BRIEF REPORT: How Well Do Clinic-Based Blood Pressure Measurements Agree with the Mercury Standard?

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BACKGROUND: Obtaining accurate blood pressure (BP) readings is a challenge faced by health professionals. Clinical trials implement strict protocols, whereas clinical practices and studies that assess quality of care utilize a less rigorous protocol for BP measurement.

OBJECTIVE: To examine agreement between real-time clinic-based assessment of BP and the standard mercury assessment of BP.

DESIGN: Prospective reliability study.

PATIENTS: One hundred patients with an International Classification of Diseases—9th edition code for hypertension were enrolled.

MEASURES: Two BP measurements were obtained with the Hawksley random-zero mercury sphygmomanometer and averaged. The clinic-based BP was extracted from the computerized medical records.

RESULTS: Agreement between the mercury and clinic-based systolic blood pressure (SBP) was good, intraclass correlation coefficient (ICC) = 0.91 (95% confidence interval (CI): 0.83 to 0.94); the agreement for the mercury and clinic-based diastolic blood pressure (DBP) was satisfactory, ICC = 0.77 (95% CI: 0.62 to 0.86). Overall, clinic-based readings overestimated the mercury readings, with a mean overestimation of 8.3 mmHg for SBP and 7.1 mmHg for DBP. Based on the clinic-based measure, 21% of patients were misdiagnosed with uncontrolled hypertension.

CONCLUSIONS: Health professionals should be aware of this potential difference when utilizing clinic-based BP values for making treatment decisions and/or assessing quality of care.

KEY WORDS: blood pressure measurement assessment; clinic method; mercury device.
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Obtaining accurate blood pressure (BP) readings is important for the management and assessment of hypertension. Clinical trials implement a strict protocol designed to minimize observer bias.[1] However, in clinical practice and in studies that assess quality of care, a less rigorous protocol is used to obtain BP values.[2] The lack of rigorous BP measurements in the clinical setting may lead to unreliable recordings and misunderstandings of patients' BP control. This may influence medication recommendations as well as assessments of clinic-based quality of care.

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Historically, the random-zero mercury sphygmomanometer has been the gold standard for BP measurements. However, owing to concern over mercury spills, the mercury devices are no longer used in the clinical setting.[3] In 1998, the American Hospital Association (AHA) and the Environmental Protection Agency (EPA) signed a memorandum of understanding to eliminate mercury from hospitals by 2005 and launched a program to assist hospitals in this process.[4] Consequently, mercury sphygmomanometers are being replaced with other BP devices. Although these devices have been compared with the mercury sphygmomanometer under strict conditions, their utility in routine clinical practice has not been thoroughly investigated.[5]

Our study evaluated the current state of the clinic-based method of BP measurement. We sought to quantify the degree of agreement between real-time primary care clinic-based assessment of BP and the standard assessment of BP using the random-zero mercury sphygmomanometer.

METHODS

Setting and Patients

The study was conducted in the general internal medicine practice at Duke University Medical Center. Patients of 3 general internal medicine physicians, who had an International Classification of Diseases—9th edition diagnosis of hypertension (401.9) and an upcoming primary care clinic appointment, were contacted for participation in the study. Approximately 392 patients received a letter 2 weeks prior to their appointment. Of these, 227 were reached by telephone for screening 1 week prior to their appointment. Patients were excluded if they were on dialysis; had recently been hospitalized for heart attack, stroke, or metastatic cancer; lived in a nursing home; or received home health care. The exclusion criteria were for a separate study. Eligible patients were scheduled to meet with a research assistant 60 minutes prior to their physician's visit. If patients were unable to meet before, they were scheduled to meet with a research assistant directly after their physician's visit. One hundred patients consented and participated in the study.

Procedure

The protocol was approved by Duke University's Institutional Review Board. A trained research assistant performed all standard BP assessments. First, the patient's arm circumference was measured at the arm's mid-point between the

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acromium and olecranon process. The proper size cuff was placed on the right arm of the patient. Patients were instructed to sit up straight, with their back against the chair, their feet flat on the floor, and the cuffed arm resting on the table at heart level. At this point, the research assistant left the room, allowing the patients to relax for 5 minutes. Upon returning, the research assistant obtained 2 BP measurements with the mercury device. Between measurements, patients were asked to raise their arm for 5 seconds and rest their arm at heart level for an additional 25 seconds. Finally, a brief interview was conducted to obtain demographic information.

