Nephrol Dial Transplant (2004) 19: 766–770 DOI: 10.1093/ndt/gfg602

Measuring blood pressure: pitfalls and recommendations

Ulrich Tholl¹, Klaus Forstner² and Manfred Anlauf¹

Keywords: anaeroid manometer; blood pressure; blood pressure measurement; clinical validation; mercury sphygmomanometer; oscillometric device; patient self-measurement

Introduction

Approximately 100 years have passed since the legendary development by the Italian Riva Rocci to measure blood pressure by an upper arm cuff with the mercury manometer and since the first description of sound phenomena above the brachial artery by the Russian Korotkoff during upper arm compression [1,2]. At present, this method has been established worldwide as the standard for non-invasive blood pressure measurement. However, new technical developments have resulted in a silent revolution of blood pressure monitoring in clinical and home use and have even been incorporated in important clinical studies [3,4]. The specific influence of the measurement method on reading accuracy has not, however, been sufficiently perceived and taken into account.

Methods of non-invasive blood pressure monitoring

There are manually operated and automatic devices. In manually operated instruments, blood pressure is measured by auscultation of Korotkoff's sound; automated instruments either record Korotkoff's sound via a microphone or (since about the 1980s) take measurements using the oscillometric principle of analysing pressure pulses in the cuff. From a technical point of view, an important factor, contributing to the measurement accuracy, represents the characteristics of different manometers. These are compared in Table 1.

Correspondence and offprint requests to: Ulrich Tholl, Zentralkrankenhaus Reinkenheide, Medical Clinic II, Bremerhaven, Germany. Email: ulrich.tholl@zkr.de

Table 1. Currently applied manometers in non-invasive blood pressure monitoring

- 1. Mechano-/mechanical pressure transducer
- a) Mercury ('shifting manometer')
- -High measurement accuracy
- -Simple baseline correction
- -Unwieldy design
- b) Aneroid
- -Devices highly sensitive to shocks
- -Frequent calibration and baseline shift required
- -Handy design, easy to transport
- c) 'Gear free' sphygmomanometer
- -Low shock susceptibility
- -Handy design
- 2. Mechano-/electrical pressure transducer
- (oscillometry and automated Korotkoff devices)
- a) Capacitance pressure transducer (plate condensors)
- -Accuracy more critical than piezoelectric pressure transformer
- -Age-dependent instability (ageing)
- -Larger component size
- -Generally lower component costs
- b) Piezoelectric pressure transformer
- -High accuracy
- -Age stability (ageing low)
- -Smaller component size
- -Generally higher component costs

Apart from ambulatory blood pressure measurement and monitoring of blood pressure in the intensive care unit, measurements of blood pressure in a clinical setting or general practice mainly involves manually operated devices. Automated instruments are the dominating tools for patient self-monitoring, mainly devices based on the oscillometric principle.

Is the mercury sphygmomanometer still 'the gold standard' of blood pressure monitoring?

It is undisputed that the mercury sphygmomanometer has the highest accuracy, with a high degree of technical agreement between devices of different producers [5]. This ensures worldwide comparability of values measured with this method. Specific advantages of mercury-based manometer devices are the simple technique and a simple baseline correction. Nevertheless, several studies

¹Zentralkrankenhaus Reinkenheide, Medical Clinic II, Bremerhaven, Germany and

²Forschungsinstitut für klinische Medizintechnik, Asperg, Germany

have reported on insufficient maintenance and calibration of mercury sphygmomanometers used in the clinical setting and in general practice. A check of the devices in a major teaching hospital showed that only 5% of the investigated instruments had been properly serviced [6] while an inspection in general practices of an English district found that only $\sim 30\%$ of the devices had been properly maintained [7]. Regular maintenance intervals are infrequently met [8]. Despite the relatively simple principle of the technique, instrument inspections disclosed defects in the manometers, cuffs and tubing systems of more than 50% of the mercury manometers in use [6]: the defects had an impact on the correctness of the readings. This means that sufficient measurement accuracy is ensured only by devices which undergo regular technical evaluation and calibration at least on a yearly basis.

