

Comparative accuracy of six ambulatory devices according to blood pressure levels

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Objective: To assess the accuracy of six ambulatory blood pressure measuring systems at low, medium and high blood pressures.

Results: The CH-Druck, Profomat, SpaceLabs 90207 and Novacor DIASYS 200R, having previously achieved A to C grading for systolic and diastolic blood pressures according to the British Hypertension Society (BHS) protocol and having fulfilled the criteria of the Association for the Advancement of Medical Instrumentation, have been recommended for measurement of ambulatory blood pressure in clinical practice; the Pressurometer IV and Takeda TM-2420, achieved only C and D grades and failed to satisfy the Association for the Advancement of Medical Instrumentation criteria. In this study the data from the original validations are re-analysed for three pressure ranges of systolic and diastolic blood pressures: low range $\leq 130/80$ mmHg, medium range 130–160/80–100 mmHg and high range $\geq 160/100$ mmHg. All six devices maintained their overall grading or improved them slightly in the low and medium blood pressure ranges, but in the high blood pressure range the CH-Druck slipped from an overall A/A grading to B/C, the Profomat 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 grading, but the results within this grading were worse in the higher blood pressure range, and the Novacor rose from C/C to C/B.

Conclusions: This analysis suggests that the CH-Druck is the most accurate ambulatory system across the pressure range, although it does not perform as well in the high blood pressure range as in the medium and low blood pressure ranges. The SpaceLabs 90207 is accurate in the low and medium blood pressure ranges and reasonably accurate in the high blood pressure range. If blood pressures only in the low and medium ranges are to be measured, a wider selection of ambulatory systems becomes available because, in addition to the CH-Druck and SpaceLabs 90207, the Profomat and Novacor DIASYS 200R are accurate.

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Keywords: CH-Druck, Profomat, SpaceLabs 90207, Novacor DIASYS 200R, Del Mar Avionics Pressurometer IV, Takeda TM-2420, validation by blood pressure level, 24-h ambulatory blood pressure, British Hypertension Society protocol.

Introduction

Ambulatory blood pressure measurement, which was confined to research for many years, is now an accepted method of investigation in clinical practice [1]. It is therefore not surprising that an increasing number of ambulatory systems are becoming available. Because these devices are technically complex and expensive, it is important that they are validated thoroughly [2]. In an effort to ensure that such devices are manufactured to meet the requirements of clinical

practice, the British Hypertension Society (BHS) published a comprehensive protocol for the evaluation of blood pressure measuring devices with special reference to ambulatory systems [3]. Six ambulatory systems (the CH-Druck [4], the Profomat [5], the SpaceLabs 90207 [6], the Novacor DIASYS 200R [7], the Del Mar Avionics Pressurometer IV [8] and the Takeda TM-2420 [9]) have been evaluated according to the BHS protocol, and the criteria of the Association for the Advancement of Medical Instrumentation [10] have also been applied to the data. In the present

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paper further analysis is performed to examine the accuracy of these ambulatory systems, not only across the blood pressure range recommended in the BHS protocol [3], but also in low, medium and high blood pressure ranges.

Methods

Validation of the CH-Druck, Profilmomat, SpaceLabs 90207, Novacor DIASYS 200R, Del Mar Avionics Pressurometer IV and Takeda TM-2420 according to the BHS protocol has been described previously [4-9]. The SpaceLabs 90207 measures blood pressure oscillometrically; all of the other devices utilize a microphone to detect Korotkoff sounds. In this analysis the results of the original validations have been re-analysed for three ranges of blood pressure based on the entry measurement for systolic and diastolic blood pressures: low range $\leq 130/80$ mmHg, medium range $130-160/80-100$ mmHg and high range $\geq 160/100$ mmHg. A total of 258 (3×86) sets of measurements were available for analysis for each of the six devices. The BHS criteria for grading are shown in Table 1. The grading achieved for each device is shown for the different blood pressure ranges in Table 2, together with the cumulative percentages for the 5-mmHg band. An example of the plotting of data is shown in Fig. 1 for systolic blood pressure for the Takeda TM-2420.

Table 1. British Hypertension Society criteria.

	Grade	Difference between standard and test device (mmHg)		
		≤ 5	≤ 10	≤ 15
Cumulative % of readings	A	80	90	95
	B	65	85	95
	C	45	75	90
	D		Worse than C	

Results

On overall analysis across the blood pressure range as recommended in the BHS protocol [3], the CH-Druck achieved A grading for both systolic and diastolic blood pressure, the Profilmomat achieved B grading for systolic and A grading for diastolic blood pressure, the SpaceLabs 90207 achieved B grading for both systolic and diastolic blood pressure, the DIASYS 200R achieved a C grading for both systolic and diastolic blood pressure, the Pressurometer IV achieved a C grading for systolic and a D grading for diastolic blood pressure, and the Takeda TM-2420 achieved a D

Table 2. British Hypertension Society (BHS) criteria for six devices for overall, low, medium and high pressure levels (graded according to BHS criteria with cumulative percentage of readings ≤ 5 mmHg tabulated for each device).

