Validation of automated oscillometric sphygmomanometer (HDBPM) for arterial pressure measurement during haemodialysis

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Abstract—*An HDBPM oscillometric sphygmomanometer used for the automatic measurement of arterial blood pressure is evaluated according to the ANSI/AAMI SP10-1992 standard. The accuracy of the HDBPM is ascertained by comparing it against the standard Riva-Rocci ascultatory method. Following the ascultatory method, two independent observers use the HDBPM devise to simultaneously measure the arterial blood pressure in 92 subjects of varying ages and having different blood pressures and arm sizes. High agreement is found when comparing the observers' pressure determinations (within 10 mmHg for 100% of observations). Correlation between the average of two ascultatory determinations and the HDBPM is high both for the systolic ($r = 0.98$) and diastolic ($r = 0.94$) pressures. The mean of the differences between the pressures measured by the observers and the HDBPM device are 0.2 mmHg (systolic) and -0.4 mmHg (diastolic). The percentages of readings within 10 mmHg between those taken by the observers and those taken by the HDBPM are 88% (systolic) and 97% (diastolic). These results largely satisfy current requirements.*

Keywords—*Blood pressure, Device accuracy, Monitoring, Artificial kidney, AAMI standard, BHS protocol*

Med. Biol. Eng. Comput., 2000, **38**, 98–101

1 Introduction

HAEMODIALYSIS IS known to have a large impact on cardiovascular functions and arterial blood pressure instability is still one of most important complications of haemodialysis (DRZEWIECKI, 1994). Blood ultrafiltration occurring in the course of treatment (~ 0.7 l/h) causes a significant reduction in the circulatory blood volume (10–15%). This transient state of hypovolemia is regarded as a serious stress for the cardiovascular system, and physiological mechanisms devoted to short-term regulation of cardiovascular functions may fail in their compensatory mission. In particular, acute hypotension affects patients with cardiovascular diseases or autonomic deficiency.

Arterial pressure monitoring during haemodialysis represents the standard manner of preventing acute hypotension or hypertensive events. Arterial pressure monitoring by automatic devices has gained acceptance in many clinical settings, especially in critical care units. In particular, modern artificial kidneys are equipped with fully automatic blood pressure monitors. Examples include the 2800 A*, Centrysystem® 3†, and INTEGRATM™‡. As an advantage, the integrated sphygmomanometer device includes automatic alarm advising that arterial blood pressure is exceeding preset limits, thus increasing nursing time for care of patients.

The accuracy of such automatic devices has a clear implication for the clinical management of the patient during the treatment, the most important of which is appropriate diagnosis and decision making. Blood pressure measurements are performed to assess how well the patient's blood pressure is being controlled during the haemodialysis-induced hypovolemia. In fact, automatic measurements could enable the artificial kidney to automatically operate corrective actions if necessary to maintain hemodynamic stability. The effectiveness of an unsupervised control system such as this, as well as the possibility of early detection of the hypotension events, strictly depends on the accuracy of the blood pressure device. It is therefore important to establish the accuracy of such automatic devices in order to allow their routine use based on reliability in the patient setting.

We have recently evaluated the performance of a novel automatic oscillometric sphygmomanometer in order to indicate the accuracy, reliability and consistency of measurements. In this paper, test protocol details, results and specific comments concerning this validation are presented.

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First received 19 July 1999 and in final form 30 September 1999

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2 Materials and methods

2.1 *HDBPM device description*

The Gambro-Dasco Blood Pressure Monitor (HDBPM) automatic sphygmomanometer is manufactured by Gambro-Dasco S.p.A. The HDBPM is an optional item of equipment specifically designed to be fully integrated in the artificial kidney INTEGRA™**. The HDBPM estimates the systolic and diastolic pressures by using the oscillometric method (DRZEWIECKI, 1994). The cuff deflation is continuous, similar to that which occurs in the manual Riva-Rocci procedure, with a deflation rate in the range 2–12 mmHg/s, depending on the detected heart rate. By adapting the deflation rate to the heart rate, the number of pressure pulses used to reconstruct the oscillation envelope curve remains fixed.

The HDBPM hardware consists of a PC board supporting all the electronics and electromechanical components (see Fig. 1). This board is normally plugged into the appropriate slot inside the artificial kidney INTEGRA™. For the present test, we removed the PC board from the artificial kidney and inserted it in a special container specifically provided for this study. The board interface was connected to the serial port of a personal computer. Measurement and data acquisition was controlled by dedicated software that includes the same code currently used by INTEGRA™††.

The safety of the device was in accordance with international standards CEI/IEC EN 60601-2-30:1995 (Particular standard for the safety of blood pressure monitoring equipment), EN 60601-1-4 (Collateral standard for the safety of programmable medical systems), EN 1060-1 and EN 1060-3 (Non-invasive sphigmomanometers–General and supplementary requirements).