Three research assistants were involved in this study. Each research assistant received training and certification for the use of the random-zero mercury sphygmomanometer by successfully completing 4 items: a videotape exam; a written exam; a demonstration of the technique and procedure for proper BP measurement; and a Y-tube stethoscope exam. We examined whether there were differences in systolic (SBP) or diastolic blood pressure (DBP) by aresearch assistant using analysis of variance. The effect of research assistant on diastolic BP (mean of observations 1 and 2) assessed with the mercury device was significant (P=.02). However, further inspection of the data revealed that two patient outliers drove the effect. When the outliers were excluded, there was no longer a significant effect by research assistant (P=.11). Excluding the 2 outliers did not significantly affect the intraclass correlation coefficient (ICC) values; therefore, we retained all patients in the analyses.

Clinic-Based Measurement

The general internal medicine clinic utilized either of the following BP devices: the Welch Allyn vital signs monitor 52000 series (an oscillometric device) or the Tycos wall aneroid sphygmomanometer. Nurses obtained patients' BP in the examination room before the physician's encounter and recorded them in the facility charts and the electronic medical records. We extracted the clinic-based BP from the patients' electronic medical records. Eighty-four percent of the clinic-based assessments occurred within 1 hour of the standard mercury assessment. The mean time difference between the standard assessment and the clinic-based readings was 24 minutes (SD =47 minutes).

Statistical Analysis

Systolic and diastolic readings were obtained for 199 of the 200 possible measurements with the mercury device. The missing datapoint was because of large arm size.

We examined the extent to which two different methods of BP assessment (mercury vs clinic) produce the same BP values in 3 ways. First, we plotted the mean of the 2 methods (X-axis) against the difference between the 2 methods (Y-axis).[6] This Bland–Altman graphical representation permits investigation of the strength of the relationship (i.e., correlation) as well as the extent of agreement (i.e., the extent to which the 2 methods produce the exact same measurements). When 2 methods have high correlation but poor agreement, this nature of disagreement is displayed by the Bland–Altman graph. If agreement between 2 methods is high, then the difference scores should be normally distributed about a mean of zero. Second, we calculated the ICCs, which assess the relationship between 2 or more variables that have the same metric and variance.[7] We used a 2-way mixed model without interaction, treating mode of assessment (i.e., mercury vs clinic) as a fixed variable and subjects as a random variable. Third, we calculated the κ for percent of BPs in control versus out of control according to type of assessment (mercury vs clinic-based) using the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) guidelines to define control.[8]

RESULTS

Patients' ages ranged from 43 to 86 years. The majority were female (77%), 78% were white, and 20% were black. Approximately one-quarter were diabetic and 94% were prescribed one or more antihypertensive medications (Table 1).

Agreement Between Mercury and Clinic-Based Measurements

The agreement between mercury and clinic-based readings was good for SBP, ICC =0.91 (95% confidence interval (CI): 0.83, 0.94), and satisfactory for DBP, ICC =0.77 (95% CI: 0.62, 0.86). The nature of disagreement is reflected in the Bland–Altman graphs, which show that the clinic-based assessments tended to overestimate both SBP and DBPs obtained by mercury. The mean difference was 8.3 mmHg (SD =13) for SBP and 7.1 mmHg (SD =12) for DBP (see Fig. 1). The ICC estimate of agreement between mercury and clinic-based DBP readings was lower than that for SBP readings because of a smaller range of DBP values.

Table 1. Characteristics and Data of the General Internal Medicine Patients

Characteristics	% (N=100)
Demographics	
Age (y) (M, SD)	64 (11)
Female	77
Male	23
White	78
Black	20
Asian	2
Married	65
Comorbidities	
Kidney disease*	5
Diabetic	26
Prescribed medication	94
Diuretics	73
Calcium channel blocker	35
ACE inhibitor	47
β-Blocker	26
Angiotensin-2 receptor blocker	26
α-1 antagonist	5
α-2 agonist	7
Data	Mean (SD)
Arm circumference (cm) (R: 24 to 49)	34 (5)
BP measurements (mmHg)	
Mercury SBP (R: 84 to 186)	128 (20)
Mercury DBP (R: 30 to 106)	67 (13)
Clinic-based SBP (R: 99 to 188)	136 (18)
Clinic-based DBP (R: 52 to 108)	74 (11)

Kidney disease defined by serum creatinine > 1.5 for males, > 1.3 for females.

ACE, angiotensin-converting enzyme inhibitors; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; R, range.

