Adler, C., Ellert, U., Neuhauser, H.K.
Disagreement of the two oscillometric blood pressure measurement devices, Datascope Accutorr Plus and Omron HEM-705CP II, and bidirectional conversion of blood pressure values
(2014) Blood Pressure Monitoring, 19 (2), pp. 109-117.

DOI: 10.1097/MBP.0000000000000037

Disagreement of the two oscillometric blood pressure measurement devices Datascope Accutorr Plus and Omron HEM-705CP II and bidirectional conversion of blood pressure values

Running head: Comparison of two oscillometric devices and bidirectional conversion models

Carolin ADLER [a,b], Ute ELLERT [a], Hannelore K. NEUHAUSER [a, b]

[a] Robert Koch Institute, Department of Epidemiology and Health Monitoring, Berlin, Germany
[b] DZHK (German Center for Cardiovascular Research), partner site Berlin, Germany

Blood Press Monit. 2014 Apr;19(2):109-17
doi: 10.1097/MBP.0000000000000037

Conflicts of Interest and Source of Funding: The authors declare that they have no conflict of interest. The study has been financed by the Robert Koch Institute.

Author responsible for correspondence and requests for reprints:

Carolin Adler, M.Sc.
Robert Koch Institute
Department of Epidemiology and Health Monitoring
General-Pape-Str. 62-66
D-12101 Berlin
Germany
Tel. +49/30/187543439
Fax +49/30/18107543462
Email: AdlerC@rki.de

Word count: 3,653
Number of tables: 3
Number of figures: 2
Number of supplementary digital content files: 0

Abstract

Objective(s): Oscillometric blood pressure (BP) measurement devices frequently replace the standard mercury sphygmomanometer. Comparisons of oscillometric devices are rare, but their agreement is important to ensure comparability of BP data. This study aims to compare two oscillometric devices, Datascope Accutorr Plus and Omron HEM-705CP II and to develop BP conversion models.

Methods: A sample of 109 adults aged 21 to 64 years had alternate same-arm BP measurements according to the International Protocol revision 2010 for the validation of BP measuring devices in adults of the European Society of Hypertension.

Results: 327 BP measurement pairs were obtained. Datascope systolic BP (SBP) pairs in mmHg were optimal (<120) for n=188, prehypertensive (120-139) for n=107 and hypertensive (≥140) for n=32 (diastolic BP (DBP) <80 n=261/80-89 n=57/≥90 n=9). Mean Omron values were higher and the difference increased with BP (mean differences Omron minus Datascope within BP ranges were in mmHg: SBP 1.1 ± 4.7, 3.0 ± 5.5 and 9.3 ± 6.7; DBP: 0.2 ± 3.3, 2.3 ± 3.4 and 5.1 ± 3.9 mmHg) and pulse pressure (pulse pressure >50 mmHg SBP difference 5.6 ± 6.3). Prevalence of hypertensive BP with Omron was 11%, with Datascope 5%. Bidirectional conversion models of SBP and DBP values include BP, pulse pressure, age, sex and the difference in the ratio of cuff-width-to-arm-circumference.

Conclusions: The disagreement of oscillometric devices can reach a magnitude that could be of interest for clinical and epidemiological contexts. Conversion formulas with BP, pulse pressure, sex, age and the cuff-width-arm-circumference-ratio may help to improve comparability.

Keywords: oscillometry; blood pressure; hypertension; prevalence; measurement; validation

Introduction

Hypertension is a widespread risk factor for cardiovascular diseases and a major determinant of mortality and morbidity [1, 2]. Estimates of hypertension prevalence and incidence are important for decisions in health policy and prevention and therefore accurate blood pressure (BP) measurement is a prerequisite for many interventions.

During the past years the oscillometric BP measurement technique increasingly replaced the auscultatory mercury sphygmomanometry in epidemiological studies [3, 4] and has been used also in clinical trials and long-outcome studies [5-7]. Although the mercury sphygmomanometer continues to be the gold standard for BP measurement, it is frequently replaced by oscillometric devices because of the toxicity of mercury [8] and observer bias [9] which are frequent with the auscultatory technique. Validation of new oscillometric BP devices is obtained through comparison with the gold standard mercury sphygmomanometer and accuracy is evaluated with criteria specified in protocols of international societies, i.e. the European Society of Hypertension International Protocol revision 2010 for the validation of BP measuring devices (ESH-IP2), and the protocols of the British Hypertension Society (BHS) and the American Association for the Advancement of Medical Instrumentation (AAMI) [10-12].

