Technical aspects of ambulatory blood pressure monitoring in the elderly

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Cardiology in the Elderly 1993, 1:464–469

Keywords: aged, blood pressure, blood pressure monitors, hypertension

Ambulatory blood pressure measurement (ABPM) has passed from research to clinical practice and is now accepted as a valuable procedure in the clinical management of hypertension [1,2]. ABPM may have a special role in the management of hypertension in the elderly. First, the technique may permit more accurate diagnosis of hypertension [3–5], especially in patients with isolated systolic hypertension [6–9]. ABPM also provides a better assessment of antihypertensive drug efficacy in elderly patients [10], thereby avoiding overtreatment [11], which may have devastating consequences in older hypertensive subjects [12]. ABPM should prove to be a better technique than conventional measurement in determining cardiovascular outcome in the elderly [5,13], and one study is presently being conducted to determine whether this is so [9,14]. Finally, ABPM is proving helpful in evaluating elderly patients with orthostatic hypotension [15].

It is well known, however, that conventional blood pressure measurement presents particular problems in the elderly [16–18], and special consideration may also have to be given to ABPM in this population [19]. In fact, the British Hypertension Society (BHS), which published recommendations in 1990 for validating ambulatory systems [20], has devoted a subsection of its revised protocol to validation of devices for measuring blood pressure in the elderly [21]. At present, ambulatory systems have not been validated specifically for older patients, though Miller *et al.* [19] have assessed the Accutracker II (Suntech Medical Instruments, Raleigh, NC) ambulatory monitor in elderly hypertensive patients, and we have evaluated six ambulatory systems according to the level of blood pressure [20]. Each of the studies reviewed here suggests that ambulatory systems should be fully evaluated for use in elderly persons, as described in the revised BHS protocol.

Age and ambulatory blood pressure measurement

Miller *et al.* [19] compared simultaneous measurements from the Accutracker II ambulatory monitor and from two trained observers who auscultated blood pressure simultaneously in the same arm in the conventional manner, using a stethoscope and mercury sphygmomanometer, in 103 subjects who ranged from 23 to 92 years of age. The difference between the Accutracker II and the mercury standard averaged 6 mm Hg for both systolic and diastolic pressures. If the criteria of the Association for the Advancement of Medical Instrumentation (AAMI) were applied to these results, the Accutracker II would fail to fulfill the accuracy requirement of this standard [22]. These findings are consistent with those of an earlier validation study performed according to the AAMI standard [23]. In the study by Miller *et al.* [19], the discrepancy between the Accutracker II and the mercury standard were systematically related to certain characteristics of the participants. Systolic blood pressure correlated significantly with age, gender, and race, with age showing the strongest correlation. For persons younger than 50 years of age, systolic blood pressure was 2.0 mm Hg lower when measured by ABPM; however, for persons over 50 years of age the difference in measurements between techniques was 8.3 mm Hg. For those over 70 years of age, this difference had increased to 11 mm Hg. When the effect of blood pressure level on the discrepancy between the techniques was examined, 31% of the variance between the techniques was attributed to age and blood pressure level, of which 17% was due to a joint effect resulting from correlation between age and level of blood pressure, 4.5% to age alone, and 9.4% to blood pressure level alone [19].

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Table 1. Grading system of BHS protocol for measuring accuracy of test devices*

	Cumulative readings differing from standard, %		
Grade	≤5 mm Hg	≤10 mm Hg	≤15 mm Hg
A	80	90	95
B	65	85	95
C	45	75	90
D	<45	<75	<90

*Numbers given represent the minimum score necessary to achieve a particular grade.
BHS—British Hypertension Society.

These results clearly suggest that ambulatory systems for use in the elderly should be evaluated specifically in an aged population and that the effects of age and blood pressure level on accuracy should be carefully examined. As Miller *et al.* [19] point out, however, it would be unwise to apply their findings to all ambulatory systems, particularly because the Accutracker II is an inaccurate device that has failed to fulfill the AAMI criteria [22]. Until validation studies are done specifically in elderly subjects, we must rely on the validation studies done in samples from the general population and use the most accurate devices for ABPM in the elderly.

