AMBULATORY BLOOD PRESSURE MONITORING EVALUATION OF A SEMI-AUTOMATED DEVICE

Pages with reference to book, From 241 To 243

Khalid M. Raja, Martin T. Rothman, Zulfiqar M.A. Khan, Ashur Khan (Cardiac Department AFIC/NIFID, Rawalpindi, The London Hospital Whitechapel, London.)

ABSTRACT

The accuracy of a semi-automated ambulatory blood pressure monitoring device (the lnstrumedix Personal Blood Pressure Transmitter') was assessed in 36 patients undergoing diagnostic cardiac catheterisation. Blood pressure readings measured by the device and by a standard manual sphygmomanometer were compared with simultaneous intra-aortic pressure measured directly via the catheter. No measurement size trends were identified for either of the two comparisons. Compared to direct intra-aortic pressure measurement, the manual sphygmomanometer gave lower systolic ($p < 0.05$), and higher diastolic readings ($p < 0.01$), while the semi-automated device gave slightly higher readings for both systolic (not significant: $p > 0.05$) and diastolic ($p > 0.05$) pressure. In this assessment the semi-automated device provided at least as accurate a reflection of intra-aortic pressure as did standard manual sphygmomanometry. This device is an accurate tool for the ambulatory assessment of blood pressure where adequacy of treatment or correctness of the diagnosis is in question(JPMA 41: 241, 1991).

INTRODUCTION

Large scale prospective epidemiological studies have shown that high blood pressure is a major independent risk factor for adult cardiovascular and renal disease[1,2] and anti-hypertensive treatment has been shown to reduce both morbidity and mortality[3-5]. Long-term anti-hypertensive therapy, however, carries an inherent risk[6], and lowering the blood pressure excessively may itself be harmful particularly in the presence of coronary disease[7]. Attaching the label "hypertensive" to an individual carries further serious implications: in addition to psychological effects, employment prospects and life insurance prospects may be affected[8]. Several studies have found ambulatory blood pressure measurement to give lower readings than repeated clinic measurements (the "white coat" syndrome) [9,10], and a better assessment of prognosis in hypertension[11,12]. A large number of semi-automated and fully automated ambulatory blood pressure measuring devices have been introduced, but these instruments may be insufficiently validated, and some are frankly inaccurate[13]. The aim of the present study was to evaluate the accuracy and validity of one semi-automated sphygmomanometer, the "Personal Blood Pressure Transmitter" (Instrumedix Inc., Seattle, USA). Using this device the blood pressure recording may be stored in a long-term memory, the values revealed to or concealed from the patient, and subsequently transmitted over the telephone system from the patient's home to a hospital-based computer analysis system (Instrumedix Inc.).

METHODS

Description of Device

The "Personal Blood Pressure Transmitter" is a portable battery- powered, semi-automated device, which measures blood pressure by sphygmomanometry, and will store and subsequently transmit the

readings using an integrated telephone modem. Zero calibration is performed automatically by the instrument each time the power is switched on, and the device is programmable for patient identity, minimum sphygmomanometer cuff pressure, and a variety of display options. A graphic display instructs the patient about the measurement procedure during which a cuff is inflated to occlude the brachial artery and then allowed to deflate automatically. The machine assesses the pressure waveform, and records its characteristics. Korotkov sounds are continuously monitored, and systolic pressure (Korotkov I), and diastolic pressure (Korotkov V) are recorded. The heart rate is calculated by averaging the Korotkov sounds, and blood pressure and heart rate may then be displayed digitally, unless the device has been programmed to conceal data from the patient. More than two hundred separate sets of blood pressure and heart rate readings can be retained in the unit's memory. The data can be transmitted through an integral modem alto a distant, IBM- compatible computer system, it may be displayed and the results printed.