However, passing these validation protocol criteria still allows for considerable disagreement between devices. For example, to pass the AAMI criteria for SBP and DBP, mean differences between measurement pairs should be ≤5 mmHg with a standard deviation of ≤8 mmHg while for BHS grade A validation, the absolute difference between measurement pairs should be within 5 mmHg in at least 60% of measurement pairs, within 10 mmHg in ≥85% and within 15 mmHg in ≥95%. The ESH-IP2 additionally requires an individual-based analysis of agreement and specifies criteria based on the frequencies of pairs ≤5 mmHg and ≥15 mmHg for every individual. The results of many validation studies are summarized on a website (http://www.dableducational.org). Most importantly, since oscillometric devices operate with their own model-specific algorithms to calculate BP values and since the manufacturer-provided cuffs and cuff selection instructions also differ, measurement agreement between oscillometric devices which were successfully validated against the mercury sphygmomanometer gold standard cannot be taken for granted.

The present study addresses this issue by comparing two oscillometric devices, the Datascope Accutorr Plus and the Omron HEM-705CP II. The Datascope Accutorr Plus is a device designed for professional use and is employed in two representative health surveys in Germany, the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) and the German Health Interview and Examination Survey for Adults (DEGS1) [13, 14] as well as other health surveys [15, 16], while the Omron device, which is designed for professional as well as home BP measurement is used by several regional German epidemiological studies with a focus on cardiovascular epidemiology [17-19]. Both devices had favorable results in several validation studies compared to the mercury sphygmomanometer gold standard [20-25] but have not been compared with each other before.

Methods

This methodological study compared two oscillometric devices: the Datascope Accutorr Plus (Accutorr Plus™, Datascope Corp., Mahwah, New Jersey, USA) and the Omron HEM-705CP II (Omron Healthcare UK Ltd, Fox Milne, Milton Keynes, MK15 0DG).

A sample of 109 adults aged 21 to 64 years (70 women, 39 men) was recruited at a scientific institute with mainly white collar workers. Informed consent and assent were obtained from all participants. Persons with arrhythmia or a pacemaker (ascertained by personal interview and pulse palpation) were excluded from the study [10]. The study was approved by the Ethical Committee of Charité University Medicine Berlin and by the German Federal Commissioner for Data Protection and Freedom of Information.

The comparison of Datascope and Omron was performed in a sequence of serial same-arm BP measurements alternating the devices and their manufacturer-provided cuffs. The study design followed the principles outlined in the ESH-IP2 [10]. At the same time, the study protocol closely followed the protocols of the German Health Interview and Examination Survey for Adults (DEGS1) which employed the Datascope Accutorr Plus, and the protocol of a regional epidemiologic study with a focus on cardiovascular diseases, the Kooperative Gesundheitsforschung in der Region Augsburg study (KORA-2000) which has served as model for several subsequent cardiovascular cohort studies in Germany [4, 17, 18]. These study protocols are in line with the standardization instructions of the ESH-IP2, but since the manufacturer´s instructions for the selection of individual cuffs for a given arm circumference (AC) slightly overlapped (e.g. instructions allowed the use of the small but also the medium cuff for AC 28.0 cm), this overlap was removed following the DEGS1 and KORA-2000 protocols in order to make instructions unequivocal.

A standardized measurement environment was created in a quiet study room. The participants sat and relaxed for at least five minutes on a height adjustable chair, their back supported. The elbow was slightly bent and lying on a table at the level of the right atrium. Both feet were straight on the floor and legs were not crossed. Manufacturer-provided cuffs were used for each device. The correct cuff size was identified by measuring the upper AC between the acromion and the olecranon.

