JOURNAL OF AMBULATORY MONITORING, 1991, VOL. 4, NO. 1, 27–33

Evaluation of the Accutracker II non-invasive ambulatory blood pressure recorder according to the AAMI Standard

EOIN O'BRIEN†, NEIL ATKINS, JAMES SHERIDAN, COLM KILLEEN, RICHARD COSTELLOE, SHANE LYDON and KEVIN O'MALLEY

Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland

The Accutracker II, a non-invasive ambulatory blood pressure recorder for the measurement of 24 h blood pressure, was assessed according to the standard of the Association for the Advancement of Medical Instrumentation (AAMI). Blood pressure was measured simultaneously with the Accutracker II recorder and a Hawksley random zero sphygmomanometer in the same arm in 85 subjects (age range 18–81 years, blood pressure range 90–211 mmHg (systolic) and 36–120 mmHg (diastolic)). The mean (± SD) difference between the Accutracker II and the Hawksley sphygmomanometer was −3 ± 11 mmHg (systolic) and −7 ± 10 mmHg (diastolic), which are both outside the recommendations of the AAMI standard of 5 ± 8 mmHg.

Introduction

With the increasing use of 24 h ambulatory blood pressure 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 Accutracker II.

Validation studies have been performed previously on the Accutracker II [3,4] but not according to the AAMI Standard [2].

Subjects and methods

The Accutracker II

The Accutracker II automatic ambulatory blood pressure recorder is a small (8 × 13 × 3 cm), lightweight (357 g) unit designed to measure blood pressure and heart rate over a 24 h period. It records by detecting Korotkov sounds with a microphone placed over the brachial artery. The electrocardiogram is recorded by three electrodes placed on the chest, and only sounds coincident with R wave activity on the ECG are recorded as blood pressures. Power is supplied by four alkaline

† *To whom correspondence should be addressed.*

0951-1830/91 $3.00

1.5 V batteries. The recorder is worn in a pouch attached to a belt or sling. Stored data are decoded and printed on a Suntech model 10411 ambulatory blood pressure unit report printer.

Validation procedure

Subjects. Eighty-five subjects (34 female, 51 male) were selected from among patients attending the blood pressure clinic, in-patients and hospital staff within the age range 18–81 years and blood pressures in the range 90–211 mmHg systolic and 36–120 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].

Simultaneous Accutracker II and Hawksley sphygmomanometer measurements. Each subject was seated, with the left arm resting comfortably on a bench at heart level [5]. The cuff of the Accutracker II (bladder size 12.5 × 23 cm) was positioned on the left arm with the microphone placed under the cuff over the brachial artery. The diaphragm of a binaural Littmann stethoscope was positioned over the brachial artery also at the lower edge of the cuff, and held lightly in place by a tourniquet to prevent friction sounds. The cuff was connected via a Y-connector to the Accutracker II and a Hawksley random zero sphygmomanometer. The Accutracker II recorder was placed in a closed drawer to eliminate noise which might interfere with the detection of Korotkov sounds by the observers. The automatic inflation/deflation system of the Accutracker II was activated and simultaneous measurements were made by two observers using Hawksley sphygmomanometers and the Accutracker recorder which deflated at a rate of 2 mmHg per second from an inflated pressure of 220 mmHg. The observers recorded their measurements without being able to see each other's readings. Three sets of measurements were made on each subject over a period of 10 min. The mean of the three measurements was used as a single value for analysis, as recommended in the AAMI Standard, thus giving 85 measurements for each comparison [2]. The mean difference and standard deviation of the difference between the observers and the Accutracker II were calculated for both systolic and diastolic blood pressure. In this study we modified the AAMI validation protocol by substituting the Hawksley random zero sphygmomanometer [6] to reduce observer bias.

Results

Observer agreement

There was no significant difference between observers for mean values of systolic blood pressure (observer A = 135 ± 30 versus observer B = 135 ± 30 mmHg) or diastolic blood pressure (observer A = 76 ± 18 versus observer B = 76 ± 17 mmHg). Systolic differences were within 5 mmHg in 98% and within 10 mmHg in 99% of subjects; 99% of diastolic readings were within 5 mmHg and 99% within 10 mmHg.