Study design

Blood pressure measurements were obtained using the device at the time of intra-aortic pressure measurement in patients undergoing routine diagnostic cardiac catheterisation. At the end of the diagnostic part of the procedure, after direct calibration of the physiological measurement system, the intra-aortic pressure was measured with the catheter tip positioned in the descending aorta, using a Hewlett Packard pressure transducer (1290A) and amplifier (8804D). Intra-aortic pressure was calculated as the mean of ten corisecutive waveforms. In each patient a second pair of blood pressure measurements was recorded by a single blinded observer using a mercury sphygmomanometer and a standard stethoscope, again using Korotkov phase I and V sounds respectively for the systolic and diastolic readings.

Data sample characteristics

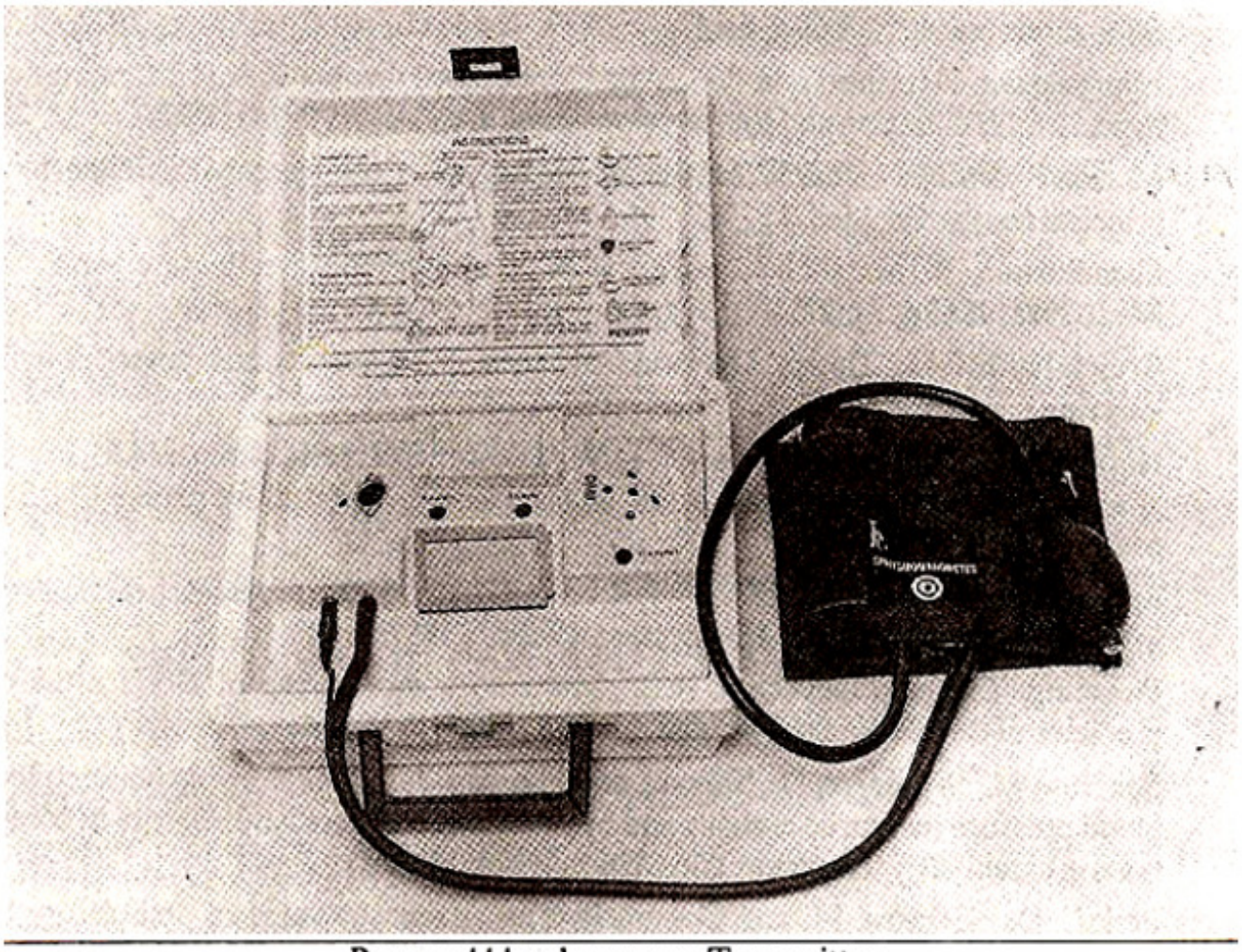
The study population consisted of 36 patients (27 male) aged 31 to 76 years (mean 55 years) undergoing diagnostic cardiac catheterisation. A total of 72 paired blood pressure readings were made: 36 pairs of intra-aortic versus the semi-automated blood pressure device; and 36 pairs of intra-aortic versus manual sphygmomanometry.