For the Datascope Accutorr Plus three different cuffs were available with a bladder size of 10.6x23.9 cm for ACs ranging from 21.0-27.9 cm (manufacturer instruction: 20.5-28.5 cm), a bladder size of 13.5x30.7 cm for ACs 28.0-35.9 cm (manufacturer: 27.5-36.5 cm) and a bladder size of 17.0x38.6 cm for ACs 36.0-46.0 cm (manufacturer: 35.5-46 cm). The Omron device was supplied with two cuff sizes: 14x48 cm for ACs 22.0-31.9 cm (manufacturer: 22-32 cm) and 16x65 cm for ACs 32.0-42.0 cm (manufacturer: 32-42 cm).

A Datascope Accutorr Plus and an Omron HEM-705CP II device with a set of manufacturer-provided cuffs were randomly selected from the study equipment of DEGS1 and KORA-2000. Both devices give BP readings to the nearest 1 mmHg and were checked for technical correctness by the German Federal Institute of Science and Technology.

Nine sequential same-arm BP measurements were performed in each participant starting with the Datascope device. The first measurement with each device was not used for analysis. Measurements were at least 30 s apart to avoid venous congestion but not more than 60 s to avoid increased variability.

The analysis was based on BP measurement pairs. Each Omron measurement was compared to the nearer of the previous and next Datascope measurement. The Datascope measurement that was closest to the Omron measurement was used to define a measurement pair.

The device differences in systolic (SBP) and diastolic (DBP) BP were calculated as Omron minus Datascope and the cuff-width/arm-circumference-ratio (CW/AC-R) and the cuff-length/arm-circumference-ratio (CL/AC-R) were computed for both devices.

BP categories were defined as optimal BP <120/80 mmHg, prehypertensive BP 120-139/80-89 mmHg and hypertensive BP ≥140/90 mmHg [1]. Pulse pressure was calculated as SBP minus DBP for both devices. The mean and standard deviation (SD) of device differences was ascertained and stratified by sex, age, BP categories, AC groups, cuff sizes, tertiles of CW/AC-R and CL/AC-R as well as the differences in CW/AC-R and CL/AC-R of the devices (≤0% and >0%) and Wilcoxon signed rank tests were performed to check for the significance of measurement differences. The frequencies of SBP and DBP differences within 5, 10, 15 and >15 mmHg were calculated and the differences were plotted against the average BP values of both devices (Bland-Altman plots). The prevalence of hypertensive BP values was determined for both devices and Cohen’s Kappa was calculated to assess agreement of allocation to hypertension status. Prediction of Datascope SBP and DBP based on Omron and vice versa was attempted through linear regression analysis. Variables initially included were: the value of SBP or DBP of the corresponding device, sex, age, AC, pulse pressure and, since they were highly correlated, the cuff sizes, the CW/AC-R, the CL/AC-R and the differences in CW/AC-R and CL/AC-R were each at a time included separately. Starting from these four full models, all non-significant variables were excluded in a stepwise order until only the significant factors ($p<0.05$) remained. IBM SPSS Statistics version 20, SPSS Inc. was used for analyses.

Results

A total of 109 participants completed the study resulting in 327 blood pressure measurement pairs for analyses. Basic characteristics of the study population are summarized in Table 1.

The mean difference of Omron-SBP minus Datascope-SBP was 2.5 ± 5.7 mmHg and 0.7 ± 3.5 mmHg for DBP ($p<0.05$), respectively. Moreover, the SBP difference was larger in men than in women (4.0 ± 6.1 mmHg vs. 1.7 ± 5.3 mmHg; $p<0.05$) and increased with age (from 2.4 ± 4.7 mmHg for age group <40 years to 4.7 ± 8.0 mmHg for > 60 years; $p<0.05$). Moreover, SBP disagreement was particularly high for hypertensive BP (BP ≥140 mmHg: mean difference ± SD 9.3 ± 6.7 mmHg; $p<0.05$) (Fig. 1) and in the highest Omron pulse pressure tertile (pulse pressure >50 mmHg: mean difference ± SD 5.6 ± 6.3 mmHg; $p<0.05$). The pattern of differences for DBP was similar. Men had a slightly higher mean difference and the difference decreased with age, but these findings were not significant. Again, the DBP difference significantly increased with DBP but only a few measurements were within the hypertensive range (Fig. 2). The CW/AC-R of Omron was higher in 96.3% of participants meaning that the Omron cuff was larger in relation to AC than the corresponding Datascope cuff. For the few cases in whom the Omron cuff was smaller (resulting in a CW/AC-R difference <0) the measurement disagreement in SBP and particularly in DBP was high (CW/AC-R <0: SBP difference 3.0 ± 3.7 mmHg ($p<0.05$) and 4.1 ± 4.3 mmHg for DBP ($p<0.05$), respectively) (Tab. 2).

