Accuracy and Reliability of the Del Mar Avionics Pressurometer III

Desmond Fitzgerald*, Denis O'Donnell, Margaret Brennan, Kevin O'Malley and Eoin O'Brien

We assessed the accuracy and reliability of the Avionics pressurometer, a fully automated ambulatory blood pressure recorder. Accuracy was assessed in 96 patients against the Hawksley random-zero sphygmomanometer. Two recordings were made with each device in a random sequence. No mean difference was found between methods. However, there was a marked variation in the difference between Avionics and Hawksley recordings. This was not due to variability in blood pressure alone since the agreement between Avionics and pressurometer systolic recordings ($r = 0.88$) was less than the agreement between sequential systolic blood pressure measurements with the Hawksley ($r = 0.976$, $P < 0.001$). In addition, a small degree of inter-device variability was demonstrated between three Avionics recorders, one device giving higher readings. Reliability was assessed in 30 patients during normal daily activities and compared with the Remler M2000. The rate of markedly artefactual recordings was higher with the Avionics. Thus, variability in Avionics recordings makes this device unreliable.

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Introduction

Ambulatory blood pressure is a better predictor of morbidity and mortality [1] and of the response to antihypertensive therapy [2] than clinic blood pressure. These data are based on the Remler M2000, a non-invasive patient-activated portable blood pressure recorder [3]. A major disadvantage of the Remler is that decoding of the data is labour-intensive and requires observer interpretation of the systolic and diastolic end-points. A fully automated ambulatory blood pressure recorder has the advantage of providing full 24-h recordings, automated interpretation of blood pressure end-points and the ability to interface with microcomputers for data analysis. We have studied the accuracy and reliability of one such device, the Avionics Pressurometer III, which records blood pressure by relating Korotkoff sounds to cuff pressure.

Methods and results

Inter-device variability

Inter-device variability of three Avionics recorders was assessed as previously described [3]. Briefly, multiple recordings were made with each device in each of 12 patients, simultaneous Avionics recording being made in different arms with both cuffs interconnected. Avionics recordings were also compared with blood pressures recorded simultaneously in the same arm with the Hawksley random-zero sphygmomanometer. This protocol reduces and controls for the effect of blood pressure variability on inter-device variability. The experiment was performed in the test mode (normal deflation) and in the automated mode (stepwise deflation) of the Avionics. In the automated mode, stepwise deflation prevented simultaneous Hawksley recordings, so the Avionics automated recordings were compared with sequential

From the Blood Pressure Clinic, The Charitable Infirmary, Jervis Street, Dublin and the Blood Pressure Measurement Laboratory and Department of Clinical Pharmacology, the Royal College of Surgeons in Ireland, St Stephen's Green, Dublin 2, Eire. *Present address: Department of Cardiology, Vanderbilt University, Nashville, Tennessee 37232, USA.

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Requests for reprints to: Dr Eoin O'Brien, The Charitable Infirmary, Jervis Street, Dublin 2, Ireland. Correspondence to: Dr Desmond Fitzgerald, Division of Clinical Pharmacology, Vanderbilt University, Nashville, Tennessee 37232, USA.

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Hawksley recordings. Avionics test mode recordings overestimated Hawksley systolic (154 ± 2.5 versus 151 ± 3.2 mmHg, mean ± s.e.m., $P < 0.001$) and diastolic blood pressures (96 ± 2.1 versus 93 ± 1.8 mmHg, $P < 0.001$). In the automated mode, the Avionics overestimated diastolic (97 ± 1.8 versus 93 ± 1.7 mmHg, $P < 0.001$) but not systolic blood pressure. One device tended to overestimate systolic and diastolic blood pressure by 3 mmHg when compared with the other two recorders; this could not be attributed to transducer drift. A total of 18 recordings failed, nine because of failure of the Avionics to recognize an auscultatory gap.

Accuracy

The accuracy of the Avionics operated in the automated mode was assessed against the Hawksley random-zero sphygmomanometer in 96 patients with a wide range of blood pressures. Two Hawksley and two Avionics recordings were made sequentially in each subject by the same observer, the order of recordings being randomized. The data were analysed by two-way analysis of variance and by covariant analysis (Table 1). Although there was no mean difference between Avionics and Hawksley recordings, this reflected a wide variation in the difference between methods. This was not due to variability in patient blood pressure alone, since the correlation between Avionics and Hawksley sphygmomanometer systolic blood pressure recordings was significantly less than between sequential Hawksley recordings ($r = 0.976$ versus 0.88, $P < 0.001$). Therefore, although Avionics and Hawksley recordings were significantly correlated, this correlation was less than would be expected for sequential blood pressure measurement.

