

Evaluation of the SpaceLabs 90202 non-invasive ambulatory recorder according to the AAMI Standard and BHS criteria

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Summary: The SpaceLabs 90202, a non-invasive ambulatory blood pressure recorder for the measurement of 24 hr blood pressure, was assessed according to the standard of the Association for the Advancement of Medical Instrumentation (AAMI) and the grading criteria of the British Hypertension Society (BHS) protocol were applied to the results.

Two observers measured BP simultaneously in the same arm with the SpaceLabs 90202 and a standard mercury sphygmomanometer at 4 mmHg deflation steps in 85 subjects [age range 22–79 years, BP range 96–212 mmHg (systolic) and 52–134 mmHg (diastolic)]. The mean difference (\pm SD) between the SpaceLabs 90202 and the mercury sphygmomanometer was -2 ± 5 mmHg (systolic) and -2 ± 5 mmHg (diastolic). The mean difference (\pm SD) between observers was 1 ± 3 (systolic) and -2 ± 3 (diastolic).

The SpaceLabs 90202 fulfills the criteria of the AAMI standard (5 ± 8 mmHg) and a B grading for both systolic and diastolic pressure is achieved with the BHS criteria.

Introduction

With the increasing use of 24 hr ambulatory BP in the evaluation and management of hypertension there is a need to ensure that the equipment used for such measurement is properly assessed for accuracy.¹ The standard of the Association for the Advancement of Medical Instrumentation (AAMI),² which has set down criteria for the validation of electronic or automated devices, has been used in this assessment of the SpaceLabs 90202. Though there are considerable differences between the AAMI Standard and the British Hypertension Society (BHS) protocol for the evaluation of ambulatory systems³ the main validation techniques have much in common, the major difference being that two observers are used throughout the validation in the AAMI Standard whereas only one observer is used in the BHS validation. The grading criteria of the BHS protocol have been applied, therefore, to the results of this study. In previous validation studies of the SpaceLabs 90202,^{4–8} deflation has been in 8 mmHg bleed steps but at this rapid deflation rate it is not possible to perform simultaneous measurement as

recommended in the AAMI Standard. In this study, therefore, the SpaceLabs 90202 was set to deflate in 4 mmHg bleed steps.

Subjects and methods

SpaceLabs 90202

The SpaceLabs 90202 automatic ambulatory BP recorder is a small ($8.6 \times 3.9 \times 14.7$ cm), lightweight (361 g) unit designed to measure BP and heart rate over a 24 or 48 hr period. It records by the oscillometric technique and stores up to 240 readings in memory over a systolic blood pressure (SBP) range of 70–285 mmHg and 40–200 mmHg for diastolic pressure (DBP) and a heart rate range of 40–180 beats per minute. Power is supplied by four alkaline C cell 1.5 V batteries. The recorder is worn in a pouch attached to a belt or sling. Stored data is decoded and displayed on a paper print-out via a local report generator (SpaceLabs Model 90206). Alternatively, the system may be interfaced with IBM compatible computer systems.

Subjects Eighty-five subjects (45 female, 40 male) were selected from among patients attending the Blood Pressure Clinic, in-patients and hospital

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staff within the age range 22 to 79 years and blood pressures in the range 96–212 mmHg systolic and 52–134 mmHg diastolic. All subjects were in sinus rhythm and had arm circumferences less than 35 cm. The age distribution of subjects fulfilled the AAMI criteria.²

Observers Two trained nurses acted as observers. Before validation they familiarised themselves with the SpaceLabs 90202.

SpaceLabs 90202 vs. observers The SpaceLabs recorder was set to deflate in 4 mmHg bleed steps, each step lasting one second followed by a three second period of constant pressure before the next deflation.

Each subject was seated with the left arm resting comfortably on a bench at heart level.⁹ The cuff of the SpaceLabs 90202 (bladder size 12.5 × 23 cm) was positioned over the left brachial artery and connected via a Y-connector to the SpaceLabs 90202 and a standard mercury sphygmomanometer. The automatic inflation/deflation system of the SpaceLabs 90202 was activated and simultaneous measurements were made by two 'blinded' observers using a double-headed Littmann stethoscope and the SpaceLabs recorder. The BP for each of 85 subjects measured three times over a period of ten minutes was averaged to give 85 sets of readings.

Results

Observer agreement There was no significant difference between observers for mean values of SBP (observer A = 151 ± 25 mmHg; observer B = 152 ± 25 mmHg; NS) or DBP (observer A = 91 ± 14 mmHg; observer B = 90 ± 14 mmHg; NS). Mean differences between observers were 1 ± 3 mmHg (systolic) and -2 ± 3 mmHg (diastolic). Systolic and diastolic differences were within 5 mmHg in 95% and 94% of subjects respectively.

