

Home Blood Pressure Monitoring and Diabetes

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Home blood pressure monitoring (HBPM) may be useful in the management of many patients with hypertension and diabetes. Blood pressure monitoring traditionally has been carried out in providers' offices. However, many patients visit their providers only once or twice a year, which limits their ability to monitor hypertension. Over the past several years, HBPM technology has evolved to a point where accuracy and ease of use now make this form of monitoring feasible and useful in many cases.

This evolution has been similar in some ways to that of blood glucose meters. When relatively accurate and easy to use blood glucose monitors were first produced, their role was a subject of debate. Today, they are widely accepted as a standard part of care. Whether HBPM will follow a similar course remains to be seen.

This article provides a brief overview of methods of blood pressure measurement, recommendations from expert groups on the use of this technology, potential benefits and problems, and a review of some of the more useful devices.

Diabetes and Hypertension

Individuals with diabetes are at great risk for cardiovascular disease. Part of this increased risk is because of hypertension. There is a very high incidence of hypertension in patients with diabetes. One survey estimated that 54.8% of Caucasians, 60.4% of African Americans, and 65.3% of Mexican Americans who had diabetes also had hypertension.¹

Several trials have also demonstrated the importance of blood pressure-lowering in hypertensive patients with diabetes. Two of the most significant of these trials were the United Kingdom Prospective Diabetes Study (UKPDS) and the Hypertension Optimal Treatment (HOT) study. The HOT study reported a 51% reduction in cardiac events in the diabetes subpopulation ($n = 1,501$) who were randomized to the more intensive blood pressure arm (goal: diastolic blood pressure of 80 vs. 90 mmHg).² The UKPDS reported significant reductions in its intensive blood pressure arm (mean result: 144/82 vs. 154/87 mmHg in the standard arm) in all diabetes-related endpoints, deaths, stroke, and microvascular endpoints.³

Currently, the American Diabetes Association (ADA) recommends a blood pressure goal of $< 130/80$ mmHg.⁴ The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) also recommends a blood pressure goal of $< 130/80$ mmHg for patients with diabetes.⁵

HBPM Recommendations

The ADA is neutral on the issue of HBPM and does not mention it in the position statement "Standards of Medical Care for Patients With Diabetes Mellitus."⁴ JNC 7 suggests that HBPM may benefit patients by providing information on response to antihypertensive medication, improving compliance with therapy, and evaluating "white-coat hypertension"⁵ (discussed below). The American Association of Clinical Endocrinologists strongly recommends

HBPM for patients with type 2 diabetes and hypertension and states that, "Patients with type 2 diabetes and hypertension should monitor their blood pressure frequently with home blood pressure self-monitoring."⁶

Potential Benefits

As is evident from the paragraph above, the role of HBPM in the diagnosis and treatment of hypertension is not yet fully delineated. Potential benefits of HBPM include distinguishing sustained hypertension from white-coat hypertension, assessing response to antihypertensive medication, improving adherence to treatment, and potentially reducing costs. The World Health Organization–International Society of Hypertension Guidelines acknowledge most of these potential benefits with the exception of cost reduction.⁷

White-coat hypertension, also known as "isolated office hypertension," is a condition in which otherwise normotensive patients have consistently elevated blood pressure during medical office visits.^{7,8} Most patients treated for hypertension who have persistently high office readings also have high out-of-office readings.⁸ However, the potential for increased cardiovascular risk in patients with white-coat hypertension is still being debated. Studies have demonstrated a link between white-coat hypertension and carotid artery atherosclerosis, changes in left ventricular structure, and endothelial function.^{9–11}

The American Society of Hypertension suggests using HBPM as a screening test for white-coat hypertension.¹² If a normal blood pressure is found at

home, it should be confirmed by ambulatory monitoring. If a high blood pressure is found, no further testing is needed and treatment should be initiated. Because of its high specificity and reasonable cost, HBPM may also be appropriate for the long-term follow-up of patients with white-coat hypertension. Unfortunately, the question of whether patients with white-coat hypertension should be treated remains unanswered.

