Evaluation of the DINAMAP Blood Pressure Monitor in an Ambulatory Primary Care Setting

Steven Ornstein, MD, Gary Markert, MPH, Laurann Litchfield, RN, and Lois Zemp
Charleston, South Carolina

Automatic blood pressure recorders have gained acceptance in many clinical settings. New devices have usually been validated with invasive monitoring as the "gold standard." There is a lack of sound empirical evidence, however, supporting the routine use of these monitors in ambulatory settings. This study evaluated the DINAMAP 8100, an oscillometric automated blood pressure monitor, using the Hawksley Random-Zero Sphygmomanometer as the standard. A sample of 80 normotensive and hypertensive ambulatory patients from the Department of Family Medicine at the Medical University of South Carolina were studied. A clinical trial was conducted in which readings from the DINAMAP 8100 were compared with those from the Hawksley Random-Zero Sphygmomanometer, in a 2 (instrument) × 2 (arm) × 2 (investigators) × 4 (pairs of simultaneous measurements) factorial design. The DINAMAP 8100 overestimated systolic readings (mean difference = 7.6 ± 9.1 mmHg, P < .0001, paired t test). More than one third of systolic measurements and one quarter of diastolic measurements were greater than 10 mmHg discrepant from the standard. The results of this study suggest that routine use of the DINAMAP 8100 would lead to serious misclassification errors in screening for hypertension and in the follow-up of known hypertensive patients. The DINAMAP 8100, therefore, is not an appropriate instrument for routine use in primary care settings.

Automatic blood pressure recorders have gained acceptance in many clinical settings and their use is being promoted in primary care. It is hypothesized that automatic blood pressure recorders eliminate observer bias, terminal digit preference, and "white coat" hypertension, and that they free the health care provider to perform other tasks concurrently. Despite these theoretical advantages, the routine use of automatic blood pressure recorders must be based on their reliability in the outpatient setting.

Noninvasive blood pressure determination depends on the principle of arterial occlusion and production of Korotkoff sounds or pressure waveforms distal to a deflating blood pressure cuff. In oscillometric devices, a microprocessor interprets blood pressure waveforms and displays blood pressure electronically.[1]

The DINAMAP monitor (Critikon, Inc, Tampa, Florida)[2,3] is a commonly used oscillometric instrument. Several studies have compared blood pressure measurements from DINAMAP monitors with those obtained by invasive monitoring in adults[2–6] and infants.[7–9] In general, correlation coefficients for regression analyses comparing mean arterial, systolic, and diastolic blood pressure measurements by these techniques have been good (0.82 to 0.98). In addition, mean differences in large numbers of comparison measurements between the two techniques have been small (less than 5 mmHg). Standard deviations of mean differences in blood pressure determinations, however, are inconsistently within acceptable limits.[10]

Studies comparing these monitors with intraarterial measurements, however, have only inferential relevance in ambulatory care settings. Historically, physicians have based their decisions regarding blood pressure management on indirect measurements made by the mercury

Submitted, revised, December 16, 1987.

From the Department of Family Medicine, Medical University of South Carolina, Charleston, South Carolina. Presented at the 15th Annual North American Primary Care Research Group, Minneapolis, Minn, May 18, 1987. Requests for reprints should be addressed to Dr. Steven Ornstein, Department of Family Medicine, Medical University of South Carolina, 171 Ashley Avenue. Charleston, SC 29425-5820.

sphygmomanometer, the device used in most epidemiologic studies relating hypertension to premature morbidity and mortality. It is imperative, therefore, that newer equipment, such as the DINAMAP monitors, always be assessed with a mercury sphygmomanometer as the standard.[11,12]

Proposed standards for the evaluation of automated blood pressure monitors in comparison with standard sphygmomanometers are that mean differences in blood pressure be less than 5 mmHg with standard deviations less than 8 mmHg.[10] In addition, it is suggested that at least 50 patients over the full range of clinically relevant blood pressures be studied. To date, no study of DINAMAP monitors has complied with these recommendations in the outpatient setting; in fact, only four reports[12–15] have assessed these monitors in ambulatory patients.