Reliability and patient acceptability

Reliability of the Avionics pressurometer was compared with the Remler M2000 in 30 patients during ambulation. Ambulatory recordings were performed in each patient at 30-min intervals on separate days with each device, the order of recorder being randomized. In two patients the Avionics pressurometer failed to record any blood pressure during ambulation. The Avionics recorded blood pressure more frequently (47.5 ± 1.7 versus 25 ± 0.64 recordings/day), because it records blood pressure during sleep. The Avionics automatically rejects recordings in which the systolic blood pressure is greater than 245 mmHg, or is less than 20 mmHg or less than the diastolic blood pressure, or where pulse pressure is less than 10% of diastolic. Using these criteria, the Avionics rejected 4.4 ± 0.71% of daily recordings. A further 1.2 ± 0.29% recordings in which systolic blood pressure was less than 40 mmHg were rejected as being artefactual. In comparison, only 1.4 ± 0.6% of Remler recordings were rejected. In addition, the Avionics failed to record heart rate in nine subjects and in the remainder over 50% of heart rate recordings were obviously artefactual (<40 or >160 beats/min).

In 30% of cases, patients reported that they had to restrict their activity while wearing the Avionics, whereas no restriction resulted from use of the Remler. However, patients found the automation useful, 45% reporting that they would prefer the Avionics if ambulatory recording was to be repeated.

Discussion

Ambulatory blood pressure measurement may be useful in assessing mortality and morbidity [1] but it is highly dependent on the quality of the data. Thus, ambulatory recorders must be accurate and reliable. The Avionics pressurometer recordings did not differ on average when compared with the Hawksley random-zero sphygmomanometer. However, there was a wide variation in the differences between methods. The

Table 1. Comparison of sequential Hawksley (H1 and H2) and pressurometer (P1 and P2) recordings.

	H1	H2		P1	P2
No. of recordings	96	96		96	96
Systolic blood pressure					
Mean ± s.e.m.	144.9 ± 3.1	144.6 ± 3.1		144.9 ± 3.8	145 ± 3.9
	r = 0.976			r = 0.969	
Correlation H1 versus P1			r = 0.88		
Mean difference ± s.e.m			0.02 ± 0.78		
			(range −14 to +41)		
Diastolic blood pressure					
Mean ± s.e.m.	87.7 ± 1.6	84.6 ± 1.4		86.5 ± 1.6	87.4 ± 1.9
	r = 0.889			r = 0.81	
Correlation H1 versus P1			r = 0.854		
Mean difference ± s.e.m.			1.2 ± 0.96		
			(range −47 to +20)		

variability between Avionics and Hawksley recordings was not due to variation in blood pressure alone since it exceeded the variability between sequential blood pressure measurements with the Hawksley sphygmomanometer. In addition, some variability was noted between the three recorders tested, which could not be attributed to transducer drift.

Despite the extreme criteria on which automated data rejection by the Avionics is based, 5% of Avionics blood pressure recordings fell within these limits. Together with the high percentage of artefactual heart rate recordings, this casts considerable doubt on the validity of the remaining recordings. Thus, despite the advantages of automated assessment of the systolic and diastolic end-points, a major disadvantage is that the actual recording cannot be assessed for artefact. In contrast, the Remler records all the data during blood pressure measurement and displays the Korotkoff sounds and cuff pressure. In addition, the Korotkoff sounds can be auscultated. Such a system allows recognition of the systolic and diastolic end-points based on clinically proven methodology and easy artefact rejection. Poor reliability of Avionics recordings is further evidenced by the poor relationship between ambulatory blood pressure recorded by the Avionics and the end organ disease [4]. In comparison, ambulatory blood pressure measurement with the Remler is a better predictor of morbidity and mortality than clinic blood pressure measurement [1].

In conclusion, Avionics pressurometer recordings vary widely compared with the standard cuff method, and ambulatory blood pressure measurements with this device are unreliable. Thus, the Avionics pressurometer cannot be recommended for ambulatory blood pressure measurement.

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