2.2 *Test protocol*

The HDBPM was evaluated according to the ANSI/AAMI SP10-1992 standard developed by the Association for the Advancement of Medical Instrumentation (AAMI) and approved by the American National Standards Institute (ANSI). This standard establishes safety and performance requirements for electro-mechanical devices used with an occluding cuff for indirect measurement of arterial blood pressure. For our purposes, this standard acts as a guideline for test methods and specific requirements relating to ambulatory blood pressure monitors such as the HDBPM.

The classic Riva-Rocci auscultatory technique was used as the reference method to which the automatic oscillometric pressure measurements were compared. Three cuffs of different size were used: one for adults with arm circumference in the range 25–34 cm, one for children or adults with small arms (18–24 cm) and one for persons with large arms (35–47 cm). The reference manometer was a standard mercury manometer with ± 1.0 mmHg of maximum calibration error at test temperature. The standard reference manometer was plugged by a 'T' connection in the pressure line joining the automatic device to the cuff (see Fig. 2). Two coupled stethoscopes were used to provide simultaneous auscultation of the Korotkoff sounds to two distinct observers. It is worth noting that the simultaneous measurement of the ascultatory and oscillometric pressure was possible because the HDBPM uses continuous cuff deflation.

According to the standard recommendations, this experimental setup makes it possible to obtain simultaneous, same-arm, arterial blood pressure measurements using both the automatic oscillometric device and standard ascultatory equipment.

Two professional nurses were trained by a physician in how to measure uring arterial pressure, in accordance with the specifications of the American Heart Association and with the 'Recommendations for Human Blood Pressure Determination by Sphygmomanometers' (KIRKENDALL *et al.*, 1981). They were also informed about the aim of the test. The blood pressure values determined by the two observers simulataneously and under blind conditions were averaged to obtain ascultatory pressure data for comparison with automatic pressure measurements.

Preliminary training involving the taking of 33 measurements was performed. The congruency between results obtained by the two observers was verified against the entire data set at the end, after all determinations had been made.

92 subjects (52 male and 40 female) were recruited from a wide range of people of differing age (11% less than 20, 27% between 21 and 40, 12% between 41 and 60 and 10% older than 60) and arm size (14% less than 25 cm and 10% greater 35 cm). Four subjects affected by renal failure and undergoing chronic haemodialysis were also included.

For each subject, three consecutive determinations were performed over a period of 10 to 30 min to provide 276 (3×92) measurements for the statistical analysis.

**Gambro-Dasco S.p.A. Medolla, Italy

††Sw Rev 1.0

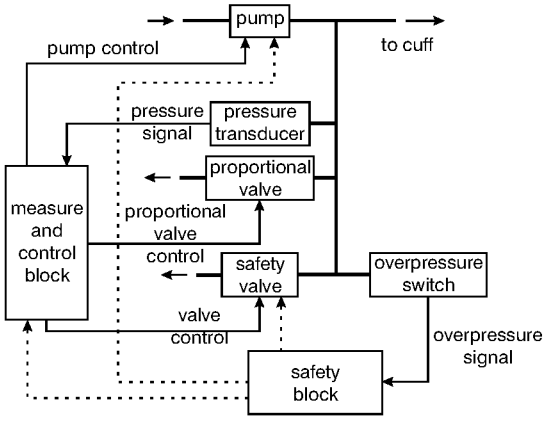

Fig. 1 *Schematic block diagram of HDBPM device*

3 Results

3.1 *Observer agreement*

Differences between the pressure determinations made simultaneously by the two observers were largely acceptable. The mean and standard deviation for the pressure differences were 0.01 ± 2.49 mmHg (systolic) and 0.00 ± 2.54 mmHg (diastolic). 100% of the determinations agreed to within 10 mmHg, while 95% were within 5 mmHg. Statistical testing (t-student) confirmed that these differences were of no significance.

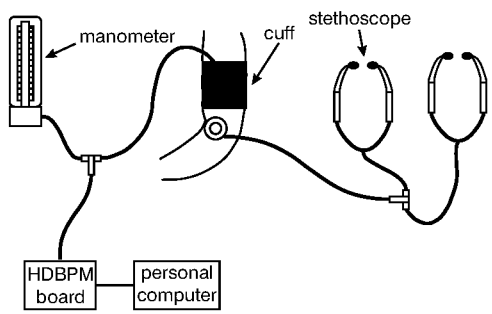

Fig. 2 *Experimental setup for simultaneous determination of ascultatory and oscillometric pressures*

3.2 *Pressure data set*

Based on the ascultatory determination, the systolic and diastolic pressures range respectively from 79 to 255 mmHg and from 48 and 128 mmHg. The systolic pressure was >180 mmHg in 9% of cases and <100 mmHg in 9% of cases. The diastolic pressure values were >100 mmHg in 5% of cases and <60 mmHg in 9% of cases. A total of 5% of the subjects were classified as hypertensive (systolic >180 mmHg and diastolic >100 mmHg) and 8% as hypotensive (systolic <100 mmHg and diastolic <60 mmHg).

