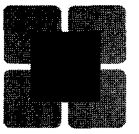

The Telelab personal blood pressure transmitter: accurate and reliable home monitoring for hypertensive patients

DONALD G. VIDT, MD; KENNITH BOLEN; RAY W. GIFFORD, JR., MD; SHARON VANDERBRUG MEDENDORP

■ We compared Telelab Personal Blood Pressure Transmitters to mercury sphygmomanometers on a random sample of 63 patients in an office setting and on 29 different patients in a home trial. Each patient was tested with the sphygmomanometer by one of two observers. Three consecutive measurements of each patient were averaged for each method. Although some differences between observers were statistically significant, they were not clinically significant. Differences between the two methods were well within the Association for the Advancement of Medical Instrumentation's accepted range for comparable medical equipment. The 29 hypertensive outpatients used the Telelab transmitter for periods ranging from 2 to 55 weeks during a clinical validation phase. The reliability and accuracy of the monitor were again demonstrated by frequent comparisons with office mercury sphygmomanometer measurements. The high degree of patient acceptance of the monitor for repeated readings over prolonged periods clearly adds to its usefulness.

□ INDEX TERMS: HYPERTENSION, AMBULATORY MONITORING IN; TELELAB □ CLEVE CLIN J MED 1991; 58:28–32

BLOOD PRESSURE measurements taken by the patient at home have been used to manage hypertension for at least 50 years.[1] Home measurements help to determine the need for pharmacologic therapy, particularly in patients with borderline or mild hypertension, and assist in the titration of antihypertensive regimens.[2–7] Even early observations noted that blood pressures measured casually at home by the patient or a family member were generally lower than those obtained in the physician's office.

From the Department of Hypertension and Nephrology (D.G.V., K.B., R.W.G.) and the Department of Biostatistics and Epidemiology (S.V.M.), The Cleveland Clinic Foundation

Address reprint requests to D.G.V., Chairman, Department of Hypertension and Nephrology, Desk A-101, The Cleveland Clinic Foundation, One Clinic Center, 9500 Euclid Avenue, Cleveland, Ohio 44195-5042.

■ *See Sheps (pp 61–63).*

Problems with home blood pressure measurements include the frequent need to calibrate mechanical manometers, the difficulty patients may have in hearing Korotkoff sounds, and tendencies to observer bias, e.g. preferring even digits rather than odd in recording blood pressures. Patients sometimes do not record accurately all relevant information, such as the time of day, that makes home measurements useful. Patients must also be trained to apply the cuff properly and to

position the stethoscope or microphone over the brachial artery.

In recent years, the stethoscope has been replaced with electronic monitors that convert Korotkoff sounds into a digital display of systolic (SBP) and diastolic (DBP) pressures. Other types of monitors, including fingertip monitors, convert oscillometric rather than auscultatory signals to analog blood pressure readings. These new electronic monitors eliminate the problems of observer bias and digit preference but not the need for accuracy in recording both blood pressure data and time of day.

Semiautomatic and fully automatic blood pressure monitors can measure blood pressure and heart rate intermittently over extended periods while patients are at work, at play, or asleep. Most common are the fully automatic monitors that are fitted at the clinic and worn by the patient for extended periods. Most electronic monitors store and analyze data and provide either digital or graphic displays of the measurements.

Ambulatory monitors have the advantage of providing a series of measurements that reflects not only the diurnal variations in blood pressure but also the changes in blood pressure during different activities. They also avoid the problems of observer bias or end digit preference.

Automatic, 24-hour monitoring can present problems, however. If measurements are taken during sleep, the inflating cuff may disturb the patient, raising blood pressure and resulting in nonrepresentative measurements. In addition, arm position and background noise can affect the accuracy of individual measurements. Wearing the monitor for long periods is inconvenient, particularly when repeated periods of monitoring are attempted. These problems, as well as the high cost ($10,000 to $15,000 per system), generally make these monitors unsatisfactory for diagnosis or management.

The purpose of this study was to evaluate the accuracy and reliability of a new semiautomatic monitor, the Telelab Personal Blood Pressure Transmitter, in office and home trials.