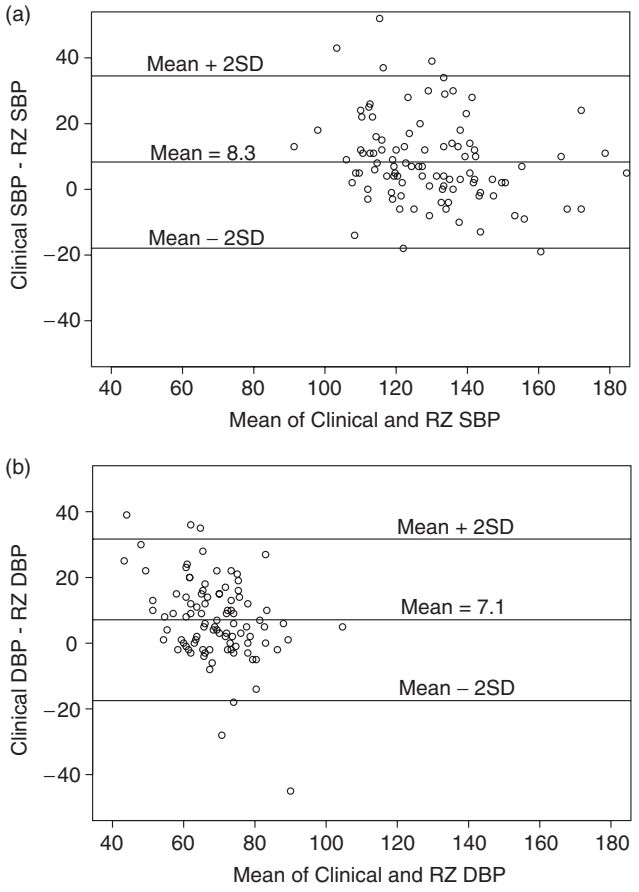

FIGURE 1. Bland–Altman graphs comparing blood pressure values obtained by the random-zero mercury sphygmomanometer versus the clinic-based method: (A) systolic blood pressures; (B) diastolic blood pressures.

We also determined agreement between methods within categories of BP control as defined by JNC 7. Twenty-three percent of the patients were classified with controlled BP ($<140/80$, or $<130/80$ for patients with diabetes or renal disease) based on the clinic as well as the mercury readings. Fifty-two percent were classified with uncontrolled BP based on the clinic as well as the mercury readings. However, 21% of the patients were characterized with uncontrolled BP based on clinic measurements, while their standard mercury assessment of BPs showed that they were in control. When categorized in this manner, agreement between clinic-based and standard methods was only moderate, $\kappa=0.47$ (95% CI: 0.30, 0.64).[9]

DISCUSSION

The gold standard for BP measurement is the utilization of the mercury sphygmomanometer and a strict protocol. In clinical practice, however, an aneroid or a digital device is used under a less stringent protocol. When the two types of assessment were compared, we found that clinic-based readings were generally higher than the values obtained using the more rigorous method. The Bland–Altman graphs specify the nature of disagreement (see Fig. 1). Specifically, clinic-based assessments tended to overestimate both SBP and DBP obtained by mercury. Of note, the clinic overestimation occurred more often with mercury readings categorized as normotensive. Hence, although the patients' BP values may be normal based on the mercury device, the clinic-based readings misdiagnosed 21% of the patients with uncontrolled BP.

Our study had several limitations. First, the clinic-based readings and the standard assessments were not taken at the same time. However, the majority of the readings (84%) occurred within 1 hour of each other. Second, we did not randomize the order of physician's visit and research assistant's meeting. However, patients who met with the research assistant before their physician's visit ($N=86$) did not have more elevated clinic BPs than patients who met with the research assistant after their physician's visit ($N=14$). Third, there was the potential for terminal digit bias by the research assistants when using the random-zero mercury sphygmomanometer. However, each research assistant was trained to perform BP measurements by decreasing the mercury column by 2 mmHg per second to prevent digit preference. On the other hand, the potential for terminal digit preference in the clinic could not be controlled. Therefore, we would consider this a characteristic of the less rigorous protocol carried out in the clinic.

In summary, we show evidence that the assessment of BPs in a primary care clinic fails to provide values that are obtained with a standard method of assessment. Furthermore, clinic-based BP values may overestimate those obtained by a standard method. The degree of overestimation is clinically important and could result in inappropriate treatment decisions. We advocate better standardization of the clinic-based method with implementation of recommended devices and a more rigorous training of the nursing staff.

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