SpaceLabs 90202 vs. observers The mean (±) systolic and diastolic pressures, and the percentages of measurements within 5, 10 and 15 mmHg for each observer and the SpaceLabs 90202 are shown in Table I. The grading criteria of the BHS protocol are shown in Table II; the SpaceLabs 90202 achieved a B grading for systolic and diastolic pressure.

Graphic presentation The data is displayed¹⁰ as plots of the mean pressure and the pressure difference between the two observers for systolic and diastolic pressure (Figure 1a & b); the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the SpaceLabs 90202 and this mean in 85 subjects is plotted for systolic and diastolic pressure (Figures 2a & 2b). Reference lines indicating mean ± 2 standard deviations and 95% confidence intervals are also shown.

Discussion

The SpaceLabs 90202 may be programmed to deflate in 4, 6 and 8 mmHg bleed steps. In practice it is generally set to deflate at the 8 mmHg rate, which is more comfortable for the subject wearing the device. It is difficult, however, to perform simultaneous measurements between the SpaceLabs 90202 and a mercury sphygmomanometer with the device deflating at this rapid rate and we chose, therefore, to perform the validation at the slower 4 mmHg rate of deflation. The difficulty in performing validation at rapid deflation rates has also been commented on by Santucci *et al.*, who attempted to correct for the rapid deflation rate of the SpaceLabs 90202 by noting the mercury readings in the stable phase at the beginning and end of each deflation decrement.⁴ It should be pointed out, however, that this validation applies to the SpaceLabs 90202 operating at the 4 mmHg bleed step rate and that the results need not necessarily

Table I Device validation for systolic and diastolic pressures in 85 subjects according to AAMI criteria

Device/Observer	Mean ± SD	Diff ± SD	AAMI criteria	Result
Observers	152 ± 25	-2 ± 5	<i>Systolic blood pressure</i>	
Test Device	150 ± 24		Mean diff. ≤ 5 mmHg	Pass
			SD ≤ 8 mmHg	Pass
Observers	90 ± 14	-2 ± 5	<i>Diastolic blood pressure</i>	
Test Device	88 ± 14		Mean diff. ≤ 5 mmHg	Pass
			SD ≤ 8 mmHg	Pass

Table II Device validation for systolic and diastolic pressures in 85 subjects according to BHS criteria

	Grade	Difference mmHg between standard and test device			
		≤5	≤10	≤15	
Cumulative % of readings	A	80	90	95	
	B	65	85	95	
	C	45	75	90	
	D	Worse than C			
SpaceLabs 90202	SBP	B	66	93	100
	DBP	B	75	92	99

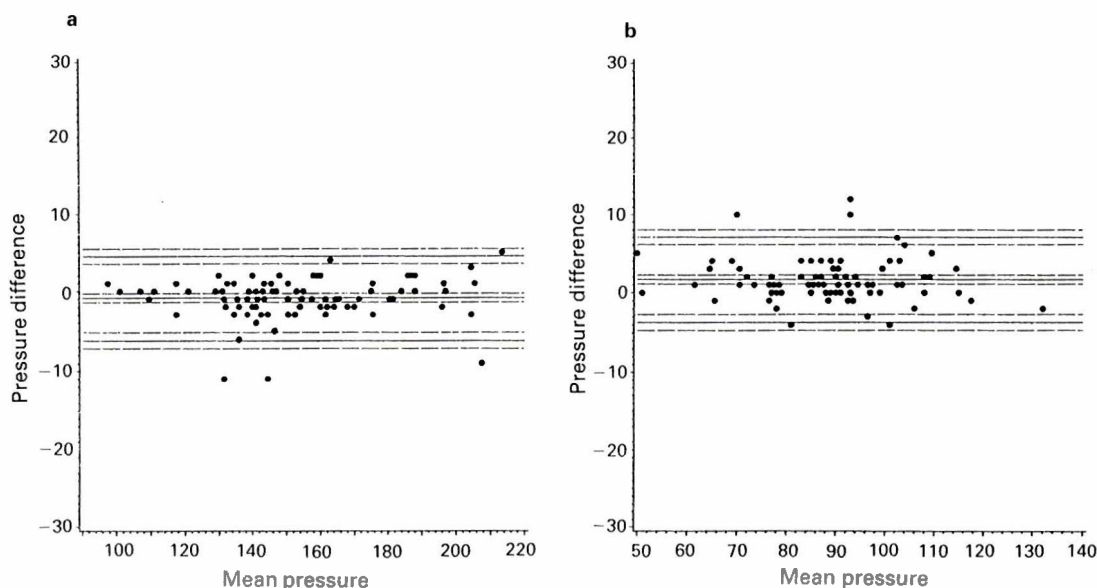
apply to the device operating at faster bleed rates.