STATISTICAL METHODS

Systolic and diastolic blood pressures measured by manual and semi-automated sphygmomanometry were compared with simultaneously recorded intra-aortic pressures. In order to assess the magnitude of disagreement, and to identify outliers (shown as empty circles in Figure 1), the difference between the pressures obtained by each method were plotted against the mean blood pressures of the methods under comparison (Figures 1 a to id). This method also excludes trends, if the between method differences and the size of the measurements are shown to be independent. Paired t-tests were used to compare the method results.

RESULTS

A plot of residuals for systolic pressure comparing manual sphygmomanometer with intra-aortic pressure readings (Figure la)



Personal blood pressure Transmitter.

showed no measurement size trends (correlation coefficient, r = - 0.247, p = 0.15), but the manual sphygmomanometer gave significantly lower readings ($p < 0.01$). A similar plot comparing the semi-automated device with intra-aortic readings for systolic pressure (Figure 1b)

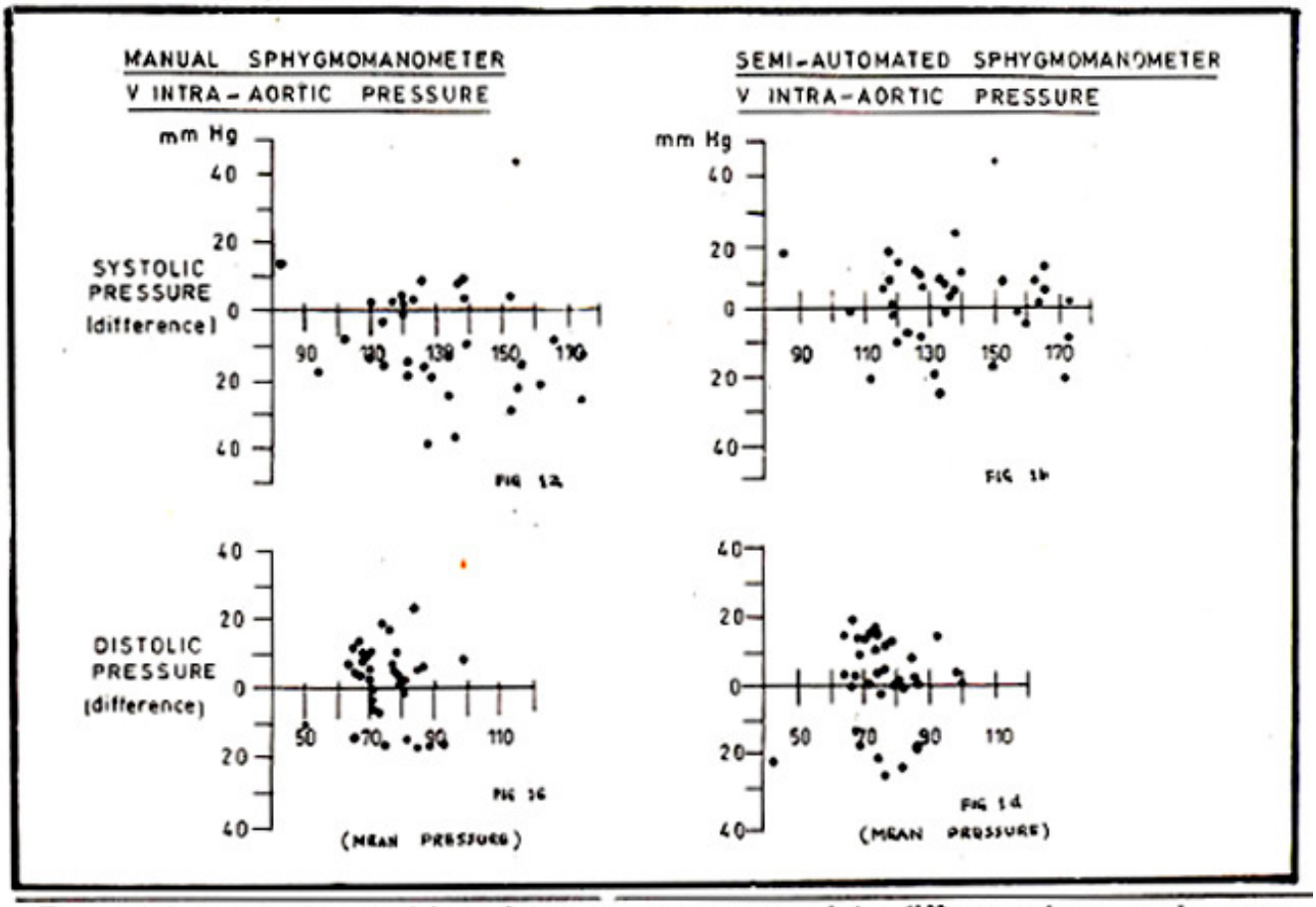


Figure 1 (a,b,,c,d). Comparision of the mean pressure and the difference between the pressures measured by each of the two methods. Sphygmomanometric pressure (manual or semi-automated) versus direct intra-aortic pressure.