HBPM clearly can be useful in assessing response to antihypertensive therapy and may allow for more rapid titration to goal. It can be used to ensure adequate blood pressure control across the drug-dosing intervals during awake hours. HBPM may be used to evaluate effects of increasing or decreasing doses of antihypertensive agents during titration. It may also be used to evaluate the relation of blood pressure levels to suspected or possible side effects of therapy (hypotension).

HBPM may increase adherence to pharmacological and nonpharmacological interventions. Hypertension is a silent disease, often without signs or symptoms, and this technology can provide tangible signs of disease control. It may increase patients' participation in their own care and possibly help them cope with the disease. In general, it may improve their adherence.

HBPM can provide a simple and cost-effective means of obtaining a large number of blood pressure readings. A study of 200 patients randomized to either usual care or home monitoring in a closed model health maintenance organization found that self-measurement of blood pressure may be cost-effective. At the end of 1 year, the costs of care were 29% lower in the self-monitoring group, and blood pressure was equally well controlled in both groups.¹³

However, widespread use of HBPM could be costly. One group estimated that the costs of routine use of HBPM on all 50 million people with hypertension in the United States would be \$2.5 billion.¹⁴ This figure assumes that there would be no savings from HBPM.

Potential savings from the use of HBPM have not yet been evaluated fully in clinical trials but include reductions in costs of medication for patients with white-coat hypertension, less need for clinic visits, and, possibly, reductions in costs associated with cardiovascular morbidity.^{12,13}

Monitors for Home Use

There are four different configurations of blood pressure monitors for home use: the mercury sphygmomanometer, the aneroid manometer, and semiautomatic manual-inflation or automatic-inflation digital devices. The majority of patients probably should be encouraged to choose a digital monitor. These systems are accurate, easy to use, and associated with less user error. Automated monitors offer both simplicity and ease of use for patients who lack the technical skills required to properly use the more sophisticated monitors.

The device with the longest history, first invented back in 1733, is a standard mercury sphygmomanometer. The reputation of the mercury sphygmomanometer in clinical settings would seem to recommend it for home use. Unfortunately, a number of contributing factors usually make it impractical for use at home. The mercury sphygmomanometer is composed of a glass tubular gauge, a reservoir of mercury, and a manually inflated cuff. Because it uses gravity to measure blood pressure, the readings are usually consistent and accurate. As the cuff inflates, back sound pressure causes the mercury to rise. The Korotkoff sounds are observed by auscultation with a stethoscope.¹⁵ Many patients do not possess the skills and dexterity required to use a mercury blood pressure monitor at home. Because of the toxicity of mercury, the U.S. Environmental Protection Agency is in the process of mandating that mercury sphygmomanometers be phased out.

The aneroid sphygmomanometer is the second type of HBPM device. This meter is composed of a numbered dial and manually inflatable cuff. The

aneroid monitor possesses drawbacks similar to the mercury sphygmomanometer because a stethoscope must be used to recognize the Korotkoff sounds. The aneroid monitor uses a mechanical bellows and lever system that can require frequent calibration to produce consistent and accurate readings. Aneroid monitors are less expensive, but also less accurate, than mercury sphygmomanometers.¹⁶

The last major two HBPM devices are digital, with either semi-automatic or completely automatic inflatable cuffs. The blood pressure reading is displayed on an easy-to-read screen that is also available in large formats for patients with visual impairment. Digital monitors almost exclusively use oscillometric measurement, in which small oscillations or changes in cuff inflation pressure are used to obtain the mean systolic and diastolic pressure and, in some cases, pulse. There is a great degree of consistency between auscultation readings obtained by practitioners and oscillometric devices.¹² The cost of a digital blood pressure monitor depends on the features it offers. Extra large displays, printers, pulse readings, and voice-announced readings are some of the optional available features.

In addition to arm band monitors, there are also wrist and finger models. Although convenient, the finger monitor has not been proven to produce accurate blood pressure readings. The device occludes a digital artery in the finger to calculate blood pressure. Because the peripheral blood vessels are susceptible to vasoconstriction, the use of a finger monitor is not recommended. Another factor that influences both finger and wrist monitors is position of the limb. Wrist monitors have improved, but their readings are dependent on the position of the arm. Because of these issues, it is probably most reasonable to recommend an arm monitor and to stress the importance of having a large enough cuff based on the device manufacturer's recommendations and patients' arm measurements.

