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Editorials

How to Use Home Blood Pressure Monitors in Clinical Practice

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The majority of home blood pressure monitors (HBPM) are purchased by consumers without physician recommendations or endorsement.[1] Industry developed the electronic HBPM in 1984 without the endorsement of any hypertension society. The number of HBPM in most affluent countries is increasing, resulting in more BP data being presented to the treating clinician. Home blood pressure digital monitor revenue in the US in 2001 is estimated to be $142.2 million and is projected to grow 22% over the next 5 years, with 10% declining aneroid monitor sales; however, office digital monitor growth over the next 5 years is projected to increase 833% (Erica Brown, Frost & Sullivan, personal communication, August 22, 2001). Primary care physicians and hypertension specialists receive the HBPM data from our patients, yet we often have not provided proper patient guidance for their usage. How can we best use these electronic devices to improve hypertension control in our patients?

We believe it is now time for hypertension specialists to endorse the proper usage of home BP devices, with proper instructions to both patients and their primary care physicians, who see most of the hypertensive patients in the world. Indeed, an ad hoc committee of the American Society of Hypertension in 1995 concluded that "self-monitoring of BP is encouraged for the majority of hypertensive patients."[2]

Modern electronic monitors measure BP using the oscillometric technique, which has been validated to correlate with the auscultatory technique in most patients with regular heart rhythms.[3] The mean BP is measured by the same technique in all monitors. Using proprietary algorithms, each manufacturer calculates systolic and diastolic BP differently. Absolute pressure measurement differs between monitors by different manufacturers, due to the difference in algorithms. When an artificial BP simulator was used, differences between HBPM were 12/9 mm Hg with pulse differences of 3 beats/min, whereas measuring in two normotensive subjects and comparing to a single model HBPM demonstrated differences of 4/7 mm Hg with pulse differences of 2 beats/min.[4,5] This is similar to the difference observed between the standardized research and casual clinical measurements. Systolic differences of 6 mm Hg and diastolic differences of 4–10 mm Hg have been reported, with 42% of subjects being falsely labeled hypertensive by casual clinical methods.[6–8] There are limited data regarding accuracy with patients with arrhythmias, such as atrial fibrillation.[9,10]

The advantage of digital HBPM is patient ease in usage compared to aneroid manometers with stethoscopes. Instruction in proper electronic manometers usage should be less than the 20–45 min required for aneroid manometers, as proper auscultation is the most difficult portion of accurate auscultatory BP measurement.[11,12] A patient handout that describes the purchase and proper usage of HBPM was developed for improved patient education and to save providers time.[13] Common errors for all types of BP measurement still need to be instructed against: proper cuff size, rest period before measurement, and avoidance of talking and crossing legs during the measurement. Patients should be instructed to use only upper arm HBPM, and the healthcare provider should indicate the proper cuff size to the patient. Patients should be specifically discouraged from purchasing finger and wrist models. Manual HBPM are significantly cheaper (approximately $30–40) than the models with the pump included (approximately $55–130); however, the automatic pump models are easier to use, especially in patients with hand arthritis.[14–16]

Manufacturers are required to pass calibration tests on HBPM that have new algorithms. There are two major reference standards that are used,[17,18] and most manufacturers perform the tests necessary for both. These standards compare standardized auscultation to the test device using multiple subjects. Before accuracy standards were developed, the HBPM was usually found to be inaccurate; however, increasingly more manufacturers are publishing accuracy assessment data before marketing their devices. The European Society of Hypertension said that the following HBPM passed both the United States and the British standards: Omron HEM 713C, Omron HEM 722C, Omron HEM 735C, and Omron HEM 737 Intellisense

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(Omron Healthcare, Vernon Hills, IL).[19] Unfortunately, many manufactured devices are sold using different names (ie, the retail store name) and model numbers than the published reports. According to the current guidelines, devices sold using different names or numbers should be subjected to separate validation. This confusing situation hopefully will be corrected in the future, by labeling the original name and number on the device or revalidating the device.