Validation of six ambulatory systems according to the British Hypertension Society protocol

We validated six ambulatory systems: the CH-Druck/Pressure Scan ERKA (Disetronic Medical Systems AG, Burgdorf, Switzerland) [24], the Profilomat (Disetronic Medical Systems AG) [25], the SpaceLabs 90207 (SpaceLabs, Redmond, WA) [26], the DIASYS 200 (Novacor, Paris, France) [27], the Pressurometer IV (Del Mar Avionics, Irvine, CA) [28], and the Takeda TM-2420 (A & D Company, Tokyo, Japan) [29] according to the BHS protocol. The AAMI criteria have also been applied to the analysis. The BHS protocol consists of six phases: 1) observer training and assessment; 2) before-use interdevice vari-

Table 2. Comparative accuracy of six ambulatory blood pressure monitors as determined by the BHS and AAMI criteria

	BHS criteria*				
Device†	Grade‡	≤5 mm Hg	≤10 mm Hg	≤15 mm Hg	AAMI criteria§
CH-Druck					
SBP	A	81	93	97	−3±7
DBP	A	85	97	98	3±6
SpaceLabs 90207					
SBP	B	69	89	96	−1±7
DBP	B	69	91	98	−3±6
Profilomat					
SBP	B	78	89	96	−4±5
DBP	A	81	93	95	0±1
DIASYS 200					
SBP	C	63	85	94	−1±8
DBP	C	64	86	96	0±8
Pressureometer IV					
SBP	C	62	82	90	−2±11
DBP	D	59	77	85	−3±11
Takeda TM-240					
SBP	D	59	78	88	−4±11
DBP	D	62	78	85	−2±11

*BHS criteria given in percents as defined in Table 1.
†Manufacturer information is as follows: CH-Druck/Pressure Scan ERKA and Profilomat, Disetronic Medical Systems AG, Burgdorf, Switzerland; SpaceLabs 90207, SpaceLabs, Redmond, WA; DIASYS 200, Novacor, Paris, France; Pressurometer IV, Del Mar Avionics, Irvine, CA; Takeda TM-2420, A & D Company, Tokyo, Japan.
‡To obtain a particular grade, cumulative percentages for all three categories had to exceed values given in Table 1.
§AAMI criteria require that the test device does not differ from the standard by more than a mean of 5 mm Hg±8 mm Hg SD for both systolic and diastolic pressures. Values given here indicate the mean difference±SD from the standard for each device.
AAMI—Association for the Advancement of Medical Instrumentation; BHS—British Hypertension Society; DBP—diastolic blood pressure; SBP—systolic blood pressure.

ability assessment; 3) in-use (field) assessment; 4) after-use interdevice variability assessment; 5) device validation; and 6) report of evaluation [20]. In each validation study, observers had to fulfill the strict requirements of the protocol [30]. All devices fulfilled the before- and after-use interdevice variability assessments. Details of the in-use assessment and evaluation of the instructional manuals, computer facilities, and other criteria stipulated in the appendices of the BHS protocol have been reported in the full reports of the individual validations [24–29].

Device accuracy was tested in the laboratory by comparing three sequential blood pressure measurements obtained from the same arm in 86 subjects with a wide range of blood pressures. The devices were graded A, B, C, or D according to the BHS criteria shown in Table 1. The percentage of measurements differing from the mercury standard by 5, 10, and 15 mm Hg or less are shown in Table 2. To obtain a particular grade, all three cumulative percentages had to exceed the tabulated values. The AAMI standard stipulates that the mean difference between a test device and mercury sphygmomanometer should not be greater than 5 mm Hg with a standard deviation not greater than 8 mm Hg for both systolic and diastolic pressures [22]. These criteria were also applied to the validation data of the six systems and are shown in Table 2. An example of the plotting of data is shown in Figure 1 for systolic pressure for the CH-Druck.

