A new audiovisual technique for recording blood pressure in research: the Sphygmocorder

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Objective: To devise a method of blood pressure measurement capable of being substituted for the fallible human observer in validation of blood pressure measuring devices.

Design: A number of components used to measure blood pressure have been combined innovatively with audiovisual recording technology to produce a system, named the Sphygmocorder, which consists of a mercury sphygmomanometer, an occluding cuff, an inflation source, a stethoscope, a microphone capable of detecting Korotkoff sounds, a camcorder and a display screen.

Methods: To determine the accuracy of the Sphygmocorder against the trained human observer, the Sphygmocorder has been validated in three separate studies in which three devices for self-measurement of blood pressure, the Omron HEM-705CP, the Phillips HP5332 and the Nissei DS-175, were being validated against two trained observers in 85 subjects with a wide range of blood pressure according to the protocol of the British Hypertension Society.

Results: The Sphygmocorder was as accurate as at least one of the observers in each of the validation studies and therefore allows replacement of trained observers by the new device.

Conclusion: The Sphygmocorder, which retains the time-honoured technique of blood pressure measurement with a mercury sphygmomanometer and an auscultating observer, and provides, in addition, objective evidence of the measurement recorded, which can be stored and re-examined, can be used as a substitute for human observers in validation studies of blood pressure-measuring devices.

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Introduction

Developments in engineering and computer technology are leading to the manufacture of an array of automated blood pressure measuring devices [1]. The British Hypertension Society (BHS) [2] and the Association for the Advancement of Medical Instrumentation (AAMI) [3] have clearly stipulated that such devices must be subjected to independent validation. A number of automated devices have been subjected to the testing requirements of the BHS and AAMI protocols [4]. One of the major difficulties with such validation procedures has been training observers to achieve a high degree of accuracy and then to maintain that accuracy throughout the study [5]. There is a need, therefore, for a technique to measure blood pressure in validation studies, which would not be dependent on observers but which would retain the traditional auscultatory methodology with the mercury sphygmomanometer. The Sphygmocorder described in the present paper provides these features.

Methods

Components of the system

The Sphygmocorder consists of a mercury sphygmomanometer (PyMaH), an occluding cuff, an inflation source, a Littman stethoscope, a microphone capable of detecting Korotkoff sounds, a camcorder and a display screen (Fig. 1). A VHS-C (JVC model GRAx7) camcorder was used to record the blood pressure

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measurements. A tie-clip capacitor microphone (Eagle Model PRO M3, London, UK) was inserted into a tube leading from one branch of the multi-aural stethoscope. Headphones connected to the camcorder are used to ensure that the quality of sound is adequate. This is necessary because the batteries in the microphone may need to be replaced and this will be indicated by deteriorating quality of the recorded sounds. The Korotkoff sounds and the synchronized visual display can be replayed repeatedly until the observer is satisfied that the measurement is accurate.

Validation of the Sphygmocorder

The Sphygmocorder was validated in three separate experiments in which three devices were being validated against two trained observers in 85 subjects with a wide range of blood pressure according to the BHS protocol, which stipulates that two observers must be trained to achieve a high level of accuracy [1]. Two observers satisfied the protocol requirements and were used throughout three validation studies to assess the accuracy of the Omron HEM-705CP, the Phillips HP5332 and the Nissei DS-175, which are oscillometric devices designed for the self-measurement of blood pressure [6]. The Sphygmocorder was included as a third 'observer' in the three sets of 255 paired measurements performed by the human observers, with all other aspects of the BHS protocol being followed strictly. An independent observer blinded to the measurements of the two observers performing the validation later determined the blood pressure recorded by the Sphygmocorder by playing back the audiotape. If there was uncertainty about a measurement, it was replayed with another observer so that a consensus measurement was achieved. The Sphygmocorder measurements were then compared with the three sets of paired measurements obtained by the two observers.

Results

The percentages of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less for each observer and the Sphygmocorder with the BHS grades are shown for each device in Table 1. To obtain a particular grade, all three cumulative percentages had to exceed the tabulated values. The Sphygmocorder gave similar grades to observer A for all three device validations but observer B gave higher grades for systolic pressure for the Omron HEM-705CP and the Phillips HP5332 devices and for diastolic pressure for the Nissei DS-175 device. The Sphygmocorder was as accurate as at least one of the two observers used in each of these experiments.

Discussion

In previous validation studies a number of strategies have been employed to overcome observer error. Using the BHS film combined with direct instruction, we have been able to bring all of the paired nurse observer measurements within 5 mmHg of each other both for systolic and for diastolic blood pressure [5]. However, whereas it is possible to bring observers to a high degree of accuracy for research work, the procedure of training