The BHS protocol for the evaluation of ambulatory systems was published when the results of this study were being analysed, and as the methodology of the main validation test fulfilled the requirements of the BHS protocol, we have applied its grading criteria to the results³ thereby showing that the SpaceLabs 90202 achieves a B grading for both systolic and diastolic pressure.

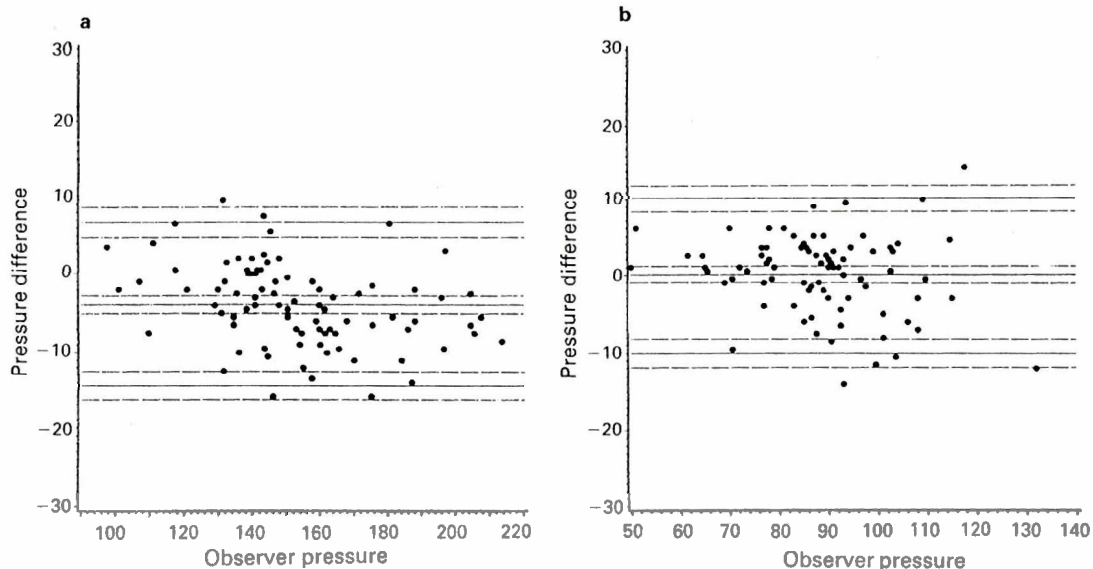
In selecting subjects for the study we were anxious to exclude as many variables as possible and we therefore excluded subjects with obese arms. Though it may be reasonable to assume that if the SpaceLabs 90202 was accurate for normal sized arms, it would be as accurate in obese subjects using a bladder with adequate dimensions

as would be the case with Korotkov sound detecting devices, the SpaceLabs 90202 measures BP oscillometrically, and it should, therefore, be validated independently in obese subjects as in other special categories, such as children and pregnant women.

Though previous validation studies on the SpaceLabs 90202⁴⁻⁸ did not fulfil the stringent criteria of the AAMI Standard, all found the device to be reasonably accurate and reliable. In the study by Santucci and colleagues,⁶ the AAMI criteria were fulfilled in a smaller number of subjects. Applying correlation coefficients, our results are similar to other studies,^{5,6,8} but this form of analysis is no longer recommended for validation studies.¹⁰



Figures 1a & 1b Plots of the mean pressure and the pressure difference between the two observers in 85 subjects for systolic (a) and diastolic pressure (b). Reference lines: mean \pm 2SD with 95% confidence intervals.



Figures 2a & 2b Plots of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the SpaceLabs 90202 and this mean in 85 subjects for systolic (a) and diastolic pressure (b). Reference lines: mean \pm 2SD with 95% confidence intervals.

It may be concluded, therefore, that the SpaceLabs 90202 satisfies the criteria of the AAMI standard in that the mean difference was less than 5 mmHg with a standard deviation less than 8 mmHg, and it achieved a B grading according to the BHS criteria. On the basis of these results the SpaceLabs 90202 can be recommended for 24 hr

ambulatory blood pressure measurement in clinical practice.

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