There are no standard guidelines developed for the assessment of HBPM accuracy after purchase. We feel that manufacturers should provide guidelines for users in their device instructions on the proper interval for calibration of the device. Many physicians instruct patients to bring HBPM to their office and perform sequential BP readings. The physician indicates accuracy if the readings are "close." This is very misleading, due to the inherent variability of BP and the lack of published standards of accuracy. Accuracy of the device is defined by both the measurement of the accuracy to a calibrated pressure and the accuracy in human subjects. There is no literature regarding accuracy assessment based on a single subject; the Association for the Advancement of Medical Instrumentation (AAMI) standard requires 85 subjects.

The individual algorithm of a HBPM will not change with time, as it is imbedded within the software/computer chips and a failure of the circuit board would not allow any measurements. A malfunction of the pressure sensor may result in undetected erroneous readings; however, the frequency of this is uncertain. To test the pressure sensor one should use a calibrated BP simulator (Bio-Tek Instruments, Winooski, VT) directly attached to the HBPM; however, a calibrated aneroid or mercury manometer can be used. For the nonautomatic HBPM, a hemostat is clamped across the tube connected to the inflation bulb, to prevent deflation while testing at different levels (60, 90, 140, and 200 mm Hg). The automatic devices need to have the automatic deflation mechanism disabled. In the Omron devices this is done with a special male adapter, obtained from Omron, and in the A&D Medical (Milpitas, CA) LifeSource models it is done by turning the maximum pressure switch repetitively up and down at least three times and then immediately pushing the "on" button. Models manufactured by other companies have no available mechanism for overriding the deflation device; however, some HBPM are manufactured by Omron or A&D Medical and are labeled by another retailer's name.

One author's (SAY) experience in testing patients' HBPM over 2.5 years found an accuracy of 0.3 mm Hg ($\pm$2.3 mm Hg) for the 91 electronic HBPM with an overall 92% accuracy, as defined within $\pm$3 mm Hg. This is similar to the pressure accuracy of 136 aneroid manometers at our institution of 0.2 $\pm$ 0.3 mm Hg with an overall 96% accuracy.[20] There are no data as to the duration of accuracy of the HBPM. AAMI standards require the device to maintain safety and performance characteristics for 10,000 full inflation-deflation cycles, however, actual usage will result in different stressors to the machines than the standard testing. We suspect that a 5-year life span is realistic.

The Treatment of Hypertension According to Home or Office Blood Pressure (THOP) trial is currently testing the hypothesis that antihypertensive treatment guided by self-measured BP may by more beneficial to the patient than treatment based on conventional BP measurement by the doctor.[21] Patients are asked to perform BP readings using a device that has a printer (Omron HEM 705CP) and measure the BP between 6 AM and 10 AM and between 6 PM and 10 PM. The patient takes the first three readings in the sitting position, followed by a single reading in the upright position. Patients are instructed to measure and print these readings the week preceding the visit to their physician. The initial difference between the average daytime (10 AM to 8 PM) ambulatory BP and HBP has been found to be small (2.2/0.9 mm Hg) and similar to differences in other studies.[22] The final results of the THOP are expected to be reported in late 2002.

The definition of adequate hypertension control differs depending on whether the measurements were taken at home or at the physician's office. Home BP is usually 8/6 mm Hg less than office BP measurements.[20] On the basis of a meta-analysis of summary statistics of published articles and a meta-analysis of data from individual subjects, 135/85 mm Hg is likely to be the upper limit of normal for self-measured BP, when the goal equivalent office BP is 140/90 mm Hg.[23] It is important to teach primary care physicians that a home BP of 140/90 mm Hg should be interpreted as uncontrolled hypertension.