3.3 *Ascultatory and HDBPM comparison*

High correlation ($r > 0.9$) was found when comparing the ascultatory and oscillometric systolic (Fig. 3) and diastolic (Fig. 4) pressures.

According to the BLAND and ALTMAN statistical method (ALTMAN and BLAND, 1986), the average pressure obtained using the ascultatory and HDBPM methods was considered a reasonable estimate of the unknown arterial pressure and was compared with the pressure differences between the ascultatory and HDBPM pressures (Fig. 5). The standard error was determined to be $-0.3\% \pm 5\%$ ($m \pm SD$) for the systolic and $0.4\% \pm 7\%$ for the diastolic pressure.

The mean and standard deviation of the differences between the ascultatory and HDBPM pressures were -0.2 ± 6.8 mmHg (systolic) and 0.4 ± 5.0 mmHg (diastolic). 88% of the differences in systolic and 97% of the differences in diastolic pressure were <10 mmHg (see Fig. 6).

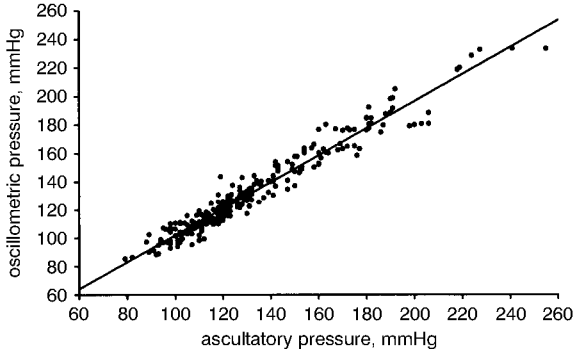

Fig. 3 *Ascultatory against oscillometric systolic pressure. Line was identified as most appropriate to pressure data. Correlation coefficient $r = 0.98$; line slope $= 0.95 \pm 0.01$; line offset $= 7.4 \pm 1.8$ mmHg*

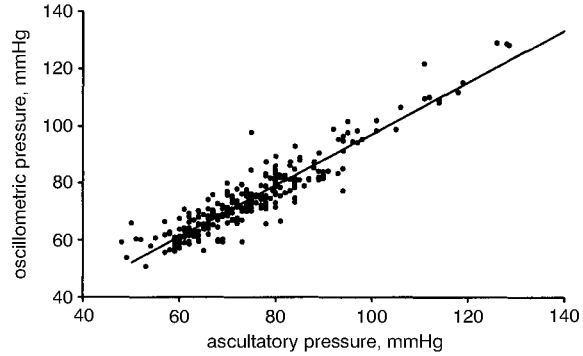

Fig. 4 *Ascultatory against oscillometric diastolic pressure. Line was identified as most appropriate to pressure data. Correlation coefficient $r = 0.94$; line slope $= 0.91 \pm 0.02$; line offset $= 6.8 \pm 1.6$ mmHg*

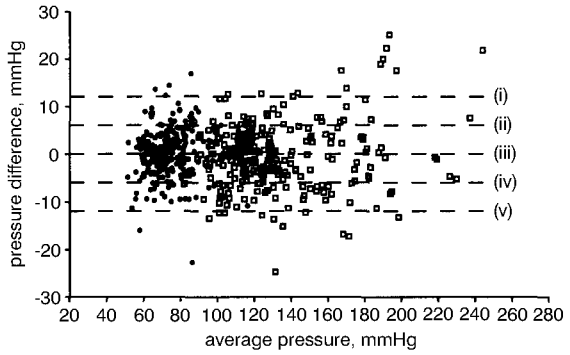

Fig. 5 *Bland-Altman scatter plot of differences between ascultatory and oscillometric pressure: (i) $m + 2$ SD; (ii) $m +$ SD; (iii) mean; (iv) $m -$ SD; (v) $m - 2$ sd; □ systolic pressure; ● diastolic pressure*

4 Concluding remarks

Oscillometry is a relative recent technique, which enables non-invasive automatic blood pressure measurements that are potentially accurate and particularly useful for clinical management of patients in critical care units (DRZEWIECKI, 1994).This technique has rapidly gained acceptance and its reliability appears to be at least as good as that of the ascultatory method. Today, most commercial automated sphygmomanometers are based on this technique and it can be considered a standard technique. However, authoritative scientific societies as well as committees for standardisation (ANSI, CEN) recommend that each new oscillometric-based device be validated before it is put into routine use.

