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The relative accuracy of simultaneous same arm, simultaneous opposite arm and sequential same arm measurements in the validation of automated blood pressure measuring devices

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Summary: With the increasing demand for accurate BP measuring devices there comes also the need for validation. Most validation procedures assess the accuracy of a test device against a known standard, most commonly a mercury sphygmomanometer. The best method for assessing device accuracy is to measure BP simultaneously in the same arm with the test device and a mercury sphygmomanometer. This is not always possible because the deflation mechanism of the test device interferes with the ability of an observer to auscultate the Korotkov sounds accurately. In this study a mathematical method of sequential comparison between the test device and a mercury standard in the same arm is described which is almost as accurate as simultaneous measurement in the same arm.

Introduction

When comparing two methods of measuring any clinical parameter, simultaneous measurements are the ideal. Any differences ascribable to factors other then the two measurement methods are thereby eliminated. For validation of automated BP measuring devices simultaneous measurements in the same arm with the test device and a mercury sphygmomanometer is the recommended procedure.[1,2] However, in practice it is rarely possible to measure BP simultaneously on the same arm using an automatic BP measuring device and standard mercury sphygmomanometer with a stethoscope.

A number of factors make simultaneous comparison impossible: if the automated device does not inflate the cuff sufficiently above the first Korotkov sound systolic pressure cannot be auscultated accurately; many devices release cuff pressure so rapidly after detecting diastolic pressure that an observer is unable to auscultate the point at which sounds disappear; many automated devices produce clicking sounds during deflation which can interfere with the auscultation of Korotkov sounds; most automated systems deflate at a rate which is too fast for accurate auscultation; many devices deflate in a stepwise manner with pauses between the steps, which may vary in duration according to the BP with reinflations of the bladder being an additional feature with some devices. If for any reason simultaneous measurement in the same arm is not possible, it is important that a mathematically sound alternative is available.

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Methods

Two alternatives to simultaneous measurement in the same arm were examined, namely, simultaneous measurements in opposite arms and sequential measurements in the same arm. In the first instance, environmental influences are identical for both arms, but an inter-arm difference may be present. In the sequential test, three measurements are made in sequence—firstly with the mercury sphygmomanometer, followed by the test device and finally with the mercury sphygmomanometer. The second measurement (the test device) is compared with the first and third measurements made by the observer. If the change in BP between the first and third readings is assumed to be linear the second measurement should be compared with the mean of the first and third readings. If, however, no assumption is made about BP change between the first and third readings other than requiring that the limits of the readings are not exceeded, a band of values exists between the first and third measurements and differences between the test and mercury measurements should be calculated from this band.

To test these alternatives, a mercury sphygmomanometer was used as the test device to eliminate inter-device differences. Eighty-five subjects aged between 22 and 79 years, with BPs ranging from 100/52 to 210/134 mmHg, after resting for 15 minutes were fitted with cuffs containing a bladder with dimensions 35 × 12 cm on each arm which were connected to a standard mercury sphygmomanometer and to each other via a Y connector to a common inflation bulb. Two trained observers simultaneously auscultated BP in one arm with a double-headed Littman stethoscope, while a third observer simultaneously auscultated BP in the other arm with a standard Littman stethoscope. This procedure was performed three times, at two minute intervals. In the analysis, the comparisons with each observer were performed separately and then combined for each measurement test. All measurements were made according to the recommendations of the British Hypertension Society.[3] The observers were trained with the British Hypertension Society video film[4] and assessed by an expert using a multi-headed stethoscope as recommended in the British Hypertension Society protocol for the evaluation of blood pressure devices.[3]

Results

The results are shown in Table 1. The percentage of measurements for the test device differing by more than 5, 10 or 15 mmHg from a mercury standard are compared with simultaneous measurements in the opposite arm and sequential measurements in the same arm analysed by two techniques. When the data from the same arm sequential measurements are analysed by calculating the differences between the mean of the first and third mercury measurements with the second measurement (which corresponds to a test device) the analysis assumes that the relationship between the first and third mecury measurement is linear which need not be necessarily so (Sequential same-arm I). If the analysis is based on the assumption that the difference between the first and third blood pressure need not be linear (Sequential same-arm II) the difference may be calculated as follows: if the second (test device) pressure lies between the first and third pressures the difference between the test device and the mercury standard is taken to be zero; otherwise the nearer of the two readings is subtracted from the test value to give the difference. Using this technique, the sequential analysis is restored to parity with the simultaneous same-arm analysis and both techniques are superior to simultaneous opposite arm comparisons.