also showed no trends (r= -0.163, p = 0.35). In this case the semi-automated device gave slightly, but not significantly, higher readings than intra-aortic measurement. Plots of residuals for both sets of diastolic blood pressure measurements showed that both manual (Figure ic) and semi- automated sphygmomanometer readings (Figure 1d) were also independent of the magnitude of the reading, when compared with simultaneously recorded intra-aortic diastolic pressures (r=- 0.072, p=0.68 and r=- 0.010, p=0.95 respectively). For diastolic pressures, both the manual sphygmomanometer and the semi-automated device gave higher readings than the corresponding direct intra-aortic measurement, the differences both reaching significance (p>0.01 and p <0.05 respectively). The outliers identified (shown as empty circles in Figures 1 a-d) measurements from two patients, each of whom had aortic regurgitation. In each case, both manual and semi-automated sphygmomanometry gave a wider pulse pressure (higher systolic and/or lower diastolic pressure) than that obtained from direct intra-aortic measurement. The mean differences between blood pressure measurements by the different methods and their associated 95% confidence intervals are summarised in Table.

	MANUAL V. INTRA AORTIC	SEMI AUTOMATED V. INTRA AORTIC
SYSTOLIC PRESSURE difference (mm Hg)	−5.2** (−1.8 → −8.6)	+2.5 (−0.4 → 5.4)
DISTOLIC PRESSURE difference (mm Hg)	+3.4** (1.4 → 5.8)	+3.4* (0.4 → 6.4)

** $P < 0.01$
* $P < 0.05$

Table. Mean difference between blood pressure measurements along with their 95% confidence intervals.