The CH-Druck was rated A for both systolic and diastolic pressures, the Profilomat was rated B for systolic and A for diastolic pressure, the SpaceLabs 90207 received a B rating for both systolic and diastolic pressure, and the DIASYS 200 received a C rating for both systolic and diastolic pressure but narrowly failed to satisfy the in-use criteria of the protocol; these four devices fulfilled the AAMI criteria for both systolic and diastolic pressures. The first Pressurometer IV device used in the test failed to function after testing in 32 subjects and had to be replaced; this system achieved a C rating for systolic and only a D rating for diastolic pressure. Similarly, the first Takeda TM-2420 used in the test broke down after testing in 36 subjects and had to be replaced; this system achieved a D rating for both systolic and diastolic pressures. Both the Pressurometer IV and the Takeda TM-2420 failed to fulfill the AAMI criteria for both systolic and diastolic pressures by virtue of large standard deviations of the differences (Table 2).

These studies showed, therefore, that the CH-Druck, Profilomat, and SpaceLabs 90207 ambulatory systems were accurate under static bench comparisons with a standard mercury sphygmomanometer. However, in light of such poor results from validation studies according to two protocols, neither the Takeda TM-2420 model tested in this validation nor the Pressurometer IV can be recommended for

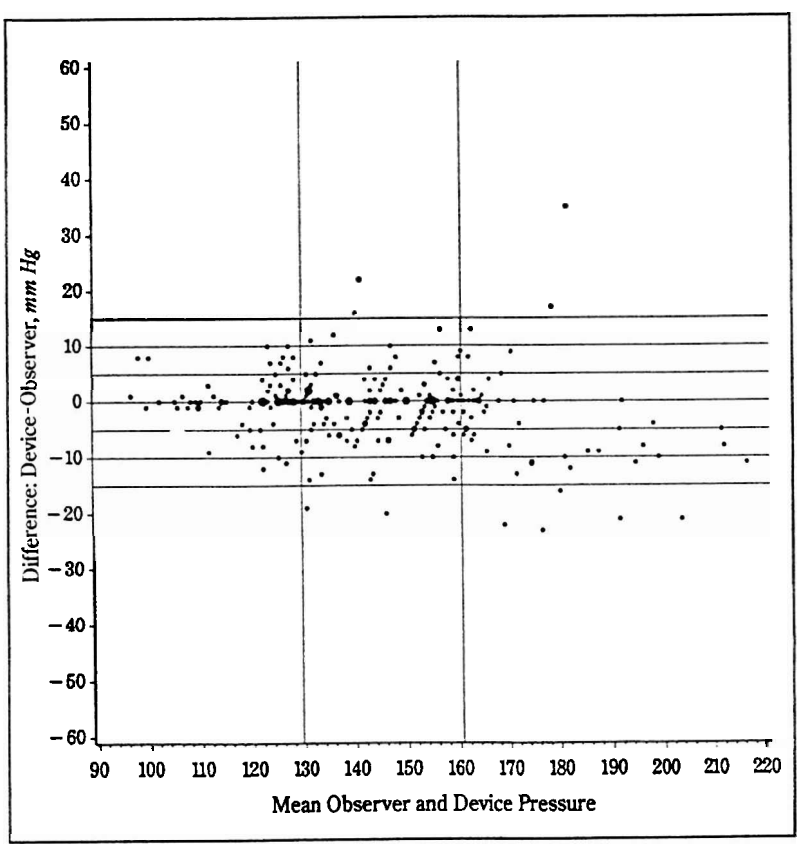

Fig. 1. Plot of pressure difference between the better of two observers and the CH-Druck and mean pressure for the CH-Druck and that observer in 86 subjects for systolic blood pressure ($n = 258$). Reference lines at 0, ±5, ±10, and ±15 mm Hg difference.