MATERIALS AND METHODS

The monitor

The Telelab Personal Blood Pressure Transmitter (Telelab, Hillsboro, Ore.) is a portable blood pressure monitor that operates by semiautomatic auscultatory sphygmomanometry.[8] The system consists of a transmitter, a cuff assembly, and a replaceable 9-volt battery. The DC-powered transtelephonic transmitter that records blood pressure and heart rate can store up to 250 measurements, as well as the date and time of each measurement. Instructions displayed on a monitor prompt the patient through the necessary actions for measuring his or her blood pressure. The blood pressure cuff assembly consists of a standard, manually inflated cuff and microphone; large adult cuff sizes are also available. An indicator alerts the user to pending battery failure. The monitor, contained in a plastic carrying case, weighs 39 ounces and is easily carried by hand or in a briefcase or shopping bag.

Blood pressure is measured at intervals during the patient's waking day, usually while the patient is seated. The monitor does not measure pressures while the patient is asleep. Measurements are initiated by the patient, who takes three readings, 2 minutes apart, at specified times. The monitor stores the data until they can be transmitted at prescribed intervals via telephone to a computer, at a time convenient to both patient and laboratory.

Methods

Phase I. Sixty-three subjects were randomly chosen from patients undergoing follow-up care at The Cleveland Clinic Foundation for hypertension. Of these 63 patients, 31 were evaluated by one observer (Group A) and 32 were evaluated by another observer (Group B). Both observers were trained nonphysicians.

Subjects were seated comfortably in a quiet examination room and were fitted with the blood pressure cuff after a brief explanation of the procedure. The cuff was attached to a desktop mercury manometer and to the Telelab Personal Blood Pressure transmitter by way of a "T" connector that permits the two methods to measure blood pressure simultaneously. Three consecutive measurements were made with both monitors at 2-minute intervals. Heart rate was recorded by the Telelab monitor each time a blood pressure reading was made; the observer counted the radial pulse for 1 minute immediately after measuring the blood pressure.

Telelab values were recorded automatically; mercury manometer measurements and pulse rate were recorded by the observer. The average blood pressure and heart rates were calculated for the two monitors and compared within and across observer groups with Student's paired *t* test. Ninety-five percent confidence intervals were also calculated for the mean differences between the two sets of measurements.

Phase II. In the second phase of the study, an additional 29 patients were sent home with the Telelab monitor. These patients, also from The Cleveland Clinic Foundation, were selected at random; none had participated in phase I, and all were undergoing evaluation, treatment, or titration of antihypertensive medications at the hypertension clinic.

Each patient was instructed in the proper use of the monitor. The monitor was then calibrated by the technical specialist in the laboratory. Before the patient's departure, the monitor was connected to a mercury manometer by a "T" connector, and three sets of simultaneous mercury and Telelab measurements were collected and recorded, as in phase I.

The patients were assigned the same monitor on which they had practiced. They were asked to take at least three sequential measurements every morning, three during the active part of the day, and three before bed. Each patient transmitted the blood pressure data by telephone to our laboratory every 2 or 3 days.

The monitor was calibrated at each return office visit. The monitors were used continuously from 2 to 55 weeks (mean = 12 weeks.) The number of office visits ranged from one to eight and varied widely because patients were not asked to return any more frequently than would be requested for routine clinical follow-up.

Repeated measures of analysis of variance were used to examine the effects of monitor type and number of visits on SBP and DBP separately. First, the possible interaction between monitor type and the number of visits was tested to determine whether the measurements differed by the number of office visits. Because no significant interaction was found, the effects of monitor type and number of visits were examined separately. Most of the analysis was achieved with Biomedical Programs software, Program 3V, (Digital Computers, Los Angeles), which takes into account that not all patients had eight office visits. Correlation coefficients were calculated for the three measurements (office Telelab, office mercury, and home Telelab), using only the first office visit measurements on each patient.