This report describes the results of such validation for the HDBPM oscillometric device according to the ANSI/AAMI SP10-1992 standard, which prescribes the protocol for comparing a new device with the ascultatory method. The British Hypertension Society (BHS) has also published a detailed protocol that establishes a rather disciplined testing procedure for evaluating automated blood pressure measuring devices (O'BRIEN *et al.*, 1990; 1993). This protocol incorporates many features of the ANSI/AAMI standard but also importantly includes a test on the observer accuracy, test for interdevice variability, and recommends in-use validation (see O'BRIEN *et al.*, 1994, for a detailed comparison between the two protocols). The BHS also deals with the assessment of patient acceptability of device. This latter aspect is important for devices used for 24 hour ambulatory BP monitoring, for which it is important to assess if the device causes, for instance, discomfort or insomnia. For use during haemodialysis, these specific aspects were considered secondary and were not evaluated in the present study.

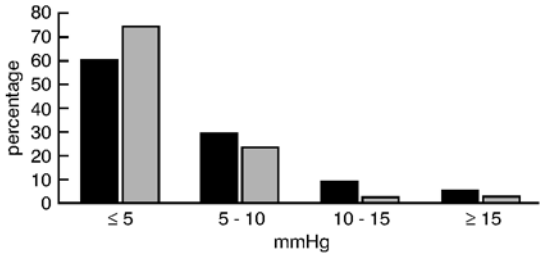

Fig. 6 *Distribution of absolute differences between ascultatory and HBPM determinations: ■ systolic pressure; □ diastolic pressure*

It is worth noting that the ANSI/AAMI protocol is not aimed at specifically clinical uses and does not address issues such as calibration or device variability or clinical performance during particular activities. By contrast, the BHS makes provision for special group validation. Since the device under validation is operative only when it is integrated in the artificial kidney, it could be intended as a device for a special patient population. We have not included subjects undergoing only chronic haemodialysis since there is no reason to deem the pressure measurement in these subjects significantly different from the standard case. It seems important to use foresight in subject selection when specific physical characteristics such as the arm size (e.g. for paediatric patients) or age or sex are involved.

Apart from these particular indications, the BHS protocol importantly suggests a grading quality criterion to express the accuracy of device. Of course, the use of this grading criterion requires the application of the entire BHS protocol. In particular–and this is a major difference–the BHS protocol (O'BRIEN *et al.*, 1990) prescribes that one of two trained observers record the three pressure measurements in half the population and that the second observer does likewise in the remaining subjects. We are aware that such a difference in the procedure could give a different grading, but for the sake of completeness, we have also expressed the accuracy according to the BHS criteria. On the basis of the results reported in Fig. 6, the HDBPM should be assessed as grade C for the systolic pressure and as grade B for the diastolic pressure.

The determination of blood pressure using the oscillometric method is prevalent in automated BP monitoring devices because automatic detection of Korotokoff sounds is apt to be affected by noise and to bring about measurement error. However, the ascultatory detection of Korotokoff sounds with a stethoscope is the standard method for measuring arterial pressure during haemodialysis and for this reason the ascultatory method was chosen as a reference for comparison with the HDBPM. In accordance with other comparative studies (KIRKENDALL *et al.*, 1981), oscillometric systolic pressure determination is less accurate than diastolic pressure determination when compared with the ascultatory method (see Fig. 6).

For the simultaneous measurement, a standard reference manometer was plugged by a 'T' connection in the pressure line. We used a manometer with a much lower compliance than the air system, including cuff and tubing lines; however, inserting the manometer alters the characteristics of the original system, which means it could affect the accuracy of the device, as reported in this note.

ANSI/AAMI SP10-1992 recommends that a realistic target for the difference between test device and reference method should be 5 ± 8 mmHg ($m \pm SD$). According to this, the HDBPM was found to be compliant with this standard. The very low values in the mean error (0.2 mmHg for systolic pressure, -0.4 mmHg for diastolic pressure) indicate close agreement between the ascultatory method and the HDBPM device, with no significant bias.

The best-fitting line for the ascultatory and HDBPM pressure data was found to have a slight offset (~ 7 mmHg) and a slope of less than one in both systolic (Fig. 3) and diastolic pressure (Fig. 4). This shows that the HDBPM tends to slightly overestimate low pressure and to underestimate high pressure with respect to the ascultatory method. This behaviour has been noted for other automatic oscillometric devices and can be considered an intrinsic characteristic of the method rather than being peculiar to this device (DRZEWIECKI, 1994)

About 90% of the differences between the ascultatory and HDBPM pressure were within 10 mmHg, which is comparable with the intrinsic variability of the ascultatory method as noted by comparing the differences in the pressure determinations of the two independent observers. It can therefore be concluded that the HDBPM provides automatic systolic and diastolic pressure measurements similar to those obtainable using the ascultatory method.

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