One study found good agreement between systolic and diastolic measurements determined by the DINAMAP 845 and those determined by the Hawksley Random-Zero Sphygmomanometer (Hawksley and Sons, Ltd, West Sussex, England) in 32 subjects. Standard deviations for differences between devices were not reported, however, and the DINAMAP 845 was found to be unreliable for measuring systolic blood pressures greater than 210 mmHg.[13] Another study of 30 hypertensive patients found small mean differences in blood pressure between the DINAMAP 845 and standard sphygmomanometer, but the DINAMAP 845 underestimated diastolic blood pressures by at least 10 mmHg more than 25 percent of the time.[14] The study concluded that classification as normotensive or hypertensive can vary according to the device used. Another study found no statistically significant differences in blood pressure readings from the DINAMAP 845 and the sphygmomanometer in systolic and diastolic measurements in multiple determinations from 15 subjects.[12] Nevertheless, the mean DINAMAP 845 diastolic reading was 5.2 mmHg lower than the sphygmomanometer mean, and standard deviations were not reported. A fourth comparison of the DINAMAP 845 with auscultation in 23 healthy volunteers found small mean differences and standard deviations in systolic and diastolic blood pressure readings,[15] within acceptable limits.

These four studies had different methodologies that may, in part, account for some of the differences in findings. Nevertheless, their contradictory conclusions indicate a need for further study of DINAMAP monitors in ambulatory settings. In addition, these four studies evaluated the DINAMAP 845, and the manufacturer has recently introduced an updated version, the DINAMAP 8100. It has been argued that objective clinical tests are required on all new automated blood pressure monitors[12,16]; therefore, a clinical trial was conducted, comparing the DINAMAP 8100 with the Hawksley Random-Zero Sphygmomanometer.

METHODS

Subjects were patients 18 years of age or older at the Family Medicine Center at the Medical University of South Carolina. The study subjects were representative of the patient population in terms of age, race, sex, and range of blood pressures. The DINAMAP 8100[17] was the study instrument, the Hawksley Random-Zero Sphygmomanometer[18] the standard device. The Hawksley is designed to reduce observer expectation and terminal-digit preference biases by leaving a variable amount of mercury (between 0 and 20 mm) in the column at the end of the blood pressure determination. This value is subtracted from observed values to obtain true measurements. The null hypothesis was that mean differences in both systolic and diastolic blood pressures between the two devices would be within 5 mmHg, with a standard deviation not exceeding 8 mmHg. Although a sample size of 30 was adequate to test this null hypothesis, to assure a wide range of blood pressure values and follow guidelines for the evaluation of these blood pressure monitors,[10] 80 patients were studied.

The two investigators who determined blood pressures, a physician (S.O.) and a registered nurse (L.L.), were trained in the use of mercury sphygmomanometers. Their proficiency was assessed by a standard videotape test that documented their accuracy, intraobserver reliability, and interobserver reliability. A training period was held to standardize procedures and familiarize the investigators with the use of the Hawksley Random-Zero Sphygmomanometer and the DINAMAP 8100 Automatic Blood Pressure Recorder. Blood pressure determinations by the DINAMAP and Hawksley instruments followed the manufacturers'[17,18] and American Heart Association[19] guidelines.

After a brief history was taken, the patient was comfortably seated, with both arms positioned at heart level. Arm circumference was measured, and identical, appropriately sized cuffs were placed on each arm, one connected to the Hawksley Random-Zero Sphygmomanometer, the other to the DINAMAP 8100. Simultaneous blood pressure measurements were then taken with the two devices and recorded on separate forms with no discussion of the findings. Four pairs of blood pressure measurements were taken in a balanced crossover design (Table 1) adapted from Zezulka et al.[20] This design permits analyses of differences in blood pressure that could be due to the instrument, observer, arm, and order. The sequence in Table 1 was randomized so that the order varied from one patient to the next. For diastolic determinations with the Hawksley sphygmomanometer, phase V Korotkoff sounds were used. The random zero factor was recorded but not subtracted until the end of the experiment. The entire procedure took 10 to 15 minutes.