RESULTS

Phase I

Some observer variability was noted in the measurement of SBP. In Group A the Telelab measurements were higher than the mercury measurements, whereas in Group B, they were lower. Although these differences are statistically significant ($P < 0.001$; mean difference of 1.4 mmHg in Group A and 1.8 mmHg in Group B), they are within the range of clinical equivalence. The differences were small enough to pool the data from both groups for further analysis.

There was also some observer variability in the measurement of DBP. The difference between the Telelab and mercury measurements taken by observer B was significantly greater than the difference between those taken by observer A. The direction of the differences was the same for both observers; the Telelab measurements were significantly higher than the mercury values ($P < 0.001$). This difference (mean value of 3.5 mmHg) was within the Association for the Advancement of Medical Instrumentation (AAMI)[9] accepted standards for equipment comparisons.

Telelab heart rate measurements were slightly lower than those taken by the observer. While this difference is statistically significant ($P < 0.001$), the mean difference of 1.7 bpm is not clinically important.

To determine whether the difference between the mercury and Telelab measurements varied with blood pressure, we created categories of blood pressures from the mercury measurements. Differences between the two types of measurements were compared for each blood pressure category with the Kruskal-Wallis test. There was a significant difference between categories in SBP but not in DBP. Multiple comparisons indicated that in the middle ranges of SBP (120 mmHg to 140 mmHg) the Telelab measurements tended to be higher, and at the outer ranges, the mercury measurements tended to be higher. The differences, while statistically significant, were all less than 5 mmHg and were clinically acceptable.

Phase II

As expected, both office Telelab and mercury measurements were significantly higher than the home Telelab measurements, but they were not significantly different from each other. This was true for both SBP and DBP.

All three measurement conditions (office Telelab, home Telelab, and office manometer) are strongly correlated for both SBP and DBP. The two office measurements had a slightly stronger correlation than either of the two combinations of home and office measurements. The correlation coefficients for office mercury and office Telelab were 0.99 for SBP and 0.98 for DBP, while for office mercury and home Telelab they were 0.81 for SBP and 0.77 for DBP. The correlation coefficients for office Telelab and home Telelab were 0.81 for SBP and 0.72 for DBP.

DISCUSSION

We compared the Telelab Personal Blood Pressure Transmitter to a mercury sphygmomanometer on a random sample of 63 patients in an office setting and on 29 different patients in a home trial. The study design and the relatively small variability in measurements produced statistically significant differences of no clinical importance. The differences were well within the accepted range (± 5 mmHg) recommended by the AAMI for validating the accuracy of blood pressure monitors.[9] Home use of the Telelab device by 29 patients verified both the accuracy and reliability of the device when used for periods of up to 55 weeks. The correlation between office mercury and office Telelab readings was exceptionally good. Although statistical differences were found between the measurements and between the observers, these differences were attributed to the study design and the low variability among the measurements; none was clinically significant.

The evidence suggests that the complications of hypertension are more closely related to ambulatory measurements of blood pressures than to casual office measurements. Sokolow and colleagues found that ambulatory blood pressure measurements were superior to casual office measurements in predicting the severity of hypertension, as indicated by the presence of retinopathy or by radiographic or electrocardiographic evidence of left ventricular hypertrophy.[10] An extension of their initial studies showed that ambulatory measurements provided better long-term predictions of fatal and nonfatal cardiovascular events than did office measurements.[11] Several studies suggest that ambulatory measurements are superior to office measurements in predicting cardiac hypertrophy.[12–14]

Home or ambulatory blood pressures are consistently lower than office blood pressures in most patients with borderline or mild hypertension.[4,5,15,16] Our study was no exception: measurements taken at home were significantly lower ($P < 0.001$) than those taken at the office with either of the two methods. The 7-day average of home Telelab measurements (taken before the periodic office checks) was lower than the 7-day averages for both the Telelab and mercury measurements taken at the office.

The Telelab Personal Blood Pressure Transmitter offered us several advantages over sphygmomanometers and automatic ambulatory monitors. Manual measurements can upset patients who worry about minor deviations. In addition, observer bias or digit preference can influence these measurements. Although automatic monitors have eliminated these problems, many patients still do not accurately record either the measurements or the date and time that they were taken. The Telelab monitor automatically records the these data; it does not permit the patient to record only favorable readings or to record false readings.