SBP differences were within ± 5 mmHg in 66% of measurement pairs, within ± 10 mmHg in 91% and were less than 15 mmHg in 98% (for DBP 89%, 99% and 100%) (Tab. 2).

Hypertension prevalence by device

The prevalence of hypertensive BP based on Omron measurements was noticeably higher as opposed to Datascope (11 vs. 5%). From 110 measurement pairs that were classified as prehypertensive with Datascope, 21% were labeled hypertensive with Omron whereas only 3% were categorized hypertensive with Datascope but were prehypertensive according to Omron. Cohen's Kappa amounted to 0.67 ($p<0.05$) (data not shown).

Conversion of SBP and DBP from Omron HEM-705CP II to Datascope Accutorr Plus and vice versa

The models for the conversion models of BP values from one device to the other were developed through linear regression analysis. Parameter selection was based on previous studies on factors influencing oscillometric measurements [26-29]. In addition, various variables reflecting cuff sizes and cuff selection rules were considered since manufacturer-provided cuffs as well as cuff selection rules were not equivalent for the two devices and could have influenced measurements [30-36]. The final models containing only the significant factors are shown in Table 3 and these can be used for equations to convert blood pressure values from Datascope to Omron and vice versa before comparisons of BP data are performed. For example, the comparability of BP data gathered within the specified German studies could be enhanced by applying these conversion formulas.

Discussion

This study compares two frequently used upper arm oscillometric blood pressure devices, Datascope Accutorr Plus and Omron HEM-705CP II, which had both previously shown good agreement with gold standard mercury sphygmomanometer measurements according to international validation protocols [20-25]. When directly comparing Datascope Accutorr Plus and Omron HEM-705CP II measurements in this study, agreement of DBP remained good (mean difference 0.7 ± 3.5 mmHg) but mean SBP difference was 2.5 ± 5.7 mmHg and higher in participants with elevated SBP, leading to a higher hypertension prevalence estimate when BP was measured with Omron as compared to Datascope (11% vs. 5%). The formulas for the conversion of BP values from one device to the other include BP, pulse pressure, sex, age, arm circumference and the difference in CW/AC-R.

Both devices passed validation protocols of international societies, i.e. the Datascope device was validated according to the protocols of the AAMI and BHS [20-22] and Omron was further evaluated with the ESH criteria [23-25]. In comparison with the mercury sphygmomanometer, Datascope Accutorr Plus SBP was on average almost identical in two studies in adults and slightly lower in children (device-observer difference 0.0 ± 7.9 mmHg [20]; 0.1 ± 7.5 mmHg [21] and -0.9 ± 4.3 mmHg [22]). Datascope DBP was lower in these three studies compared to the auscultatory method with a mercury sphygmomanometer (device-observer difference -0.4 ± 5.8 mmHg [20]; -2.5 ± 5.2 mmHg [21] and -1.3 ± 6.5 mmHg [22]). For the specific Omron model HEM-705CP II no validation studies are available, but three validations were conducted for the model Omron 705IT, which was declared equivalent [37].

The Omron 705IT SBP was on average slightly higher than mercury sphygmomanometer readings by 0.6 ± 6.0 mmHg in one validation study in adults [23] and slightly lower by 0.2 ± 4.5 mmHg in a second validation study in adults [24]. In children the Omron 705IT SBP was higher by 4.0 ± 4.8 mmHg [25]. Moreover, another 705IT equivalent, the Omron M6 upper arm device (HEM-7001-E) was separately validated and consistently slightly overestimated SBP by approximately 1 mmHg. DBP on the other hand was underestimated by this Omron device in a similarly magnitude (around 1 mmHg) in all studied groups (adults, obese adults, elderly) [38-40].