DISCUSSION

Previous studies have shown that indirect methods of measuring blood pressure may be inaccurate when compared with simultaneous intra-aortic pressure recordings, whether using standard manual sphygmomanometry[14] or automated and semi-automated devices[15]. It is a general observation that intra aortic pressure readings are slightly higher than the peripheral arterial pressure measured with manual sphygmomanometer. In this study systolic sphygmomanometry as expected but slightly higher when measured with this particular device as compared to the intra-aortic systolic pressure readings. However, this was not statistically significant. The measurement of diastolic blood pressure both with manual sphygmomanometry and with this semi automated device were equally high as compared to intra-aortic readings, both reaching the statistical significance. At present the epidemiological studies of hypertension and prognosis relates to the blood pressure measurements and reading obtained with manual sphyg. momanometery. In the light of slightly higher systolic blood pressure readings obtained by this device, the possibility of labelling slightly more people as hypertensive (systolic) should be kept in mind. In our own setting how much this device is going to be of use is a difficult question. Obviously the device needs a lot of patient education and hospital support. However, at present it can be used as a research tool and in the management of difficult hypertensives in the specialised centres. This device is portable, convenient to use and was free from mechanical and electronic problems for the duration of the study. Accurate semi-automated sphygmomanometer is probably the best means of assessing ambulatory blood pressure for both the patient and the doctor. The measuring procedure and the recording of multiple readings is simplified and importantly, observer's bias is also removed. More

widespread use of suitably validated devices is likely to reduce significantly the current tendency towards over diagnosis and overtreatment in hypertension[16,17].

REFERENCES

1. Gordon, T. and Kannel, W.B. Predisposition to atherosclerosis in the head, heart, and legs. JAMA., 1972'221:661.
2. Kannel, W.B., Woft, P.A., McGe, D.L, Dewber, T.R., McNamara, P. and Caatel ii, W.P. Systolic blood pressure, arterial rigidity, and the risk of stroke. JAMA., 1981;245: 1225.
3. Veteran Administration Cooperative StudyGroup on Antihypertensive Agents. Effects of treatment on morbidity in hypertension. Ill. Influence of age, diastolic pressure, and prior cardiovascular disease; furtheranalysis ofside effects. Circulation, 1972; 45:991.
4. Hypertension Detection and Follow-up Cooperative Group. Five year findings of the hypertension detection and follow-up program. JAMA., 1979; 242:2562.
5. Medical Research Council Working Party. MRC trial oftreatmentofmildhypertension; principal results. Br. Med. J., 1985; 291:97.
6. Flamenbaum, W. Metabolic consequences Of antihypertensive therapy. Ann. Intern. Med., 1983; 98(5 pt.2): 875.
7. Cruickahank, J.M., Thorp, 3M. and Zacharias, F.J. Benefits and potential harm of lowering high blood pressure. Lancet, 1987; 1:581.
8. Haynes, RB., Sackett, DL, Taylor, D.W., Gibson, E.S. and Johnson, AL. Increased absenteeism from work after detection and labellingof hypertensive patients. N. Engl. J. Med., 1978; 299:741.
9. Kenny, R.A., Brennan, M., 0' Malley, K. and O'Brien, E. Blood pressure measurements in borderline hypertension. 3. Hypertens. (Suppl), 1987; 5:483.
10. Pickering, T.G. and Devereux, RB. Ambulatory monitoring of blood pressure as predictorof cardiovascular risk. Am. Heart J., 1987; 114 (4 Pt.2): 925.
11. Sokolow, M., Werdegar, D., Kain, H. and Hinman, AT. Relationship between level of blood pressure measured casually and by portable recorders, and severity of complica. tions in easential hypertension. Circulation, 1966; 34:279.
12. Perloff, D., Sokolow, M. and Cowan, R. The prognostic value of ambulatory blood pressure. JAMA., 1983; 249: 2792.
13. Sleight, P. Ambulatory blood pressure monitoring (editorial). Hypertension, 1985; 7:163.
14. Gould, B.A., Kirso, HA, Hornung. R., Altman, D.G., Cashman, P.M. and Raftery, E.B. Assessment of accuracy and role of self- recorded blood pressures in the management of hypertension. Br. Med.J., 1982; 285:1691.
15. Hynyor, SN., Flynn, .LM. and Cocchineas, C. Compariaion of performance of various spbygmomanometers with intra-arterial blood pressure readings. Br. Med. 3., 1978; 2:159.
16. O'Brien, E. and O' Malley, K. Overdiagnosing hypertension. Br. Med. J., 1988; 297:1211.
17. Beevers, DO. Overtreating hypertension. Br. Med. 3., 1988; 297: 1212.