Accuracy of automated community pharmacy–based blood pressure devices

Jasmine Gonzalvo and Alan Zillich

Abstract

Objectives: To estimate accuracy and reliability of pharmacy-based fixed-location automated blood pressure devices (ABPDs) and to test the hypothesis that an ABPD is less accurate with more variable results than a home blood pressure device (HBPD).

Methods: Randomized study comparing 99 ABPDs with an Omron Digital HBPD in Indiana pharmacies. Each site was visited by one of five study investigators. A questionnaire was used to collect information about ABPDs. To test the ABPD against the HBPD, investigators measured their own blood pressure with each device three times in random order.

Results: No significant differences were observed between HBPD and ABPD diastolic readings, whereas a statistically significant difference between HBPD and ABPD systolic readings was found. ABPD measurements are as reliable as HBPD measurements when comparing single measurements from each, but reliability differs with more than one reading.

Conclusion: Compared with a valid HBPD, the ABPD produces inaccurate systolic blood pressure values but similar reliability. Regular blood pressure measurement by health professionals remains optimal for managing hypertensive individuals.

Keywords: Blood pressure monitors, automated blood pressure devices, home blood pressure devices, hypertension.

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Sustained elevated blood pressure is known to cause deleterious cardiovascular effects. Approximately 29% of adults in the United States live with hypertension.[1] Community-based blood pressure screening can play a role in improving identification of hypertension. Health care providers should be educated on distinctions among blood pressure readings from available devices to provide optimal care for hypertensive patients. Inaccurate blood pressure readings may result in medication mismanagement and adverse effects.

Consumer-operated, fixed-location automated blood pressure devices (ABPDs) found in public settings have gained popularity. Advantages include no consumer cost, ease of access and use, and elimination of white coat hypertension (i.e., patients showing elevated blood pressure in clinical settings but not other settings). The accuracy and reproducibility of these devices, however, may be variable.[2–4]

Automated home blood pressure devices (HBPDs) provide alternatives for blood pressure monitoring. Accuracy of HBPDs has been proven according to scientific device standards.[5–8] HBPDs using arm cuffs for measurement have been proven superior to devices using the wrist or finger.[9] A review concluded that home blood pressure measurement with a validated device should be integrated into management by clinicians.[10] Home blood pressure monitoring has been shown to correlate more strongly with target organ damage compared with office blood pressure measurements.[11] A statement from cardiovascular associations recommended routine home blood pressure monitoring for individuals with hypertension.[12] Therefore, regular blood pressure monitoring using an HBPD is a logical intervention for antihypertensive individuals.

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Objectives

Estimating accuracy of various community blood pressure devices important, considering the meaningful role of home blood pressure monitoring.[12] This study aimed to estimate accuracy and reliability of fixed-location ABPDs. Investigators hypothesized that fixed-location ABPDs are less accurate with more variable results than an HBPD.

Methods

A randomized study compared 99 fixed-location ABPDs with a scientifically validated HBPD. This study was approved by the Purdue University Institutional Review Board. A randomized list of 30 pharmacies was generated from phone books in five regions throughout Indiana (Figure 1). Five investigators were assigned a list of 30 randomized pharmacies per region. Within regions, a pilot was conducted in 2 of 30 pharmacies to refine methods. For inclusion, each store must have had an ABPD available for public use and provided permission for data collection from a pharmacy or store manager. The investigators then contacted 20 pharmacies to confirm eligibility. On site, a questionnaire was presented to the store representative to collect information about the ABPD (Table 1).

Next, investigators recorded ABPD and HBPD readings. An Omron digital HBPD (model HEM-737A; Omron, Vernon, IL) was used as the "standard" device certified by the European Society of Hypertension as valid and reliable.[5] Consistent with American Heart Association guidelines, each investigator refrained from smoking, eating, exercise, and caffeine for 30 minutes and remained seated for 5 minutes before blood pressure measurement.[13] Six measurements were taken at each site, three with each device, according to manufacturer instructions. Order was determined by lottery-type drawing containing each combination of six measurements. A short resting period was observed between readings using the same arm.

Mean HBPD and ABPD measurements were computed separately for each site. Mean diastolic blood pressure (DBP) and systolic blood pressure (SBP) measurements were determined via HBPD and ABPD at each site and compared using t test. $P < 0.05$ was considered statistically significant. Reliability was tested with intraclass correlation coefficients (ICCs) for both DBP and SBP readings. ICCs assess the consistency between measures of the same class.[14] The HBPD ICC single-measure result was used in comparison with ICC results for both a single and an average of three measurements from the ABPD to assess differences.

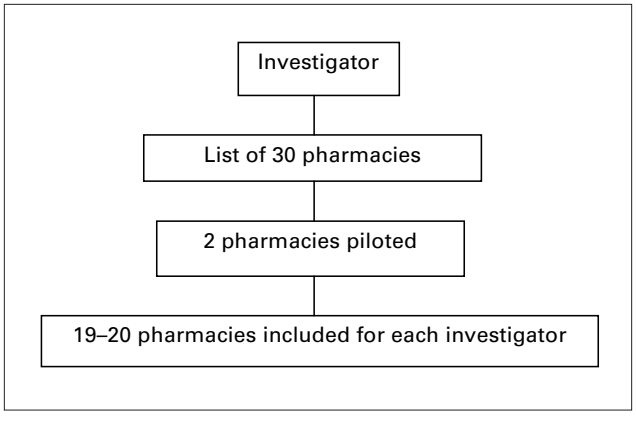

Figure 1. Methods for each investigator

Results

A total of 99 pharmacies and ABPDs were tested. Table 1 lists characteristics of pharmacies and machines. Results of the paired t test did not reveal a significant difference between HBPD and ABPD DBP, whereas a statistically significant difference was observed between HBPD and ABPD SBP (116.1 vs. 119.4 mm Hg; $P < 0.001$, $t = 4.9$, df = 98) (Table 2).

ABPDs have acceptable reliability for both SBP (ICC = 0.813) and DBP (ICC = 0.747) (Table 3). To compare reliability, the HBPD ICC single measure for SBP was compared with the ABPD. The same method was used for DBP. Results showed ABPD SBP and DBP measurements exhibit com-

Table 1. Pharmacy and ABPD characteristics

Characteristic	No. (%)
No. pharmacies/ABPDs	99
Type of pharmacy	
Grocery store	40 (40.4)
Community chain	34 (34.3)
Mass retail	22 (22.2)
Community independent	3 (3.0)
Prescriptions filled hourly, mean ± SD	19.7 ± 26.3
No. times BP machine used daily, mean ± SD	33.2 ± 26.3
Age of ABPD (years), mean ± SD	5.2 ± 2.9
ABPD manufacturer	
Cardiotech	23 (23.2)
Life Clinic	5 (5.1)
Vita-Stat	71 (71.7)
Ownership of ABPD	
Store owned	26 (26.3)
Store leased	46 (46.5)
Unknown	27 (27.2)

Abbreviation used: ABPD, automated blood pressure device; BP, blood pressure.

Table 2. Blood pressure measurement comparison (n = 99)

	Mean ± SD (range)	Paired difference (95% CI)	*P*
SBP			
HBPD	116 ± 11.3 (91–150)	—	
ABPD	119 ± 12.5 (96–146)	3.2 (1.9–4.5)	<0.001
DBP			
HBPD	1 ± 8.6 (47–95)	—	
ABPD	70 ± 8.9 (37–91)	0.78 (–0.62 to 2.2)	0.27

Abbreviation used: ABPD, automated blood pressure device; DBP, diastolic blood pressure; HBPD, home blood pressure device; SBP, systolic blood pressure.