Table 1 Effect of test methodology on percentage of test values differing by defined limits from standard readings

		% differences within		
		5	*10*	*15*
			(mmHg)	
Simultaneous same-arm	SBP	89	97	99
	DBP	91	100	100
Simultaneous opposite arm	SBP	74	95	98
	DBP	64	94	99
Sequential same-arm I	SBP	69	91	98
	DBP	84	99	100
Sequential same-arm II	SBP	85	98	99
	DBP	92	99	100

Discussion

In the analysis, the comparisons with each observer were performed separately and then combined. A word of caution is necessary on this aspect of data handling. It is common practice to calculate the mean of a group of readings before analysis, as is recommended, for example, in the AAMI Standard.[1] There is nothing intrinsically wrong with this practice except that there is a tendency to misinterpret the results simply because any standard deviations in subsequent analysis, by being smaller, may give an impression of improved accuracy. By way of demonstration, let us assume that a device being tested behaves quite erratically for individual readings but that over a set of readings the sum of any errors is near zero. If the mean of such a set of readings was used in comparative analysis, the device would appear to be very accurate. A similar argument may be made against using the mean of a number of control readings for comparison with a test reading. It is recommended, therefore, that comparisons should first be made for individual readings, the results being combined later if required.

Inter-arm differences vary in individuals from measurement to measurement. Thus, even the traditional method of restricting subjects to those with an inter-arm difference of not more than 5/5 mmHg, does not eliminate the problem. Most dramatically in this study, the number of diastolic differences of not more than 5 mmHg drops from 91% for simultaneous measurement in the same arm to 64% for opposite arm measurements with systolic pressure readings dropping from 89% to 74%.

From a mathematical and physiological viewpoint there is no basis for assuming that the mean of two BP measurements taken in sequence is a correct estimate of the actual BP at a moment between the times at which they were taken. It is unlikely that the change in BP between two measurements taken within a short space of time is strictly linear -- the assumption underlying a comparison of a test device pressure with the mean of two bracketing mercury readings. This causes a bias against the device being tested which is illustrated by the results showing that the proportions of systolic blood pressures in the 0–5 mmHg category differ significantly ($P<0.01$) from the proportion in the same category of the simultaneous same arm test.

By taking the first and third measurements to be simply limits within which the test measurement may lie in sequential testing, systolic pressure accuracy at the 5 mmHg level is very close to simultaneous measurement in the same arm (89% vs. 85%) and for diastolic pressure there is virtually no difference (91% vs. 92%).

In conclusion, therefore, the best method of comparing a test device with a standard is by simultaneous measurement in the same arm but when this is not possible sequential measurements in the same arm analysed as described are superior to simultaneous measurements in opposite arms.

Acknowledgements

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References

1. American National Standard for Electronic or Automated Sphygmomanometers. Association for the Advancement of Medical Instrumentation. USA. 1987.
2. O'Brien, E., Petrie, J., Littler, W. *et al.* The British Hypertension Society Protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990, **8:** 607–619.
3. Petrie, J.C., O'Brien, E., Littler, W.A. & de Swiet, M. Recommendations on blood pressure measurement. *Br Med J* 1986, **293:** 611–615.
4. Jamieson, M., Petrie, J., O'Brien, E., Padfield, P., Littler, W.A. & deSwiet, M. 'Blood Pressure Measurement'; video for the British Hypertension Society. Distributed by the British Medical Journal Publications. London. 1990.