Accuracy of the SpaceLabs 90207 ambulatory blood pressure measuring system in normotensive pregnant women determined by the British Hypertension Society protocol

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Introduction

The SpaceLabs 90207 monitor (Redmond, Washington, USA) for ambulatory blood pressure measurement was evaluated according to the protocol of the British Hypertension Society (BHS) [1] in normotensive pregnant women. We have previously evaluated the SpaceLabs 90207 in normotensive and hypertensive men and non-pregnant women according to the BHS protocol [2]. In this evaluation the device achieved B grading for systolic and diastolic pressure and fulfilled the criteria of the Association for the Advancement of Medical Instrumentation (AAMI) [3].

Methods and results

The BHS evaluation programme consists of six phases: I, Observer training and assessment; II, Before-use interdevice variability assessment; III, In-use (field) assessment; IV, After-use interdevice variability assessment; V, Device validation; and VI, Report of evaluation [1]. The present paper is concerned only with the accuracy of the SpaceLabs 90207 in pregnancy and is concentrated, therefore, on the main validation test, as the other protocol requirements have been met by the earlier validation of the device [2]. The observers participating in the study passed the accuracy criteria of phase I as laid down in the protocol [1].

Device validation

Eighty-six normotensive pregnant women were recruited. In five the endpoint for diastolic pressure was so variable that these subjects were excluded from the analysis, leaving 81 subjects in whom three sequential measurements were performed in the same arm with the SpaceLabs 90207 and a standard mercury sphygmomanometer using Korotkoff phase V (disappearance of sounds) for diastolic pressure. The mean and standard deviation of the first mercury sphygmomanometer measurements were (systolic/diastolic) 112±11/66±12 mmHg. The SpaceLabs 90207 was graded A for systolic and C for diastolic pressure according to the BHS protocol (Table 1). Applying the AAMI accuracy criteria [4], the SpaceLabs 90207 fulfilled the requirement for systolic but not diastolic pressure, mean differences being 5±4 for systolic and 1±9 mmHg for phase V diastolic pressure.

Table 1. British Hypertension Society grading criteria.

	Differences between standard and test device (mmHg)		
Grade	≤5	≤10	≤15
Cumulative % of readings			
A	80	90	95
B	65	85	95
C	45	75	90
D	Worse than C	Worse than C	Worse than C
SpaceLabs 90207			
SBP A	88	100	100
DBP C	55	78	92

SBP, systolic blood pressure; DBP, diastolic blood pressure. Diastolic blood pressure taken as disappearance of Korotkoff phase V sounds.

Comment

Hypertensive disease associated with pregnancy remains a major cause of morbidity and maternal death

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[4,5] and contributes significantly to perinatal morbidity and mortality [6,7]. Any technique that can give some insight into hypertensive disease in pregnancy is therefore to be welcomed. The recent development of accurate devices for 24-h ambulatory blood pressure is one such technique.

The SpaceLabs 90207 achieved a top A grading for systolic pressure according to the criteria of the BHS protocol and a C grading for diastolic pressure. It satisfied the criteria of the AAMI standard for systolic pressure but not for diastolic pressure. The SpaceLabs 90207 has previously achieved B grading for both systolic and diastolic pressure and satisfied the AAMI criteria for both systolic and diastolic pressure in normotensive and hypertensive non-pregnant subjects [2]. Moreover, the device has been shown to be more accurate in the low than in the high pressure range [8].

The grading achieved for systolic pressure is a grade better than in non-pregnant subjects and that for diastolic pressure is a grade lower. The better systolic performance can be explained by the fact that the SpaceLabs 90207 is more accurate in lower than higher pressure ranges [8]. One of the interesting features to emerge from the validation study in 86 subjects was the lability of diastolic pressure as measured by auscultation in pregnant subjects, which suggests that the apparent device inaccuracy in recording diastolic pressure in pregnancy may be attributed to this phenomenon rather than to inherent inaccuracy of an automated device. Indeed, such is the confusion on this issue [9,10] that there may be much to support the recommendation made by Seligman in 1987 [11] that systolic rather than diastolic pressure should be used in the detection and management of hypertensive disease in pregnancy.

The revised BHS protocol makes pregnancy a special category in which a separate validation must be performed for devices claimed as suitable for measuring blood pressure in pregnancy [12]. The only other published study of device validation in pregnancy was performed in 30 pregnant subjects using the Takeda TM-2420, which fulfilled the AAMI criteria for accuracy [13]. In this study, the Hawksley random zero sphygmomanometer, which has been shown to underestimate blood pressure [14], was substituted for the standard mercury sphygmomanometer and may have influenced the results [15]. Clearly, more information is needed on the performance of blood pressure measuring devices in pregnancy and it is no longer valid to assume that because a device is accurate in the non-pregnant population, it will also be accurate in pregnancy.

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