TABLE 1. CROSSOVER TECHNIQUE FOR BLOOD PRESSURE MEASUREMENT IN ONE SUBJECT COMPARING TWO BLOOD PRESSURE RECORDERS, THE DINAMAP 8100 AND THE HAWKSLEY RANDOM-ZERO SPHYGMOMANOMETER

Reading	Observer 1	Observer 2
First	Left arm, Hawksley	Right arm, DINAMAP
Second	Right arm, Hawksley	Left arm, DINAMAP
Third	Right arm, DINAMAP	Left arm, Hawksley
Fourth	Left arm, DINAMAP	Right arm, Hawksley

TABLE 2. DEMOGRAPHIC CHARACTERISTICS OF THE STUDY SUBJECTS

Race-Sex Group	Number	Percent
White male	7	8.75
White female	23	28.75
Nonwhite male	15	18.75
Nonwhite female	35	43.75
Total	80	100.00

Mean age, 51.0 ± 18.5 years
Age range, 18 to 86 years

Statistical analyses were performed with the SAS statistical package[21] on an IBM PC-AT computer and included (1) scatter plots of mean systolic and diastolic blood pressure measurements obtained by the two devices for each patient, (2) paired *t* tests comparing mean differences between devices in each systolic and diastolic blood pressure determination, (3) frequency distributions of differences between devices in each systolic and diastolic blood pressure measurement, and (4) a four-way analysis of variance, assessing the effect of instrument, observer, arm, and order on blood pressure measurements.

RESULTS

The demographic characteristics of the study subjects are presented in Table 2. These characteristics were representative of the patient population at the Family Medicine Center. Fifty-six percent of patients reported a diagnosis of hypertension; 46 percent stated they were currently under treatment for this problem.

Scatter plots of mean systolic and diastolic measurements by device are presented in Figures 1 and 2. The correlation coefficient for mean systolic measurements

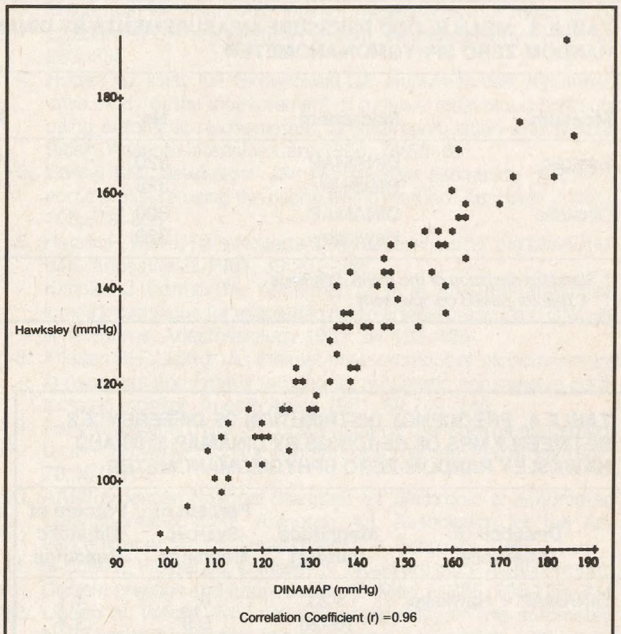

Figure 1. Scatter plot of mean systolic blood pressures (DINAMAP vs Hawksley) by patient (n = 80)

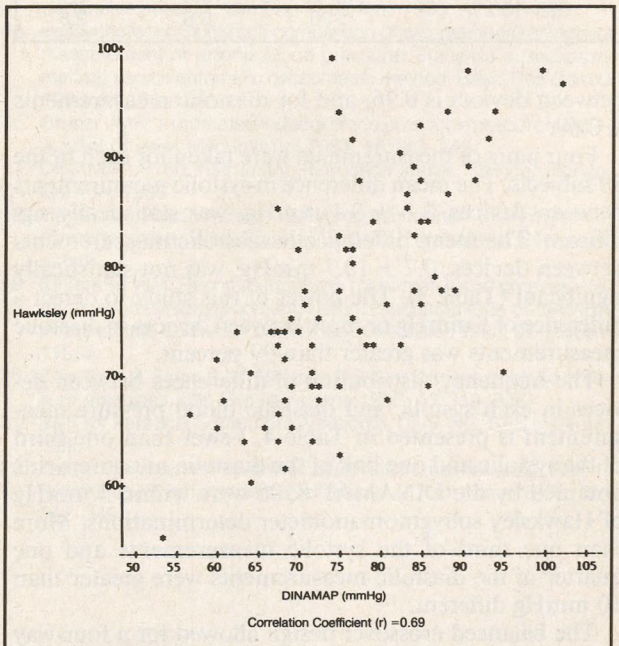

Figure 2. Scatter plot of mean diastolic blood pressures (DINAMAP vs Hawksley) by patient (n = 80)