Table 3. Ratings for six devices on measurements of low, medium, high, and overall blood pressure levels*

Device‡	Level†			
	Low	Medium	High	Overall
CH-Druck/Pressure Scan ERKA	A(90)/A(84)	B(75)/A(88)	B(81)/C(75)	A(81)/A(85)
Profilomat	A(82)/A(83)	B(74)/A(82)	C(77)/D(74)	B(76)/A(81)
SpaceLabs 90207	B(77)/B(79)	B(70)/B(68)	C(58)/C(52)	B(69)/B(69)
DIASYS 200	C(71)/C(68)	C(64)/C(60)	C(55)/B(73)	C(63)/C(64)
Pressureometer IV	B(74)/D(60)	C(62)/D(63)	D(53)/D(39)	C(62)/D(59)
Takeda TM-2420	B(71)/D(56)	C(64)/D(65)	D(42)/D(67)	D(59)/D(62)

*Grades are given according to British Hypertension Society criteria for systolic/diastolic blood pressure, with the cumulative percentage of readings differing from the standard by ≤5 mm Hg given in parentheses after each grade.
†Ranges for each blood pressure level are defined as follows: low, ≤130/80 mm Hg; medium, 130/80–160/100 mm Hg; high, ≥160/100 mm Hg; overall, 90/56–196/136 mm Hg.
‡Manufacturer information is as follows: CH-Druck and Profilomat, Disetronic Medical Systems AG, Burgdorf, Switzerland; SpaceLabs 90207, SpaceLabs, Redmond, WA; DIASYS, Novacor, Paris, France; Pressurometer IV, Del Mar Avionics, Irvine, CA; Takeda TM-2420, A & D Company, Tokyo, Japan.

ambulatory blood pressure measurement in clinical practice.

Effect of blood pressure level on ambulatory blood pressure monitoring

During the performance of these validation studies, a tendency was noted for accuracy to deteriorate with increasing levels of blood pressure. Further analysis was done, therefore, to examine the accuracy of these six ambulatory systems, not only across the blood pressure range recommended in the BHS protocol but also in low (≤130/80 mm Hg), medium (130/80 to 160/100 mm Hg), and high (≥160/100 mm Hg) blood pressure ranges [31]. The cumulative percentages for the 5-mm Hg band according to tertiles of pressure are shown in Table 3. An example of the plotting of data is shown in Figure 2 for systolic pressure for the Takeda TM-2420.