Validation procedure

Simultaneous Accutracker II and Hawksley sphygmomanometer measurement. The mean (±SD) for systolic blood pressures were 132 ± 27 mmHg

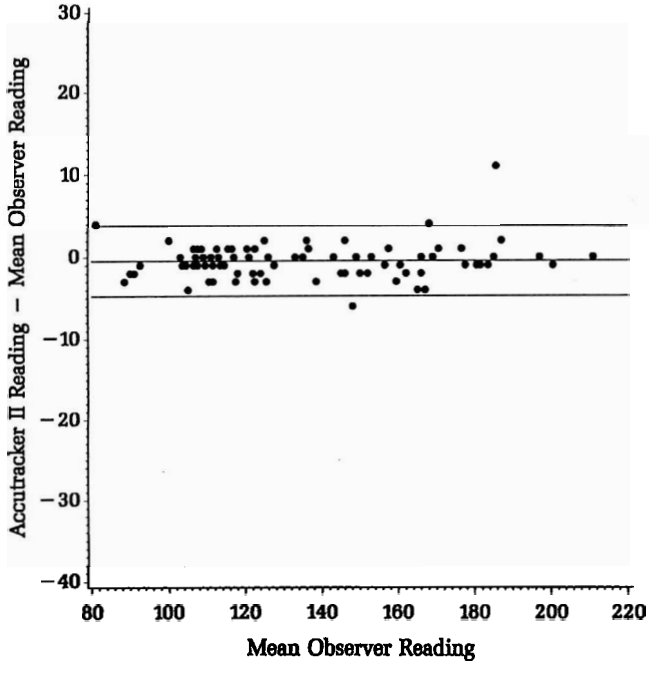
Table 1. Validation results for Accutracker II.

Device/observer	*n*	Mean ± SD	Mean difference ± SD
Systolic blood pressure			
Observer A	85	135 ± 30	−3 ± 11
Accutracker II	85	132 ± 27	−3 ± 11
Observer B	85	135 ± 30	
Diastolic blood pressure			
Observer A	85	76 ± 18	−7 ± 11
Accutracker II	85	69 ± 15	−7 ± 10
Observer B	85	76 ± 17	

Table 2. Comparison of the Accutracker II (AT) with two observers (A and B) using Hawksley sphygmomanometers.

Observer versus device	Difference (mmHg)	*n*	Percentage
A versus AT			
Systolic blood pressure	≤5	46	54
	≤10	60	71
	≤15	68	80
Diastolic blood pressure	≤5	32	38
	≤10	54	64
	≤15	70	82
B versus AT			
Systolic blood pressure	≤5	50	59
	≤10	61	72
	≤15	71	84
Diastolic blood pressure	≤5	30	35
	≤10	59	60
	≤15	69	81
Mean (A and B) versus AT			
Systolic blood pressure	≤5	47	55
	≤10	60	71
	≤15	68	80
Diastolic blood pressure	≤5	28	33
	≤10	54	64
	≤15	68	80
A versus B			
Systolic blood pressure	≤5	83	98
	≤10	84	99
	≤15	85	100
Diastolic blood pressure	≤5	84	99
	≤10	84	99
	≤15	84	99

(a)



(b)

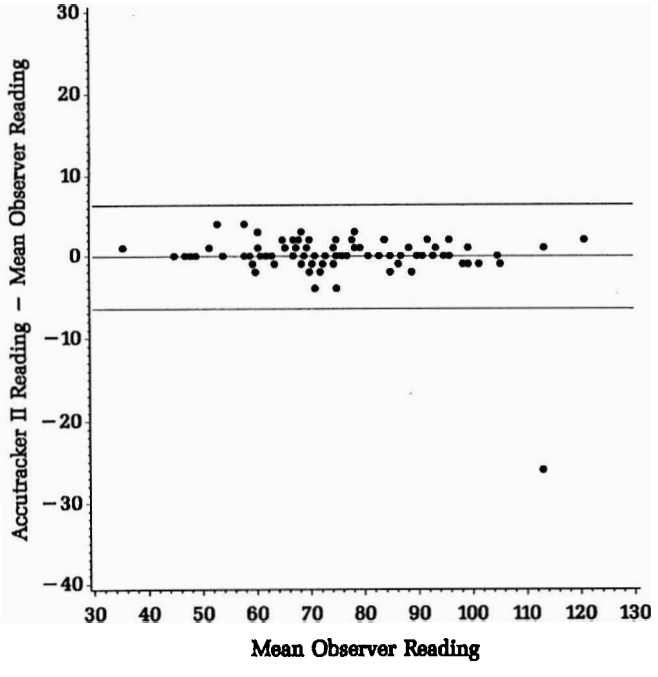
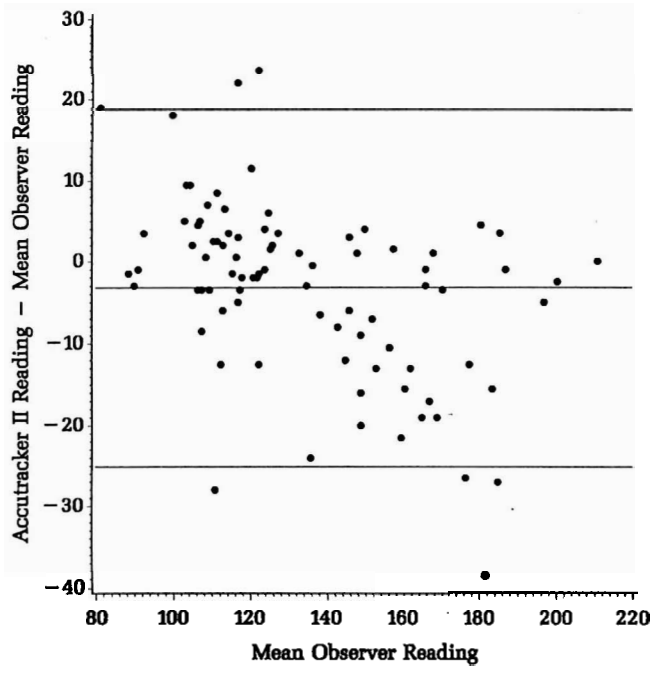