Restrictions of the use of mercury in medical devices have already been imposed in the Netherlands and Sweden. This was felt to be necessary to avoid occupational health hazards and environmental contamination. This raises the question of whether mercury sphygmomanometers should still be used as standard devices for measuring blood pressure [5,9].

Are aneroid manometers a first-choice alternative?

Aneroid sphygmomanometers are the most commonly used alternative devices for measuring blood pressure in the clinical setting and in general practice. Instead of transferring pressure to a mercury column, they are designed to transfer the detected pressure via a mechanical system and an elastic expansion chamber to a gauge needle [10]. The devices are characterized by their handy design and even portability. The mechanism is, however, highly sensitive towards any mechanical strain. It can be easily damaged by any mechanical impact, mainly the result of accidental falls or pushes; accuracy can also decrease over time during clinical use. This may result in both calibration errors (which are often not immediately apparent) and baseline shifts. In addition, the technical design differs widely between models from different manufacturers. Dependent on the kind of application of these devices, instrument evaluation studies demonstrated technical defects or unacceptable measurement inaccuracy in up to 60% of the devices that had been evaluated [7,11,12]. Reading errors occur more frequently in the range of high blood pressure values where aneroid manometers tend to underestimate the blood pressure of the patient [13]. Portable instruments, in particular, show a higher technical failure rate [13]. In general practices the percentage of regularly serviced and recalibrated instruments is sometimes below 5% [7]. If, however, aneroid manometers receive regular technical maintenance, their measurement accuracy is identical to the standard mercury manometer devices. This has been tested for wall-mounted instruments [14]. Therefore, only devices which undergo a regular (half-) yearly technical inspection including recalibration,

ensure a reliable measurement accuracy. Under these circumstances they can be adopted as a potential alternative to mercury sphygmomanometers. However, as a result of the widespread lack of such checks, one must unfortunately assume that the percentage of erroneous measurements is high. In particular, this applies to devices in which the manometer is not cuff-integrated, since the latter can act as a 'shock protection'.

The new development of a mechanical gear free sphygmomanometer (Durashock, Welch-Allyn) apparently combines the advantage of a handy design with lesser susceptibility to shock and impact. The calibration stability is therefore higher than for aneroid manometers. This hypothesis has to be addressed in further clinical investigations.

Are oscillometric measurements reliable?

Oscillometric monitoring requires the recording of pressure pulses in the cuff which arise through volume pulses of the artery. The course of the pulse pressure curve is recorded as the so called 'pulse oscillogram'. By referring to the pulse amplitudes, an envelope curve is provided. The maximum of this oscillation envelope curve corresponds to the mean arterial pressure. Both systolic and diastolic blood pressures are determined from the shape of the envelope curve by means of a micro-computer [15–17]. The underlying algorithms are specific for the respective commercial instruments. They are well guarded secrets of the manufacturers [5]. Users generally will not be informed about changes in the use of algorithms. In addition to the algorithms and the quality of the electromechanical pressure transducer (Table 1), further errors can influence the measurement accuracy of oscillometric devices. The recording of the oscillation pattern significantly depends on the anatomical position, elasticity and size of the artery. In addition, the size, histo-anatomy and distribution of the surrounding tissue affects the accuracy. This is particularly true for the circumference of the measurement site. Basically, the device calibration depends on the application site (upper arm, wrist, finger) [18]. Changes of the vascular wall elasticity and arteriosclerotic vascular changes also affect the course and pattern of the pulse oscillogram. Finally, oscillations are also dependent on the size and material of the cuff and of pressure tube connections.

The impact of these physiological-anatomical and technical factors on the device-specific oscillometric measurement accuracy requires a critical review of the measurement accuracy by referring to an adequately sized patient sample. Unfortunately, such evaluation is not mandatory for all markets [19]. For example, according to the European standard (EN1060 1-3) [20–22] the CE (European Conformity Mark) identification does not include such a mandatory clinical evaluation of the measurement accuracy [23]; an omission, which is not commonly known by prescribing practitioners or users of the instruments. Therefore, only a small