The Telelab monitor records blood pressure measurements over a longer period than do the automatic ambulatory monitors. Its accuracy and reliability have been demonstrated over weeks of repeated measurements. The opportunity to observe fluctuations in blood pressure over longer periods than is possible with automated devices may prove an advantage in the evaluation of patients with borderline, labile, or suspected office hypertension.

The difficulties in convincing patients to agree to repeated 24-hour measurements with automated equipment makes such monitors of little value for titrating drug therapy. We found the Telelab personal blood pressure transmitter to be useful in guiding drug titration without subjecting patients to the inconvenience of frequent office visits. Measurements stored in the monitor are transmitted by telephone into our computerized data bank and are immediately available to the physician for use in adjusting dosages.

The Telelab monitor has a distinct disadvantage when compared to 24-hour blood pressure monitors in that it does not measure pressure during sleep. However, the significance of SBP and DBP measurements during sleep has not been determined.

REFERENCES

1. Ayman D, Goldshine, AD. Blood pressure determinations in patients with essential hypertension. I. The difference between clinic and home readings. Am J Med Sci 1940; **200**:465–474.
2. Pickering TG, Harshfield GA, Devereux RB, Laragh JH. What is the role of ambulatory blood pressure monitoring in the management of hypertensive patients? Hypertension 1985; **7**:171–177.
3. Sleight P. Ambulatory blood pressure monitoring (editorial). Hypertension 1985; **7**:163–164.
4. Health and Public Policy Committee of the American College of Physicians. Automated ambulatory blood pressure monitoring. Ann Intern Med 1986; **104**:275–278.
5. White WB. Assessment of patients with office hypertension by 24-hour noninvasive ambulatory blood pressure monitoring. Arch Intern Med 1986; **146**:2196–2199.
6. Waeber B, des Combes BJ, Porchet M, Biollaz J, Schaller MD, Brunner HR. Ambulatory blood pressure recording to identify hypertensive patients who truly need therapy. J Chron Dis 1984; **37**:55–57.

7. des Combes BJ, Porchet M, Waeber B, Brunner HR. Ambulatory blood pressure recordings. Reproducibility and unpredictability. Hypertension 1984; **6:**110–114.
8. Bolen K, Vidt DG, Gifford RW Jr. The Telelab personal blood pressure transmitter: validation and clinical application. (Abstract) Clin Pharmacol Ther 1987; **41:**217.
9. Proposed Standard for Electronic or Automated Sphygmomanometers. Arlington, Va: Association for the Advancement of Medical Instrumentation; 1985.
10. Sokolow M, Werdegar D, Kain HK, et al. Relationship between level of blood pressure measured casually and by portable recorders and severity of complications in essential hypertension. Circulation 1966; **34:**279–298.
11. Perloff D, Sokolow M, Cowan R. The prognostic value of ambulatory blood pressures. JAMA 1983; **249:**2792–2798.
12. Rowlands DB, Ireland MA, Glover DR, McLeay RAB, Stallard TJ, Littler WA. The relationship between ambulatory blood pressure and echocardiographically assessed left ventricular hypertrophy. Clin Sci 1981; **61(Suppl):**101s–103s.
13. Drayer JIM, Weber MA, DeYoung JL. BP as a determinant of cardiac left ventricular muscle mass. Arch Intern Med 1983; **143:**90–92.
14. Devereux RB, Pickering TG, Harshfield GA, et al. Left ventricular hypertrophy in patients with hypertension: importance of blood pressure response to regularly recurring stress. Circulation 1983; **68:**470–476.
15. Pickering TG, Harshfield GA, Kleinert HD, Blank S, Laragh JH. Blood pressure during normal daily activities, sleep, and exercise. Comparison of values in normal and hypertensive subjects. JAMA 1982; **247:**992–996.
16. Kleinert HD, Harshfield GA, Pickering TG, et al. What is the value of home blood pressure measurement in patients with mild hypertension? Hypertension 1984; **6:**574–578.