Figure 1. Plots of the mean pressure of the two observers' measurements with a Hawksley sphygmomanometer versus the difference between them in 85 subjects for systolic (a) *and diastolic pressure* (b).



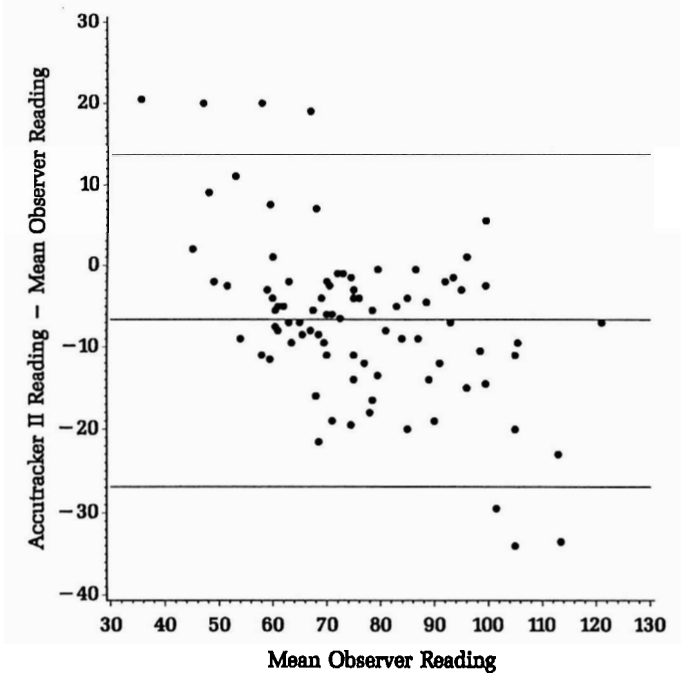


Figure 2. *Plots of the mean pressure of the two observers' measurements with a Hawksley sphygmomanometer versus the difference between them in 85 subjects for systolic* (a) *and diastolic pressure* (b).

(Accutracker II) and 135 ± 29 mmHg (Hawksley) with a difference of −3 ± 11 mmHg. The corresponding diastolic blood pressure values were 69 ± 15 mmHg (Accutracker II) and 76 ± 17 mmHg (Hawksley) with a difference of −7 ± 10 mmHg. Fifty-five per cent of systolic and 33% of diastolic differences were within 5 mmHg. Seventy-one per cent of systolic and 64% of diastolic differences were within 10 mmHg (tables 1 and 2). In addition to the above analysis, we also used the method of Bland and Altman [7] to display the data (figures 1 and 2).

Discussion

In this study the Accutracker II ambulatory system was evaluated according to the American National Standard for Electronic or Automated Sphygmomanometers of the AAMI [2] which was modified by substituting a Hawksley random zero sphygmomanometer [6] for a standard mercury sphygmomanometer to reduce observer bias, and the results were plotted according to the recommendations of Bland and Altman [7] rather than as a conventional scatterplot as recommended in the Standard. The Accutracker II failed to satisfy the AAMI validation criteria, the mean difference for systolic pressure being −3 ± 11 mmHg and for diastolic pressure −7 ± 10 mmHg, which is outside the criteria of 5 ± 8 mmHg set down in the Standard [2].