proportion of automated devices on the market have been qualified by clinical evaluations according to generally accepted protocols of an independent institution or scientific society such as the British Hypertension Society (BHS) [24], the Deutsche Hochdruckliga [German Hypertension Society (test seal)] [25], the American Association for the Advancement of Medical Instrumentation (AAMI) [26] or according to the DIN58130 standard [27] (for a current review of the results of clinical device evaluation see: Deutsche Hochdruckliga: www.hochdruckliga.info) [28–31]. Due to the unsatisfactory number of sufficiently evaluated instruments, a proposal to simplify the evaluation procedure has been made by the ESH Working Group on Blood Pressure Monitoring [32]. Further efforts are currently under discussion to standardize the underlying clinical protocols imposing an obligatory regulation in order to carry out such evaluations (EN standard 1060, part 4). Successfully evaluated devices may not guarantee a specific monitoring accuracy for all kinds of users. Therefore, in addition to the general exclusion of patients suffering from frequent cardiac arrhythmia (in particular atrial fibrillation) a comparative monitoring including the standard Korotkoff method is urgently required to evaluate the individual monitoring accuracy of a device for each single user. Clinical evaluation studies demonstrate that the measurement accuracy in wrist type devices is significantly lower compared with upper arm monitoring devices [33]. The wrist-type device market-share in Germany is $\sim 60-80\%$ despite the fact that the evaluation according to the 'test seal protocol' (Deutsche Hochdruckliga) has only been passed by one of 13 tested wrist devices [30,34].

Significance of user handling and skill for the measurement accuracy

The quality of blood pressure monitoring does not only depend on possible limitations arising from technical aspects, but does more commonly also depend on the correct handling by the user. Guidelines on the correct methodology of blood pressure measurement, as published by various professional societies [35-37] are, however, often insufficiently followed. This is particularly true with respect to the need for a sufficient resting period prior to blood pressure measurements. A further prerequisite is the need to prevent disturbing external influences on patients during measurement (hustle and bustle, noise, talk). In wrist device measurements, the cuff is often not accurately positioned at the heart level. In manual measurements, the cuff pressure often is released too fast. It is recommended that the pressure in the cuff is decreased no faster than 3 mm mercury per second. Furthermore, often the appropriate size of the cuff is not selected or the results are invalidated by movement artefacts. Talking should be strictly avoided while the blood pressure is measured. The results displayed by the device should also not be rounded up or down towards expected values [10,38].

The benefits of patient self-monitoring in the diagnosis [39] and treatment of hypertension by means of automated oscillometric monitors has been amply documented. Valid measurements can be obtained by medically unskilled users. For that reason patient self-monitoring has been incorporated into clinical recommendations for treatment and diagnosis of hypertension [36,37,40]. Sufficient training of the user in the correct procedure of blood pressure measurement is, however, mandatory before treatment decisions can be based on the recorded data [35,41]. Instructions concerning correct data documentation are important in order to avoid incorrect conclusions about the effectiveness of a treatment. A study addressing the reliability of blood pressure values measured and recorded by patients demonstrated that on average 36% of the recorded data are not written up and documented [42]. Automatic device memory functions or telemetric data transfer from the devices to an analysing receiver module could optimize the patient data recording [43].

Perspectives in clinical and general practice blood pressure measurements

The necessity to overcome the mercury manometer based technology has led to the development of new devices which detect the cuff pressure with an electronic pressure transducer and subsequently display the pressure either in analogue format on an LED display (Accoson-Green light) or on a digital display [5,44]. Thus, blood pressure can be measured either by using the auscultation of Korotkoff's sounds and/or by adopting the oscillometric principle. After clinical validation of the algorithms and a survey of the user acceptance in day-to-day clinical practice, such devices may replace conventional mercury and aneroid manometers in the future.

Despite (and due to) the supposedly simple measuring technique, blood pressure monitoring requires more user attention to proper device technique and its frequent maintenance. The user should be trained in the technique of measurement and should adhere to published recommendations on the execution of the measurement. Only then will the quality of blood pressure monitoring be commensurate with the importance of hypertension as one of the most relevant health problems.

Conflict of interest statement. U. Tholl, K. Forstner and M. Anlauf are involved in validation tests of blood pressure measuring devices for independent institutions such as the German Hypertension Society, the 'Stiftung Warentest' and for different producers of devices.