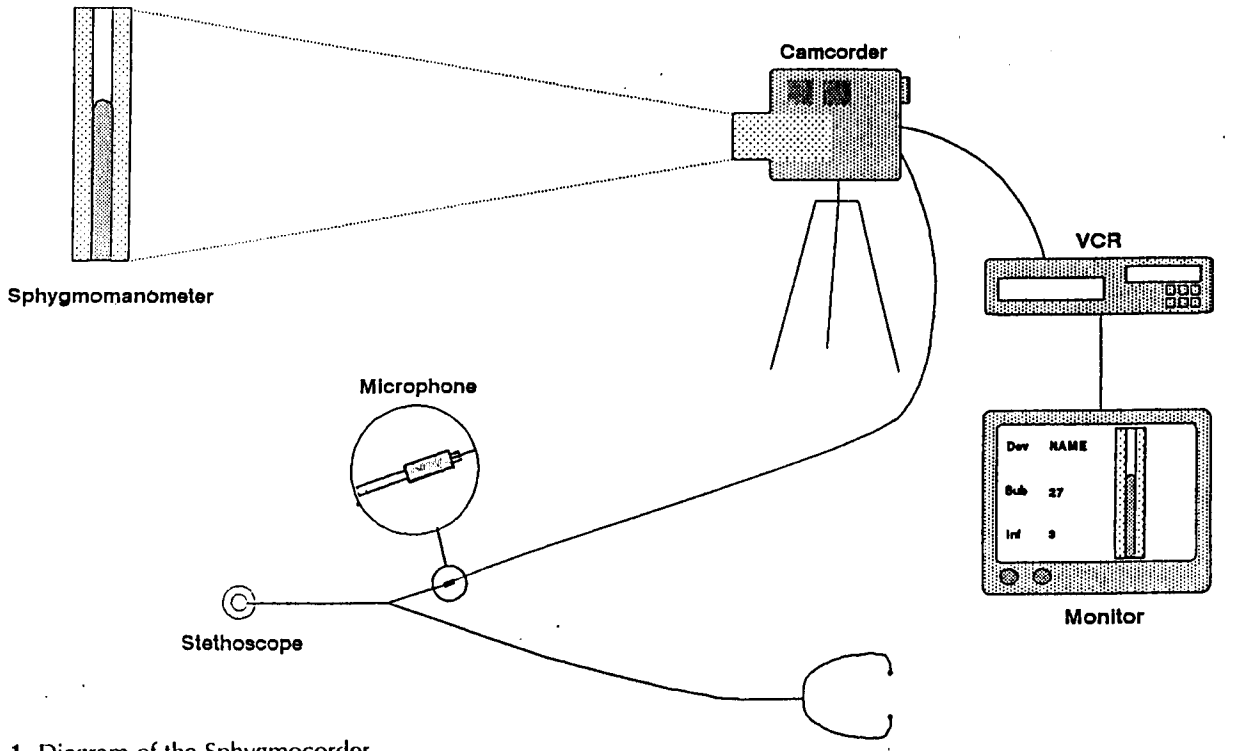

Fig. 1. Diagram of the Sphygmocorder.

Table 1. Comparison of the Sphygmocorder with two observers in three validation studies (n = 255 readings) of the Omron HEM-705CP, the Phillips HP5332 and the Nissei DS-175 devices applying the British Hypertension Society (BHS) grading criteria.

	BHS grades			
	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade
Omron HEM-705CP				
Observer A, SBP	49	77	92	C
Observer A, DBP	68	89	96	A
Observer B, SBP	52	78	93	B
Observer B, DBP	73	90	96	A
Sphygmocorder SBP	48	77	92	C
Sphygmocorder DBP	66	91	97	A
Phillips HP5332				
Observer A, SBP	38	68	84	D
Observer A, DBP	67	91	99	A
Observer B, SBP	42	70	85	C
Observer B, DBP	68	91	99	A
Sphygmocorder SBP	39	67	84	D
Sphygmocorder DBP	64	91	98	A
Nissei DS-175				
Observer A, SBP	36	56	71	D
Observer A, DBP	65	88	94	B
Observer B, SBP	38	59	75	D
Observer B, DBP	66	88	95	A
Sphygmocorder SBP	38	60	75	D
Sphygmocorder DBP	58	84	93	B

DBP, diastolic blood pressure; SBP, systolic blood pressure.

is time-consuming and expensive. Moreover, observers may lose accuracy with time and require retraining [7].

Two devices have been designed specifically for research use, the London School of Hygiene Sphygmomanometer [8] and the Hawksley random-zero sphygmomanometer [9], but both have been shown to be inaccurate [10,11] and neither can now be recommended for validation studies [12]. Semi-automated and automated devices have the potential advantage of eliminating errors of interpretation together with observer bias and terminal digit preference. However, this apparent advance has to be balanced against the considerable inaccuracy of most such devices [13,14], especially at higher pressure levels [6,15,16]. Therefore, it will be some time before automated devices can be substituted for the traditional standard, namely an accurate observer using a standard mercury sphygmomanometer and stethoscope.

In the present study the Sphygmocorder gave the same grading for device accuracy as did one observer (observer A), whose measurements gave marginally inferior grades to those of the second observer (observer B). According to the BHS protocol, devices should be judged on the basis of the best observer and it might be argued that the Sphygmocorder provided independent evidence that the grading of observer A was the more accurate assessment. However, the difference between observers A and B in terms of grading was only 1% in two instances and 2% in three instances, thus raising the issue of whether or not a small tolerance value should be a feature of the next revision of the BHS protocol.

In conclusion, the Sphygmocorder innovatively combines technology that has been available for some time to provide the facility of storing data that can be reviewed while preserving the time-honoured technique of blood pressure measurement with the mercury sphygmomanometer and an auscultating observer. In addition, with the Sphygmocorder bias is eliminated from measurement by having two or more observers review a blood pressure recording as often as desired, with discussion if necessary, in difficult cases. In the same way, terminal digit preference can be eliminated. Weak Korotkoff sounds, which can be a source of doubt and error in once-off auscultation, can be reviewed at leisure using the Sphygmocorder. Moreover, the Sphygmocorder reduces the recruitment of additional patients to studies in which blood pressure measurements are considered inadequate because of inattention or loss of concentration on the part of the observers. The Sphygmocorder, by replacing the human observer, removes the onerous procedure of training observers and facilitates greatly the execution of validation studies, which were formerly dependent on training and recruiting observers.

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