The results of previous validation studies of the Accutracker ambulatory device have been difficult to assess, if for no reason other than the surprising lack of information as to which model the validation study is assessing [8–13]. It may be assumed that where the model being validated is not clearly denoted by a number [8–13] it is the earlier product—the Accutracker I. When a new model of an existing ambulatory system is introduced a complete validation must be performed on the new system, and assumptions of accuracy (or inaccuracy) should not be made for a new device on the basis that the detecting or recording mechanism remains unchanged [14]. There is now a further model of the Accutracker with a quieter motor [4], and it is to be hoped that this device will be clearly identified by the manufacturers as being different, so that the validation studies for each successive model may be attributed correctly. In a validation study by Jyothinagaram *et al.* [13] not only is the model not identified, but serious errors are made in the conclusions to the study. The AAMI criteria for accuracy [2] are attributed incorrectly to the draft recommendations of the British Hypertension Society [14] which, in fact, utilizes a different and more stringent approach to validation. Despite the Accutracker failing the AAMI criteria for systolic pressure (mean 4.7, standard deviation ± 10.3), it is stated in the summary that the accuracy criteria of the British Hypertension Society [14] have been satisfied, and by implication that the Accutracker is acceptable for clinical use according to these standards, which clearly would not have been the case.

Only two validation studies can be clearly identified as having been performed on the Accutracker II [3, 4], and as each used a different methodology and analysis to the AAMI Standard [2], meaningful comparison with our study is not possible. This emphasizes the need for a standardized approach to validation procedures for ambulatory blood pressure recording systems [1].

We conclude that the Accutracker II, having failed to fulfil the AAMI criteria, cannot be recommended for ambulatory measurement of blood pressure.

Acknowledgements

Grants from the Charitable Infirmary Trust and the Royal College of Surgeons Research Fund are acknowledged with gratitude.

References

1. O'Brien, E., O'Malley, K. and Sheridan, J. (1989) The need for a standardized protocol for validating non-invasive blood pressure measuring devices. *Journal of Hypertension*, 7 (Suppl. 3), S19–S20.
2. *American National Standard for Electronic or Automated Sphygmomanometers* (1987) Association for the Advancement of Medical Instrumentation, USA.
3. White, W. B., Lund-Johansen, P. and Omvik, P. (1989) Comparison of three noninvasive ambulatory blood pressure monitors with intra-arterial blood pressure during rest and exercise. *Journal of Hypertension*, 7, (Suppl. 6), S404–S405.
4. White, W. B., Lund-Johansen, P., McCabe, E. J. and Omvik, P. (1989) Clinical evaluation of the Accutracker II ambulatory blood pressure monitor: assessment of performance in two countries and comparison with sphygmomanometry and intra-arterial blood pressure at rest and during exercise. *Journal of Hypertension*, 7, 967–975.
5. Petrie, J. C., O'Brien, E. T., Littler, W. A. and de Swiet, M. (1986) Recommendations on blood pressure measurement: British Hypertension Society. *British Medical Journal*, 293, 611–615.
6. Wright, B. M. and Dore, C. F. (1970) A random-zero sphygmomanometer. *Lancet*, i, 337–338.
7. Bland, J. M. and Altman, D. G. (1986) Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*, i, 307–310.
8. White, W. B., Schulman, P., McCabe, E. J. and Nardone, M. B. (1987) Clinical validation of the Accutracker, a novel ambulatory blood pressure monitor using R-wave gating for Korotkoff sounds. *Journal of Clinical Hypertension*, 3, 500–509.
9. Nelson, K. S., Weber, R. R., Elliott, W. J., Zebrauskas, D. and Murphy, M. B. (1988) Evaluation of the Suntech Accutracker: a novel noninvasive ambulatory blood pressure monitor. *American Journal of Hypertension*, 1, 121S–123S.
10. Torre, L. B., Rouse, I. L. and Beilin, L. J. (1989) Reproducibility of 24-hour non-invasive ambulatory blood-pressure monitoring using the Suntech Accutracker. *Clinical and Experimental Physiology*, 16, 247–251.
11. Baig, M. W., Wilson, J., Wade, G., Lonsdale, D. and Perrins, E. J. (1989) Clinical evaluation of the Accutracker ambulatory blood-pressure monitoring system. *Journal of Ambulatory Monitoring*, 2, 175–182.
12. Philips, D. I. W., Braithwaite, J., Newcombe, R. G. and Lazarus, J. H. (1989) A clinical evaluation of the Accutracker—a lightweight ambulatory blood pressure monitor. *Journal of Ambulatory Monitoring*, 3, 463–465.
13. Jyothinagaram, S. G., Watson D. and Padfield P. L. (1990) Suntech Accutracker ambulatory blood pressure monitor—clinical validation. *Journal of Ambulatory Monitoring*, 3, 63–67.
14. O'Brien, E., Petrie, J., Littler, W., deSwiet, M., Padfield, P.L., O'Malley, K., Jamieson, M., Altman, D., Bland, M. and Atkins, N. (1990) The British Hypertension Society Protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *Journal of Hypertension*, 8, 607–619.