	Overall		Low		Medium		High	
	SBP	DBP	SBP	DBP	SBP	DBP	SBP	DBP
CH-Druck								
BHS grade	A	A	A	A	B	A	B	C
Percentage < 5 mmHg	81	85	90	84	75	88	81	75
Profilmomat								
BHS grade	B	A	A	A	B	A	C	D
Percentage < 5 mmHg	76	81	82	83	74	82	77	74
SpaceLabs 90207								
BHS grade	B	B	B	B	B	B	C	C
Percentage < 5 mmHg	69	69	77	79	70	68	58	52
Novacor DIASYS 200R								
BHS grade	C	C	C	C	C	C	C	B
Percentage < 5 mmHg	63	64	71	68	64	60	55	73
Pressurometer IV								
BHS grade	C	D	B	D	C	D	D	D
Percentage < 5 mmHg	62	59	74	60	62	63	53	39
Takeda TM-2420								
BHS grade	D	D	B	D	C	D	D	D
Percentage < 5 mmHg	59	62	71	56	64	65	42	67

Overall pressure range $90-196/56-136$ mmHg, low pressure range $\leq 130/80$ mmHg, medium pressure range $130-160/80-100$ mmHg, high pressure range $\geq 160/100$ mmHg. SBP, systolic blood pressure; DBP, diastolic blood pressure.

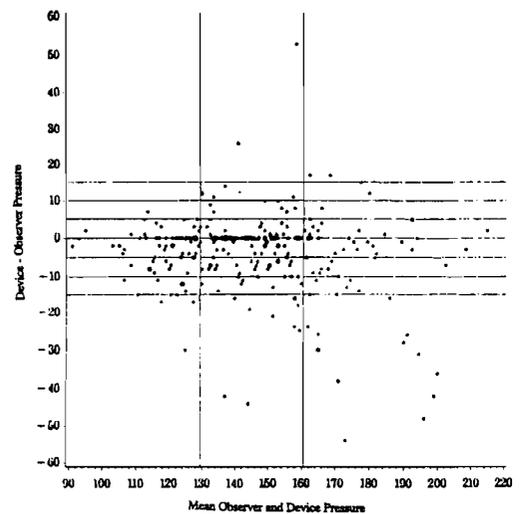


Fig. 1. Plot of pressure difference (mmHg) between the better of two observers and the Takeda TM-2420 and the mean pressure (mmHg) for the Takeda TM-2420 and that observer in 86 subjects for systolic blood pressure ($n = 258$). Reference lines, 0, ± 5 , ± 10 and ± 15 mmHg difference.

grading for both systolic and diastolic blood pressure [4-9].

When the data are analysed according to tertiles of blood pressure for low, medium and high pressure ranges, all six devices maintained their overall grading or improved them slightly in the low and medium pressure ranges, but in the high pressure range the CH-Druck slipped from an overall A/A grading to B/C

in the high pressure range, the Profimat from B/A to C/D, the SpaceLabs from B/B to C/C, the Pressurometer IV from C/D to D/D, with the Takeda remaining unchanged with a D grading but the results within this grading were worse in the higher pressure range, and the Novacor rose from C/C to C B.

Discussion

In previous validation studies of ambulatory systems using the BHS protocol [3] we observed a tendency for ambulatory systems to become less accurate with increasing blood pressure levels [4-9]. However, the BHS protocol, although stipulating the necessity of including subjects with blood pressures in the low, medium and high ranges, does not provide for separate analysis within these ranges [3]. We therefore re-analysed the original results of our validation studies of the CH-Druck, Profimat, SpaceLabs 90207, Novacor DIASYS 200R, Del Mar Avionics Pressurometer IV and Takeda TM-2420 ambulatory blood pressure measuring systems to determine whether the blood pressure level does influence accuracy.

In the original validation studies the CH-Druck and Profimat were the only systems to achieve a grade A rating, and the Pressurometer IV and Takeda TM-2420 were the only systems to obtain a grade D rating. However, when the results are re-analysed according to the blood pressure level none of the six devices achieve an A grading in the high pressure range, the highest grade achieved being B for systolic blood pressure (CH-Druck) and B for diastolic blood pressure (Novacor DIASYS 200R).

The results suggest that all six ambulatory devices are less accurate in subjects whose blood pressures at entry to the validation study are >160/100 mmHg. This finding has obvious implications, as ambulatory blood pressure measuring devices are used most often in clinical practice to determine a diagnosis or to assess the efficacy of antihypertensive drug treatment in patients whose blood pressure may be in the range in which these devices are least accurate. However, it must be emphasized that experience in interpreting data for blood pressure ranges is limited, and the number of subjects included for analysis is necessarily considerably lower than that used for the overall analysis. Although it would be preferred 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 for deteriorating accuracy in the higher blood pressure ranges demonstrated in this analysis is one that potential users should be aware of and to which manufacturers should pay attention. Furthermore, both the Association for the Advancement of Medical Instrumentation [10] and BHS [3] valida-

tion procedures may mask the important influence of blood pressure level on device accuracy, and future revisions should make provision for analysis by blood pressure level.

In choosing an ambulatory system, consideration must be given to the accuracy of the device in measuring the blood pressure levels likely to be encountered in the subjects in whom ambulatory blood pressure is being measured. On the basis of these results, the CH-Druck emerges as the most accurate ambulatory system across the blood pressure range, although it does not perform as well in the higher pressure range as in the medium and low pressure ranges. The SpaceLabs 90207 is accurate in the low and medium pressure ranges but drops to C grading in the high pressure range, marginally less than the CH-Druck, which achieves B/C grading in that range. When accuracy of measurement is required across the whole blood 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. If blood pressures only in the low and medium ranges are to be measured, a wider selection of ambulatory systems become available because, in addition to the CH-Druck and SpaceLabs 90207, the Profimat and Novacor DIASYS 200R may be recommended.

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