Accuracy

The greatest barrier that HBPM device manufacturers have had to overcome is the questionable accuracy of these products. This industry historically has lacked strict guidelines for manufacturing processes and overall performance. A device can give inaccurate data for many reasons. However, operator error and device malfunctions are the most common. An occasional reading of ± 5 mmHg has never proven to be clinically significant and is usually considered acceptable.

Before the Association for the Advancement of Medical Instrumentation (AAMI) standards were applied to blood pressure devices, many of these products were inaccurate. The governmental regulatory group responsible for the HBPM device sector is the Food and Drug Administration (FDA).^{16,17} The FDA uses the AAMI standards as the American national standards.

A device expected to be sold or distributed in the United States should meet AAMI standards. However, a manufacturer can still market a device without evidence that it has passed the AAMI standards because testing is not required. The manufacturer is prohibited only from making claims about accuracy if their device has not been tested and shown to meet AAMI standards. Patients can protect themselves from inferior products by purchasing only monitors bearing the AAMI seal.

The most rigorous testing to date was conducted by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) using two of the most popular protocols: the AAMI standards and the British Hypertension Society (BHS) protocol.¹⁸ The ESH group classified devices as "recommended," "questionable recommendation," or "not recommended." Of 23 devices tested, only five received the ESH recommended rating. These monitors, which all use the upper arm for monitoring, are Omron HEM 705-CP, Omron HEM 722 C, Omron HEM 735C, Omron HEM 713C, and Omron

HEM 737 with Intellisense.

The market is flooded with HBPM device manufacturers offering closely competitive products. These products continue to change with respect to the variety of functions and, therefore, degree of complexity. Providers should stress the crucial importance of accuracy as the primary goal for patients' device selection.

The sheer number of products available can cause patients understandable confusion and afford pharmacists and care providers the opportunity to provide their patients with sound information before they buy a monitor. Most patients will purchase monitors from retail pharmacies where they can seek the advice and assistance of pharmacy staff. Internet-based medical device retailers are another common venue for purchasing monitors.

Data gathered by Information Resources, Inc., showed that at least 65% of HBPM devices in the United States are sold by Omron Healthcare Corporation.¹⁹ Along with Omron, manufacturers such as A & D Medical LifeSource, Lumiscope, Mark of Fitness, Panasonic, Samsung, and many others are producing high quality, clinically tested monitors for home use.

A recent *Consumer Reports* article tested 16 of the top-selling home monitors. The number one recommended automatic inflation monitor was the Omron Intellisense HEM-711AC, which can detect irregular heartbeats in addition to accurate blood pressure.²⁰ The Intellisense monitors have incorporated design technology known as "fuzzy logic," which is potentially capable of calculating an anticipated systolic blood pressure so as to keep over-inflation of the cuff to a minimum. This feature has reduced the level of discomfort often associated with high cuff pressures and is now integrated by most manufacturers.

The latest A & D Medical LifeSource home monitor, model #UA-787, introduces the Easycuff system.²¹ It features a semi-rigid plastic component added to

the cuff design to enable the cuff to mold itself better to a user's arm. The Easycuff system can record a blood pressure and pulse rate reading without interference from any type of irregular heartbeat. The *Wall Street Journal* recently named this monitor best overall.²²

Patient Information

Patients who begin using HBPM should be instructed on proper technique. Generally speaking, the automated systems are easier for patients to master. Patients should have an understanding of what their goal blood pressure is and when to be concerned about a high or low reading. Patients should also understand that their blood pressure will fluctuate. Finally, they should be advised to bring their meters to their medical appointment to have them tested against an office standard.

It is probably also useful to help patients determine a regular testing schedule. The ad hoc panel of the American Society of Hypertension recommends that patients take at least a single or double reading in the morning and evening. When assessing the influence of work-related stressors into blood pressure management, patients should be encouraged to take readings on both work and non-work days of the week.

Conclusions

HBPM technology has advanced in recent years such that affordable, sophisticated, accurate, and easy to use automated systems are now available. Incorporation of this technology into the therapeutic plans of patients with diabetes and hypertension may be beneficial. HBPM may increase patients' adherence to therapeutic plans, facilitate titration of pharmacological regimens, and reduce patients' overall health care costs.

