects the validity of indirect blood pressure readings.\textsuperscript{18} One might hypothesize that differences in arterial responsiveness to cuff pressure at different zero levels in the elderly might introduce a spurious correlation, but there is no direct evidence to support this hypothesis.

One further observation might be of relevance: The mean blood pressure found in the study of Kronmal et al.\textsuperscript{12,13} is considerably lower than would have been expected based on other studies of blood pressure in the elderly. When the observations from the Middlesex study are restricted to people over age 65 and weighted according to the sampling fractions used by Kronmal et al as reported in Fried et al.,\textsuperscript{19} the mean blood pressure becomes 143.6/77.9 mm Hg. This marked difference in mean blood pressure is difficult to explain given the reported sample selection strategies of the two surveys. It is possible that the factor leading to the lower mean blood pressures might also be responsible for the higher zero blood pressure correlations found by Kronmal et al.,\textsuperscript{12,13} although it is difficult to identify a selection or other bias that would operate in this fashion.

Decisions about the value of the random-zero sphygmomanometer in epidemiologic and clinical research will depend on factors other than a potential zero-corrected blood pressure correlation. The consistent observation that random-zero blood pressure values are approximately 2 mm Hg lower than those obtained with a standard mercury sphygmomanometer is a matter for concern. This would argue that consistency of use within a study is of considerable importance. Further work is needed to establish the role of the random-zero sphygmomanometer in clinical research.

References
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