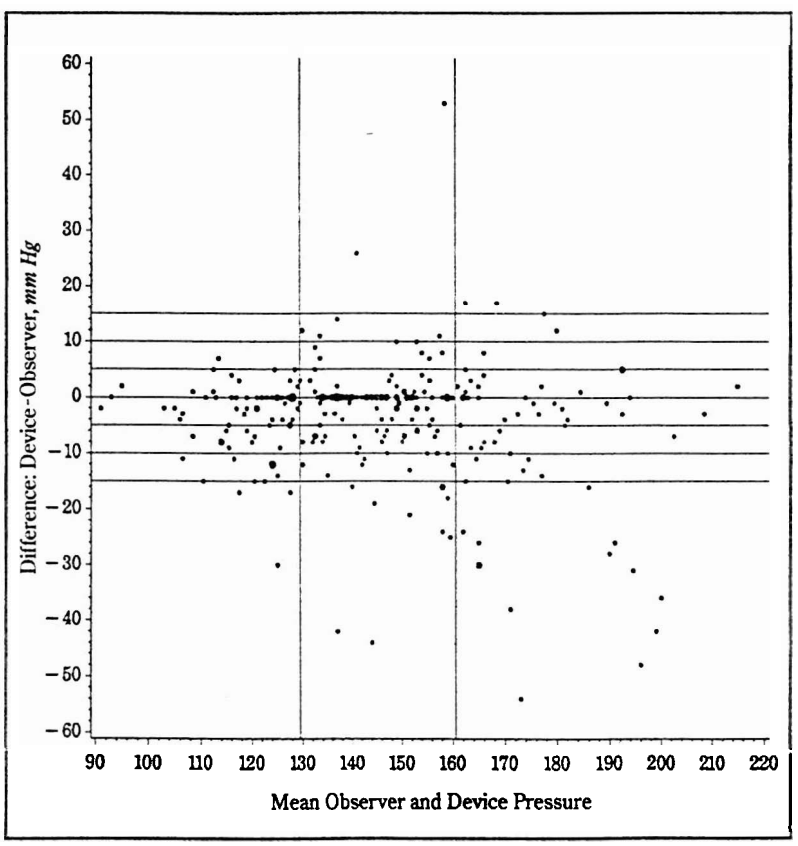

Fig. 2. Plot of pressure difference between the better of two observers and the Takeda TM-2420 and mean pressure for the Takeda TM-2420 and that observer in 86 subjects for systolic blood pressure ($n = 258$). Reference lines at 0, ±5, ±10, and ±15 mm Hg difference.

When the data were analyzed according to tertiles of pressure for low-, medium-, and high-pressure ranges, all six devices held their overall rating or improved slightly in the low- and medium-pressure ranges. In the high-pressure range, however, the CH-Druck slipped from an overall A/A rating to a B/C rating, the Profilomat from B/A to C/D, the SpaceLabs from B/B to C/C, and the Pressurometer IV from C/D to D/D. The Takeda remained unchanged with a D/D rating, but the results within this rating were worse in the high-pressure range. The Novacor rose from C/C to a C/B rating.

These results suggest that all six ambulatory devices are less accurate in subjects whose blood pressures at entry to the validation study are above 160/100 mm Hg. This finding has obvious implications, because ambulatory blood pressure measuring devices are used most often in clinical practice to determine diagnosis or to assess the efficacy of antihypertensive drug treatment in patients whose blood pressures may be in the range in which these devices are least accurate, a situation which is especially likely in the elderly. It must be emphasized, however, that experience in interpreting data for pressure ranges is limited, and the number of subjects included for analysis is necessarily considerably less than that used for the overall analysis. Although it would be preferable to have 85 patients in each tertile of blood pressure range, the feasibility of doing such a validation is daunting, and we believe that the trend toward deteriorating accuracy in the higher-pressure ranges shown in this analysis is one that potential users and manufacturers should recognize. Furthermore, the original AAMI [22] and BHS [20] validation procedures may mask the important influence of pressure level on device accuracy. The BHS protocol has addressed this issue in the revised protocol [21].

Conclusions

In choosing an ambulatory system, consideration must be given to the accuracy of the device in measuring the levels of blood pressure likely to be encountered in the patients in whom ambulatory blood pressure is being measured. Based on these results, the CH-Druck emerges as the most accurate ambulatory system across the pressure ranges, although it does not perform as well in the high-pressure range as in the medium- and low-pressure ranges. The SpaceLabs 90207 is accurate in the low- and medium-pressure ranges but is not as accurate in the high-pressure range. The rating of this device is marginally lower than that of the CH-Druck, which achieves a C/B rating in this range. The Profilomat falls to a D/D rating in the high-pressure range. When accuracy of measurement is required across the whole pressure range, it would seem from tertile analysis that the only devices to be recommended from the six tested are the CH-Druck and SpaceLabs 90207. Certainly, on the basis of present knowledge, it would seem reasonable to recommend these systems for ABPM in the elderly, but given the evidence presented, it is imperative to conduct validation studies on these devices in elderly subjects according to the revised BHS protocol.

Acknowledgment

Support from the Charitable Infirmary Charitable Trust, the Royal College of Surgeons in Ireland, and the Irish Heart Foundation is acknowledged with gratitude.

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- • Of special interest
- •• Of outstanding interest

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