References

 Riva-Rocci S. Un nuovo sifigmomanometro. Gazz Med Torino 1896; 47: 981–996

- 2. Korotkoff NS. On methods of studying blood pressure. Bull Imperial Mil Med Acad 1905; 11: 365–367
- Hansson L, Zanchetti A, Carruthers SG et al. Effects of intensive blood-pressure lowering and low dose aspirin in patients with hypertension: principle results of the Hypertension Optimal Treatment (HOT) randomised trail. HOT study group. Lancet 1998; 351: 1755–1762
- 4. Anlauf M, Tholl U, Hirche H, Weber F. A silent revolution in blood pressure measurement? Some late remarks in regards to the HOT study. *J Hum Hypertens* 2001; 15: 649–650
- Pickering TG. What will replace the mercury sphygmomanometer? Blood Press Monit 2003; 8: 23–25
- Markandu ND, Whitcher F, Arnold A, Carney C. The mercury sphygmomanometer should be abandoned before it is prescribed. J Hum Hypertens 2000; 14: 31–36
- Knight T, Leech F, Jones A, Walker L, Wickramasinghe R, Angris S, Rolfe P. Sphygmomanometers in use in general practice: an overlooked aspect of quality in patient care. *J Hum Hypertens* 2001; 15: 681–684
- Krass ME, La Barber LP, Torres MA. Blood pressure measurement in family physician offices. Family Med 1988; 20: 25–27
- 9. O'Brien E. Has conventional sphygmomanometry ended with the banning of mercury? *Blood Press Monit* 2002; 7: 37–40
- Beevers G, Lip GYH, O'Brien E. Blood pressure measurement. Part II—Conventional sphygmomanometry: technique of auscultatory blood pressure measurement. *Brit Med J* 2001; 322: 1043–1047
- Waugh JJS, Gupta M, Rushbrook J, Halligan A, Shennan H. Hidden errors of aneroid sphygmomanometers. *Blood Press Monit* 2002; 7: 309–312
- 12. Ashworth M, Gordon K, Baker G, Deshmukh A. Sphygmomanometer calibration: a survey of one inner-city primary care group. *J Hum Hypertens* 2001; 15: 259–262
- Bailey RH, Knaus VL, Bauer JH. Aneroid sphygmomanometers. An assessment of accuracy at a university hospital and clinics. *Arch Intern Med* 1991; 151: 1409–1412
- Canzanello VJ, Jensen PL, Schwartz GL. Are anaeroid sphygmomanometers accurate in hospital and clinic settings? Arch Intern Med 2001; 161: 729–731
- Yarows SA, Julius S, Pickering TG. Home blood pressure monitoring. Arch Intern Med 2000; 160: 1251–1257
- Young P, Geddes LA. A surrogate arm for evaluating the accuracy of instruments for indirect measurement of blood pressure. *Biomed Instrum Technol* 1990; 24: 130–135
- Forstner K. Fehler bei der Blutdruckmessung mit modernen Automaten; Fehlereinflüsse der noninvasiven oszillometrischen Blutdruckmessung. Fortschritte der Medizin 1999; 117: 22–25
- Wonka F, Seelig HD. Vergleichende Betrachtung der Blutdruckmessung am Oberarm und Handgelenk. In: Mieke S, ed. Nichtinvasiv Blutdruckmessgeräte—Messtechnische Prüfung von Medizinprodukten mit Messfunktion (3). Vol. PTB-MM-10. Physikalisch Technische Bundesanstalt, Braunschweig und Berlin, 1999: 52–71
- O'Brien E, Beevers G, Lip YH. Blood pressure measurement, part IV—automated sphygmomanometry: self blood pressure measurement. *Brit Med J* 2001; 322: 1167–1170
- European Committee for Standardisation. European Standard EN 1060-1. Specification for non invasive sphygmomanometers part 1. General Requirements. Brussels, 1995
- European Committee for Standardisation. European Standard EN 1060-2. Specification for non-invasive sphygmomanometers part 2. Supplementary requirements for mechanical sphygmomanometers. Brussels, 1995
- European Committee for Standardisation. European Standard EN 1060-3. Supplementary requirements for electro-mechanical blood pressure measuring systems. Brussels, 1997
- Mieke S, Eickelkamp U. Prüfung nichtinvasiver Blutdruckmeßgeräte nach DIN EN 1060. In: Mieke S, ed. Nichtinvasive Blutdruckmessgeräte—Messtechnische Prüfung von