TABLE 3. MEAN BLOOD PRESSURE MEASUREMENTS BY DINAMAP 8100 AND HAWKSLEY RANDOM-ZERO SPHYGMOMANOMETER

Measure	Instrument	No.	Mean	Mean Difference	SD*	P Value**
Systolic	DINAMAP	320	138.5	7.6	9.1	.0001
	Hawksley	320	130.9			
Diastolic	DINAMAP	320	76.4	0.6	10.7	.27
	Hawksley	320	77.0			

* *Standard deviation of the mean difference*
** t *Test for paired comparisons*

TABLE 4. FREQUENCY DISTRIBUTION OF DIFFERENCES BETWEEN PAIRS OF READINGS BY DINAMAP 8100 AND HAWKSLEY RANDOM-ZERO SPHYGMOMANOMETER

Direction of Difference	Magnitude (mmHg)	Percent of Systolic Readings	Percent of Diastolic Readings
DINAMAP < Hawksley	>20	0	4.1
	16–20	0.9	3.4
	11–15	1.9	7.2
	6–10	3.4	15.0
Difference between −5 and +5 mmHg		30.9	45.6
DINAMAP > Hawksley	6–10	27.2	12.2
	11–15	18.8	6.3
	16–20	10.3	3.4
	>20	6.6	2.8

between devices is 0.96, and for diastolic measurements is 0.69.

Four pairs of measurements were taken for each of the 80 subjects. The mean difference in systolic measurements between devices, 7.6 ± 9.1 mmHg, was statistically significant. The mean difference in diastolic measurements between devices, 0.7 ± 10.7 mmHg, was not statistically significant (Table 3). The power of this study to detect a difference of 5 mmHg or more between devices in diastolic measurements was greater than 99 percent.

The frequency distribution of differences between devices in each systolic and diastolic blood pressure measurement is presented in Table 4. Fewer than one third of the systolic and one half of the diastolic measurements obtained by the DINAMAP 8100 were within 5 mmHg of Hawksley sphygmomanometer determinations. More than one third of the systolic measurements and one quarter of the diastolic measurements were greater than 10 mmHg different.

The balanced crossover design allowed for a four-way analysis of variance, which assessed the relative contribution of observer, order, and arm, along with instrument, to blood pressure determinations. These analyses confirmed the significant difference in systolic blood pressure determinations between instruments (P = .0001), and the absence of a significant difference in diastolic measurements (P = .46). There were no significant differences between observer (P = .35), order (P = .27), or arm (P = .90) for systolic blood pressure determinations. For diastolic measurements, observer was barely statistically significant (mean difference 1.8 mmHg, P = .05); order (P = .09) and arm (P = .96) were not statistically significant.

DISCUSSION

Utilization of time-saving technology in ambulatory settings may be appealing to busy primary care physicians. Automated blood pressure determination has particular appeal because hypertension is a common chronic disease, and screening for this problem is recommended for all patients.[22] Nevertheless, the replacement of standard mercury sphygmomanometers by automated methods must await rigorous evaluation of these technologies in ambulatory settings.

This study demonstrates that the DINAMAP 8100 is not a suitable replacement for the sphygmomanometer in primary care settings. The instrument does not meet proposed standards for acceptable performance.[10] Mean differences in systolic blood pressures are 7.6 mmHg higher with the DINAMAP than with the standard device. Standard deviations for differences are 9.1 for systolic blood pressure and 10.7 for diastolic pressure readings.

These differences are important clinically. Using a standard definition of 140 mmHg or less as normal for systolic blood pressures, the prevalence of systolic hypertension in this population was 35 percent. The sensitivity of the DINAMAP 8100 was 93 percent, the specificity 81 percent, the positive predictive value 72 percent, and the negative predictive value 95 percent. Similarly, using a standard definition of 90 mmHg or less as normal for diastolic blood pressure, the prevalence of diastolic hy-

pertension in this population was 14 percent. The sensitivity of the DINAMAP 8100 was 45 percent, the specificity 96 percent, the positive predictive value 63 percent, and the negative predictive value 92 percent. The error rate of the DINAMAP 8100 (incorrectly assessing a patient's blood pressure as normotensive or hypertensive) was 15 percent for systolic blood pressure and 11 percent for diastolic blood pressure. The low positive predictive values limit this instrument's usefulness for the management of hypertensive patients. The low sensitivity for diastolic hypertension limits its usefulness as a screening device.

