CONCEPTS IN HYPERTENSION

A Journal Article-Based Approach to Understanding the Clinical Aspects of Hypertension

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The Home BP Monitor Bombshell - "Approved" but not accurate

Article of Interest

Coleman A et al. Validation of the Omron M7 oscillometric BP monitoring device according to the British Hypertension Society Protocol. Blood Pressure Monitoring. 2008. (Click to access)

Context and Study Objective

Home blood pressure (BP) monitoring is widely recommended. Yet few physicians are aware that these machines can be sold without independent verification of their accuracy. In this paper, Coleman examined the Omron M7, an upper arm electronic (oscillometric) monitor, for accuracy according to the widely respected British Hypertension Society validation protocol.

Design, Setting, Participants

- The article details the exacting, multiphase certification procedure. The most demanding step requires the recruitment of eighty-five individuals with BP ranging from <90 to >180 mm Hg systolic and <60 to >110 mm Hg diastolic. A participant's BP is taken with the test device and then in the same arm with 2 mercury sphygmomanometers. The mercury units are connected in series allowing for the 2 measurements to be executed simultaneously.
- A minimum of 3 paired readings (test vs mercury unit 1 or 2) per participant are recorded generating 255 pairs of values.
- Measurements begin after 5 minutes' rest with 30-60 seconds between readings.
- The accuracy of the submitted model is graded as follows: An "A" rating is awarded if the difference in BP between the test and a mercury apparatus is ≤5 mm Hg at least sixty percent of the time, ≤10 mm Hg eighty-five percent of the time, and ≤15 mm Hg ninety-five percent of the time. Grades of "B" and lower are assigned to models with lesser degrees of accuracy. Devices designated "A" for systolic and diastolic values are preferred.
- Omron sponsored the study; the authors declare no conflicts of interest.

Results

- Study characteristics: 85 participants. Mean age: 50. 50% women. Mean BP: 140/85 mm Hg.
- Completion of the protocol required 27 months.
- Table: The model achieved an "A" rating for both systolic and diastolic pressures across a broad range of BPs.

Percentage of Paired Readings Differing by 5, 10, 15 mm Hg			
	≤ 5 mm Hg	≤ 10 mm Hg	≤ 15 mm Hg
Mercury Unit 1 vs Test Device			
SBP	66 %	89 %	98 %
DBP	70 %	94 %	100 %
Mercury Unit 2 vs Test Device			
SBP	69 %	86 %	98 %
DBP	69 %	95 %	100 %

Clinical Perspective

- It's troubling that BP monitors can be brought to market in the absence of independent assessment of their accuracy. The complex and time-consuming validation protocols are cited as disincentives for doing so.
- Because Omron submits its devices for external certification, I recommend them. The inexpensive 3 series (BP710N) is widely available and the standard cuff accommodates the arm of obese patients.
- Of note, even validated BP machines are not accurate among those with arrhythmias, a "special population" for which additional examination is required.
- Disclosures: I have no conflicts to declare, including with respect to Omron.

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