- Medizinprodukten mit Messfunktion (3). Vol. PTB-MM-10. Physikalisch Technische Bundesanstalt, Braunschweig und Berlin, 1999: 41–51
- 24. O'Brien E, Petrie J, Littler WA *et al.* The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; 11 [Suppl 2]: S43–S63
- Tholl U, Anlauf M. Hochdruckliga schafft Gütesiegel für Blutdruckmessgeräte. MMW-Fortschritte der Medizin 1999; 42: 717
- Association for the Advancement of Medical Instrumentation.
 American National Standard. Electronic or Automated Sphygmomanometers. AAMI, Arlington, VA, 1993
- Deutsches Institut f
 ür Normung: Normenausschuß Feinmechanik und Optik. DIN-Norm 58130. Pforzheim, 1999
- Tholl U, Anlauf M. Das Gütesiegel der Hochdruckliga und andere Validierungsprotokolle von Blutdruckmeßgeräten. Nieren- und Hochdruckkrankheiten 1999; 28: 470–476
- O'Brien E, Waeber B, Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *Brit Med J* 2001; 322: 531–536
- 30. Tholl U, Anlauf M, Lichtblau U, Dammer R, Roggenbuck U, Hirche H. The 'Stamp of Quality' (Gütesiegel) protocol of the German League against Hypertension—a new validation protocol for blood pressure measuring devices and results of 28 device tests. *J Hypertens* 2003; 21 [Suppl 4]: 232–233
- 31. O'Brien E. State of the market in 2001 for blood pressure measuring devices. *Blood Press Monit* 2001; 6: 171–176
- 32. O'Brien E, Pickering T, Asmar R *et al.* Working group on blood pressure monitoring of the European Society of Hypertension international protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; 7: 3–17
- 33. Kikuya M, Chonan K, Imai Y, Goto E, Ishii M. Accuracy and reliability of wrist-cuff devices for self-measurement of blood pressure. *J Hypertens* 2002; 20: 629–638
- Tholl U, Anlauf M, Lichtblau U, Dammer R, Roggenbuck U, Hirche H. Oszillometrische Handgelenk-Blutdruckmessung; beeinflusst der Diabetes die Messgenauigkeit? *Diabetes und Stoffwechsel* 2003; 12 [Suppl 1]: 138–139
- 35. O'Brien E, Asmar R, Beilin L et al. on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. J Hypertens 2003; 21: 821–848
- 36. Deutsche Liga zur Bekämpfung des hohen Blutdruckes e.V. Leitlinien für die Prävention, Erkennung, Diagnostik und Therapie der arteriellen Hypertonie. Dtsch Med Wochenschr 2001; 126: S201–S238
- Chobanian AV, Bakris GL, Black HR et al. The seventh report of the Joint National Committee on prevention, detection, evaluation and treatment of high blood pressure. The JNC Report. J Am Med Assoc 2003; 289: 2560–2572
- 38. Tholl U. Praktische Durchführung der Blutdruckmessung. Fortschritte der Medizin 1999; 117: 26–31
- 39. Den Hond E, Celis H, Fagard R *et al.* on behalf of the THOP investigators. Self-measured versus ambulatory blood pressure in the diagnosis of hypertension. *J Hypertens* 2003; 21: 717–722
- 2003 European Society of Hypertension. European Society of Cardiology guidlines for the management of arterial hypertension. J Hypertens 2003; 21: 1011–1053
- 41. Mengden T, Chamontin B, Chau NGP, Gamiz JLP, Chanudet X. User procedure for self-measurement of blood pressure. *Blood Press Monit* 2000; 5: 111–129
- Mengden T, Medina RMH, Beltran B, Alvarez E, Kraft K, Vetter H. Reliability of reporting self-measured blood pressure values by hypertensive patients. Am J Hypertens 1998; 11: 1413–1417