How does the clinician use the HBPM after determining it is accurate and assuring that the patient is using it correctly? The device is best used to help to control known hypertension, not for the diagnosis of new hypertension. We encourage all patients with hypertension to use HBPM. Patients may be given charts to graph the readings, with the expected normal range highlighted (Fig. 1). Trends and averages of the measurements are easier to appreciate in graphic form than randomly placed numbers on the back of a shopping list. Patients having their medication adjusted are told to measure their BP twice a day in the morning and before dinner for 2 to 4 weeks, depending on the medication. Stable hypertensives are told to monitor BP on the first day of the month and more frequently if the readings are elevated. The charts are faxed or mailed to the physician's office and necessary therapy adjustments are performed, with the cycle repeated until adequate hypertension control is achieved. Newer HBPM with memory and optional computer links, although much more costly, allow graphic display and statistical analysis of the data. A new telecommunication service consisting of automatic transmission of BP data over telephone lines, computerized conversion into report forms, and weekly electronic transmission of the reports to physicians and patients was found to decrease BP by 5/2 mm Hg compared to usual

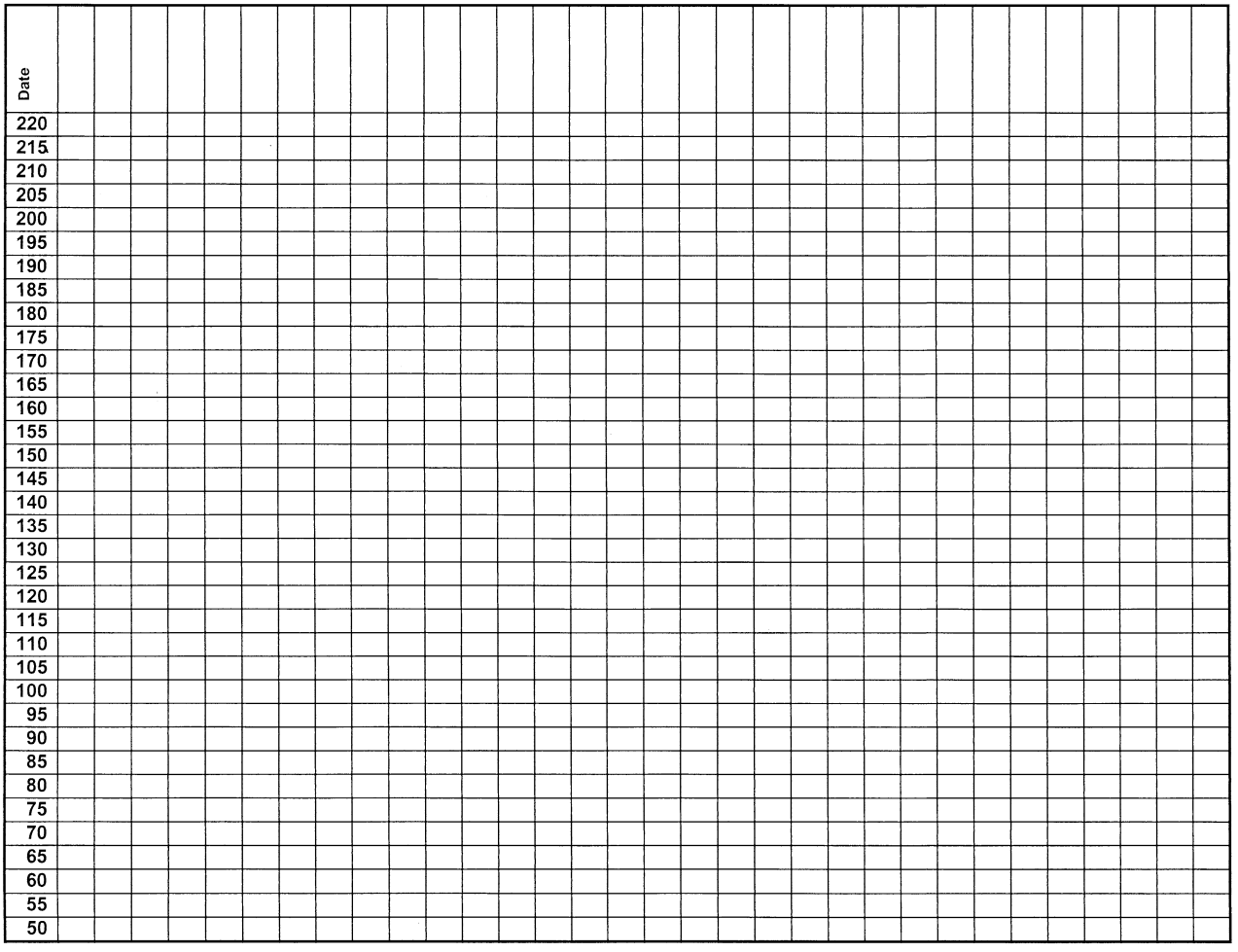

FIG. 1. Patient handout to record the systolic and diastolic blood pressure with an "*X*."

care.[24] This may eventually become the standard method of hypertension monitoring.

The American College of Physicians/American Society of Internal Medicine this year completed a questionnaire to develop relative value units and possible future reimbursement for home monitoring review, potentially including home BP and glucose monitoring. Reimbursement for monitoring home BP therapy is long overdue and would encourage patient usage of HBPM and potentially improve compliance and hypertension control. Patients who use HBPM often feel that they help them better cope with disease and reassure them.[25,26] Although there is a lack of well-designed studies regarding the improvement in compliance and control of hypertension and cost-effectiveness with the usage of HBPM, some recent studies are positive.[27] Based on an analysis in 1992, in the US an estimated $300 million/year could be saved with the usage of HBP monitoring.[27] This savings would be much greater in 2001.

In summary, in recommending a sphygmomanometer in every home as early as 1972, Burch observed:

> It is not more possible to regulate BP medicine elegantly for a patient with hypertension, without home recording of BP than it is to regulate the dose of insulin for a patient with diabetes mellitus without checking his urine for glucose at home.[28]

