Accuracy of the SpaceLabs 90207, Novacor DIASYS 200, Del Mar Avionics Pressurometer IV and Takeda TM-2420 ambulatory systems according to British and American criteria

Eoin O'Brien, Fainsia Mee, Neil Atkins and Kevin O'Malley*

Journal of Hypertension 1991, **9** (suppl 6):S332–S333

Keywords: SpaceLabs 90207, Novacor DIASYS 200, Del Mar Avionics Pressurometer IV, Takeda TM-2420, validation, twenty-four-hour ambulatory blood pressure, British Hypertension Society protocol, Association for the Advancement of Medical Instrumentation standard.

Introduction

Ambulatory blood pressure measurement, which has been confined to research for many years, is now an accepted investigation in clinical practice [1]. In an effort to ensure that the devices meet the requirements of clinical practice the British Hypertension Society (BHS) has published a comprehensive protocol for the evaluation of blood pressure measuring devices with special reference to ambulatory systems [2]. Four ambulatory systems, the SpaceLabs 90207 [3], the Novacor DIASYS 200 [4], the Del Mar Avionics Pressurometer IV [5] and the Takeda TM-2420 [6] have now been evaluated according to the BHS protocol. The evaluation was performed under standardized conditions for each ambulatory system, allowing comparison between devices.

Methods

The BHS evaluation consisted 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 [2].

The accuracy of the devices was tested in the laboratory by comparing sequential blood pressure measurements obtained from the same arm in 86 subjects with a wide range of blood pressure [3–6]. The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less is shown in Table 1. The devices were graded A, B, C or D according to the BHS criteria set out in Table 1. The Association for the Advancement of Medical Instrumentation (AAMI) [7] has stipulated that the mean difference between a test device and mercury sphygmomanometer should not be greater than 5 mmHg, with a standard deviation not greater than 8 mmHg for both systolic and diastolic pressures. These criteria were also applied to the validation data of the four systems.

Table 1. British Hypertension Society grading criteria.

			Difference between standard and test device (mmHg)			
		Grade	≤5	≤10	≤15	AAMI
Cumulative % of readings		A	80	90	95	
		B	65	85	95	
		C	45	75	90	
		D		Worse than C		
SpaceLabs 90207	SBP	B	69	89	96	−1±7
	DBP	B	69	91	98	−3±6
DIASYS 200	SBP	C	63	85	94	−1±8
	DBP	C	64	86	96	0±8
Pressurometer IV	SBP	C	62	82	90	−2±11
	DBP	D	59	77	85	−3±11
Takeda TM-2420	SBP	D	59	78	88	−4±11
	DBP	D	62	78	85	−2±11

SBP, systolic blood pressure; DBP, diastolic blood pressure; AAMI, Association for the Advancement of Medical Instrumentation.

The in-use assessment phase of the BHS protocol permits an assessment of the performance of ambulatory devices while in use. Three devices of each of the four

From the Blood Pressure Unit, Beaumont Hospital, and the *Department of Clinical Pharmacology, Royal College of Surgeons in Ireland, Dublin.

Sponsorship: This study was supported by the Charitable Infirmary Charitable Trust, the Royal College of Surgeons in Ireland and the Irish Heart Foundation.

Requests for reprints to: Dr E. O'Brien, Blood Pressure Unit, Beaumont Hospital, Dublin, Ireland.