REFERENCES

- Harris M: Racial and ethnic differences in health care access and health outcomes for adults with type 2 diabetes. *Diabetes Care* 244:454-459, 2001

²Hansson L, Zanchetti A, Carruthers SG, Dahlof B, Elmfeldt D, Julius S, Menard J, Rahn KH, Wedel H, Westerling S: Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. *Lancet* 351:1755–1762, 1998

³United Kingdom Prospective Diabetes Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998

⁴American Diabetes Association: Standards of medical care for patients with diabetes mellitus (Position Statement). *Diabetes Care* 26 (Suppl. 1):S33–S50, 2003

⁵U.S. Department of Health and Human Services: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication No. 03-5233, 2003 (available at www.nhlbi.nih.gov/guidelines/hypertension/express.pdf)

⁶American Association of Clinical Endocrinologists: Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management—2002 update. *Endocrine Pract* 8 (Suppl. 1):41–82, 2002

⁷Chalmers J, MacMahon S, Mancia G, Whitworth J, Beilin L, Hansson L, Neal B, Rodgers A, Mhurchu CN, Clark T: 1999 World Health Organization International Society of Hypertension guidelines for the management of hypertension. *J Hypertens* 17:151–183, 1999

⁸Kaplan NM (Ed.): *Kaplan's Clinical Hypertension*. 7th edit. Baltimore, Md., Williams & Wilkins, 1998

⁹Muscholl M, Hense H, Brockel U, Doring A, Riegger G, Schunkert H: Changes in left ventric-

ular structure and function in patients with white coat hypertension: cross sectional survey. *BMJ* 317:565–570, 1998

¹⁰Gomez-Cerezo J, Blanco J, Garcia I, Anaya P, Raya P, Vazquez-Munoz E, Hernandez F: Non-invasive study of endothelial function in white coat hypertension. *Hypertension* 40:304–309, 2002

¹¹Muldoon M, Nazzaro P, Sutton-Tyrrell K, Manuck S: White-coat hypertension and carotid artery atherosclerosis. *Arch Intern Med* 160:1507–1512, 2000

¹²Pickering T: Recommendations for the use of home (self) and ambulatory blood pressure monitoring. *Am J Hypertens* 9:1–11, 1996

¹³Soghikian K, Casper SM, Fireman BH, Hunkeler EM, Hurley LB, Tekawa IS, Vogt TM: Home blood pressure monitoring: effect on use of medical services and medical care costs. *Med Care* 30:855–865, 1992

¹⁴Appel LJ, Stason WB: Ambulatory blood pressure monitoring and blood pressure self-measurement in the diagnosis and management of hypertension. *Ann Intern Med* 118:867–882, 1993

¹⁵Beevers G, Lip GY, O'Brien E: ABC of hypertension: blood pressure measurement. Part II—conventional sphygmomanometry: technique of auscultatory blood pressure measurement. *BMJ* 322:1043–1047, 2001

¹⁶U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiologic Health, Office of Device Evaluation: Non-invasive blood pressure (NIBP) monitor guidance. www.fda.gov/cdrh/ode/noninvas.html (Accessed Oct. 10, 2003)

¹⁷U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiologic Health, Office of Device

Evaluation: Use of standards in substantial equivalence determinations. www.fda.gov/cdrh/ode/guidance/1131.html (Accessed Oct. 10, 2003)

¹⁸O'Brien E, Waeber B, et al. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *BMJ* 322:531–536, 2001

¹⁹Bultemeier N, White JR, Campbell RK: Home monitoring of blood pressure. *U.S. Pharm* 26:83–90, 2001

²⁰Blood pressure monitors. *Consumer Reports* June 2003, p. 22–26

²¹A & D Medical LifeSource: Blood pressure readings in half the time (Press Release). www.lifeforceonline.com/PressReleases.cfm (Accessed Sept. 18, 2003)

²²Jefferies NA: Taking blood pressure without raising it. *Wall Street Journal* online Nov. 12, 2002. www.wsj.com (Accessed Sept. 21, 2003)

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Note of disclosure: Dr. White has received honoraria for speaking engagements from Omron Healthcare Corp., which manufactures home blood pressure monitoring devices.