If we are going to improve the treatment of hypertension, we need to rely on proper BP data obtained under appropriate conditions and methods. Uniformly dismissing the home collection of this data as not accurate is losing an important additional tool to help our patient's care.

> Our "Age of Anxiety" is, in great part, the result of trying to do today's job with yesterday's tools—with yesterday's concepts.[29]

> To do good work, one must first have good tools.[30]

All tools may be improved, and we believe that the necessary tools are already available. The First International Consensus Conference of Self-Blood Pressure Measurement provided a complete overview of the state of HBPM and noted that the HBPM was valuable for the evaluation of hypertension treatment efficacy.[31,32]

Physicians treating diabetes have successfully lobbied for home glucose monitoring and reimbursement for their patients in the US. Because hypertension control is equally

important in this and other high-risk populations, we would encourage hypertension societies to actively campaign for hypertensive patient reimbursement for HBPM. Physicians interpreting home BP data should also be reimbursed for this valuable procedure. We would further recommend hypertensive societies' accreditation and endorsement of properly validated HBPM by a seal, similar to the American Heart Association program. We should advocate that all future HBP monitoring devices have labels with the name and model number of the device that was validated, rather than the name of the retailer selling the device. HBPM should all have a standard method to prevent autodeflation, allowing for office calibration, and where purchased, a measuring strip to assure proper cuff size should be available.

Although we have taken for granted that BP is accurately being measured by the auscultatory method in physician's offices and hospitals throughout the world, recent clinical hypertension research has used electronic BP monitors in addition to auscultation.[33] Many hospitals routinely use oscillometric machines for BP determinations, and the clinical usage of mercury is being banned throughout the world, resulting in the loss of our gold standard. This change from auscultation to oscillometric determination of BP in hospitals has occurred without the agreement or recommendation of the American Society of Hypertension or other physician organizations. Because we now have developed appropriate standards for accurate HBPM, we should not continue to ignore the utility of HBPM in the treatment of hypertension, or passively watch as the most important aspect of treating hypertension, accurate BP determination, is determined by others.[33]

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