- 43. Rogers M, Small D, Buchan DA *et al.* Home monitoring service improves mean arterial pressure in patients with essential hypertension. *Ann Intern Med* 2001; 134: 1024–1032
- 44. Wright JM, Mattu GS, Perry TL *et al.* Validation of a new algorithm for the BPM-100 electronic oscillometric office blood pressure monitor. *Blood Press Monit* 2001; 6: 161–165

Nephrol Dial Transplant (2004) 19: 770-773

DOI: 10.1093/ndt/gfh030

Renin-angiotensin system and atherosclerosis

Karsten Grote, Helmut Drexler and Bernhard Schieffer

Abteilung Kardiologie und Angiologie, Medizinische Hochschule Hannover, Hannover, Germany

Keywords: angiotensin II; AT_1 receptor; atherosclerosis; inflammation; renin–angiotensin system

Cardiovascular (CV) events remain the main cause of morbidity and mortality in industrialized societies. Atherosclerosis is a chronic inflammatory disease [1] initiated and perpetuated by a variety of CV risk factors such as smoking, diabetes mellitus, hypertension and elevated plasma low-density lipoprotein (LDL) [2]. Atherosclerotic plaques are conglomerates composed of dysfunctional endothelial cells, smooth muscle cells, lipid-laden macrophages and T lymphocytes. These lipid-laden activated macrophages and T-lymphocytes stimulate their neighbouring cells to erode the collagen and elastin framework which forms the plaque's cap [1–5]. Myocardial infarction, stroke or sudden cardiac death are the fatal end-points of progressive atherosclerosis and are thought to be the result of these pathological remodelling processes [2]. Recent studies have identified morphological characteristics likely to be associated with a plaque's tendency to rupture, underlining the possibility of using such hallmarks clinically to predict, control and monitor plaque evolution. From a mechanical point of view, the delicate balance of plaque stability is controlled, on the one hand, by the intrinsic properties of the tissue and, on the other hand, by the external forces to which the plaque is subjected, i.e. mechanical forces of the blood flow and local formation of vasoconstrictors, such as angiotensin II (ANGII). Based on these observations, an increase in lipid content and a decrease in collagen content have been long suspected to reduce the mechanical strength of the plaque. Rapid recruitment of inflammatory cells together with local tissue release of chemoattractant factors therefore is not only one of the hallmarks of the

Correspondence and offprint requests to: Bernhard Schieffer, MD, Abteilung Kardiologie und Angiologie, Medizinische Hochschule Hannover, Carl-Neuberg-Strasse 1, D-30625 Hannover, Germany. Email: Schieffer.Bernhard@MH-Hannover.de

atherosclerotic lesion but also at the origin of lesion formation. This process requires the concerted action of chemoattractants, cytokines and adhesion molecules. In this regard, the role of a hierarchical immunoinflammatory response initiated by mechanical stress and/or LDL-cholesterol stimulates a cascade of mechanisms involving receptors of the innate immunity, i.e. Toll-like-receptors as well as cytokines, chemokines and eicosanoids. Central to many of these pathophysiological processes is the renin–angiotensin system (RAS), specificically its effector peptide ANGII. Binding of ANGII to the angiotensin II type 1 (AT₁) receptor induces calcium-dependent vasoconstriction, leading to an increase in systemic and regional blood pressure [3]. The direct relationship between blood pressure and the incidence of CV events is well accepted. The increase in risk can be attributed to structual and functional changes in target organs. In addition, AT₁ receptor activation contributes independently to chronic CV disease by promoting vascular growth and proliferation, and endothelial dysfunction [4].

Here we focus on the impact of an activated RAS on atherogenetic plaque development and the therapeutic effects on atherosclerosis obtained by RAS inhibition.

Activation of the renin-angiotensin system in atherosclerosis

Activation of the RAS may exert numerous adverse effects on the CV system (i.e. arterial hypertension, chronic renal failure and, potentially, atherosclerosis). Traditionally, the RAS has been described as an endocrine system in which renin of renal origin acts on angiotensinogen (an acute phase protein) of hepatic origin to produce angiotensin I in the plasma, which in turn is converted by pulmonary endothelial angiotensin-converting enzyme (ACE) to ANGII [5]. The latter is considered to be the main mediator of