The study findings suggest that it is not appropriate to use the DINAMAP 8100 routinely in ambulatory settings where accurate blood pressure determinations are important to diagnose hypertension or to manage it as a chronic problem. These findings do not invalidate the use of this instrument in other clinical settings, such as operating rooms and intensive care units. In these settings, assessment of trends in blood pressure is more important than exact measurements. The DINAMAP 8100 may be well suited for this purpose.

More research is needed in this area. This study was limited by the assessment of only one instrument. The particular instrument tested may have idiosyncratic problems. In addition, the DINAMAP is available in several different models, and other manufacturers produce automated blood pressure recorders; however, there is scant literature assessing these instruments in primary care.[12] It is disturbing that in mid-1986, as this study was being designed, there were no publications in the peer-reviewed literature assessing the DINAMAP 8100. Yet at the same time, a marketing spokesman for the company indicated that the instrument was already a popular seller (Andy Schultz, October 1986). Research must precede widespread utilization if primary care physicians are to use technology appropriately and responsibly.

Acknowledgment

This study was supported in part by Baum, Inc, Copaigue, New York, and by Critikon, Inc, Tampa, Florida.

References

1. Paulus DA: Noninvasive blood pressure measurement. Med Instrum 1981; 15:91–94
2. Ramsey M: Noninvasive automatic determination of mean arterial pressure. Med Biol Eng Comput 1979; 17:11–18
3. Yelderman M, Ream AK: Indirect measurement of mean blood pressure in the anesthetized patient. Anesthesiology 1979; 50: 253–256
4. Rutten AJ, Ilsley AH, Skowronski GA, Runciman WB: A comparative study of the measurement of mean arterial blood pressure using automatic oscillometers, arterial cannulation and auscultation. Anaesth Intensive Care 1986; 14:58–65
5. Borow KM, Newburger JW: Noninvasive estimation of central aortic pressure using the oscillometric method. Am Heart J 1982; 103:879–886
6. Hutton P, Dye J, Prys-Roberts C: An assessment of the DINAMAP 845. Anaesthesia 1984; 39:261–267
7. Kimble KJ, Darnall RA, Yelderman M, et al: An automated oscillometric technique for estimating mean arterial pressure in critically ill newborns. Anesthesiology 1981; 54:423–425
8. Friesen RH, Lichtor JL: Indirect measurement of blood pressure in neonates and infants utilizing an automatic noninvasive oscillometric monitor. Anesth Analg 1981; 60:742–745
9. Park MK, Menard SM: Accuracy of blood pressure measurement by the DINAMAP monitor in infants and children. Pediatrics 1987; 79:907–914
10. AAMI/American National Standard for Electronic or Automated Sphygmomanometers. Arlington, Va, Association for the Advancement of Medical Instrumentation, February, 1987
11. O'Brien E, Fitzgerald, O'Malley K: Blood pressure measurement: Current practice and future trends. Br Med J 1985; 290:729–734
12. Linden W, Wright JM: Lack of comparability of two automated blood pressure monitors in a hypertensive population. Clin Invest Med 1986; 9:71–75
13. Silas JH, Barker AT, Ramsay LE: Clinical evaluation of DINAMAP 845 automated blood pressure recorder. Br Heart J 1980; 43: 202–205
14. Bassein L, Borghi C, Costa FV, et al: Comparison of two automatic devices and the standard mercury sphygmomanometer in hypertensive patients. Clin Exp Hypertens 1985; A7:387–390
15. Pessenhofer H: Single cuff comparison of two methods for indirect measurement of arterial blood pressure: Standard auscultatory method versus automatic oscillometric method. Basic Res Cardiol 1986; 81:101–109
16. Bruner JMR: Automated indirect blood pressure measurement—A point of view. Med Instrum 1984; 18:143–145
17. DINAMAP 8100 instrument instruction leaflet. Tampa, Florida, Critikon, 1986
18. Hawksley Random-Zero Sphygmomanometer Instrument instruction leaflet. West Sussex, England, Hawksley & Sons, (undated)
19. Kirkendall WM: Recommendations for human blood pressure determination by sphygmomanometers (Subcommittee of the AHA Postgraduate Education Committee). Circulation 1980; 62:1146A–1155A
20. Zezulka AV, Sloan PJM, Beevers DG: Comparison of blood pressure machines. Clin Exp Hypertens 1985; A7:319–326
21. SAS for Personal Computers, Version 6. Cary, NC, SAS Institute, 1985
22. Frame PS: A critical review of adult health maintenance. Part 1: Prevention of atherosclerotic diseases. J Fam Pract 1986; 22: 341–346