In addition, the predecessor model Omron HEM-705CP was evaluated in validation studies and furthermore in studies with modifications of the formal validation protocols (e.g. regarding measurement procedure, cuff selection or subject/ BP requirements). Again, SBP was mostly overestimated and DBP predominantly underestimated [41-46]. However, it is not clear if any alterations of the measurement algorithm were performed between the Omron HEM-705CP and its successor HEM-705CP II that could have had an effect on the measurements. Hence, the results of these studies are may not be transferable.

Thus, although both oscillometric devices passed international validations, underestimation of SBP by one device and overestimation by the other device may result in a surprising difference if the devices are compared to one another. Secondly, validation studies often used the same cuffs for the auscultatory and oscillometric measurements, but in our study the manufacturer-provided cuffs were applied which differ in size and ratios of cuff width and cuff length to AC. Last but not least, though both devices are based on the oscillometric technique, manufacturers develop their own algorithms to calculate SBP and DBP from pulse oscillations in the cuff. For this reason some measurement disagreement between oscillometric devices is likely [47].

Not all validation studies for Datascope and Omron report on the device performance at different blood pressure levels. Similarly to other studies, we observed an increasing device disagreement with rising SBP in this study [41, 44, 48]. For Datascope, two studies found an increasing disagreement with the gold standard mercury sphygmomanometer at SBP extremes

(>190 mmHg) [20, 21], whereas for Omron SBP measurement difference increased at higher SBP in one study, but agreement was similarly good within all BP ranges in another study [23, 24].

For DBP, all three validation studies with Datascope found a similarly good agreement over the whole DBP range, whilst the Omron 705IT as well as the Omron M6 showed either an increasing disagreement at low [24, 38] or at high [23, 25, 39] BP levels. Moreover, one study with the M6 found that with increasing BP a disagreement >10 mmHg was more prevalent in a group with obese adults but not in the group with normal adults [40].

However, for many oscillometric devices the measurement differences increase with rising BP and a study comparing six electronic devices with a mercury sphygmomanometer showed, that for four out of six devices accuracy deteriorated in the highest pressure category (>160/100 mmHg) [48].

Sex, age and AC were associated with device differences, too. Men had a higher SBP and DBP mean difference than women and the SBP difference increased with age for both sexes, whereas for DBP the difference non-significantly decreased with age. However, this observation is limited by the small sample size in the oldest age group. Sex-related differences were also reported elsewhere [18, 26, 49]. The effect of age on oscillometric BP measurement accuracy was often subject to investigation and is influenced by alterations in the viscoelastic structure of the arterial wall and the pulse pressure amplitude, i.e. the increase in arterial stiffness but also other factors that are associated with age (e.g. soft arm tissue, CW/AC-R, atrial fibrillation or heart rate) [50, 51].

The different cuff sizes were associated with BP discrepancy. For the majority of persons, the Omron cuff was larger in relation to the AC than the corresponding Datascope cuff, reflected in a CW/AC-R difference >0%. Consequently, overcuffing due to a cuff size that is too big for a given AC [32, 35] was more likely with the Omron device. In fact, the measurement disagreement was smaller if the Omron cuff was larger and especially the DBP difference was high within the few cases, where the Omron cuff was smaller than the Datascope cuff. Notably, overcuffing with Omron probably leads to an underestimation of BP. For this reason, the measurement disagreement could be even higher with better fitting Omron cuffs.

Finally, oscillometric measurement accuracy is also affected by arterial stiffness [26, 29, 51, 52] Arterial stiffness may lead to broader plateaus and more complex shapes of oscillometric BP waveform [27, 51, 53] and may differentially influence oscillometric BP values calculated on the basis of device-specific algorithms. Indeed, the exact way of calculating SBP and DBP is proprietary and one cannot discern how a specific device model operates in the presence of arterial stiffness. We used pulse pressure as an indicator for arterial stiffness, because it tends to increase with stiffer arteries. The measurement difference in SBP increased with pulse pressure but the DBP difference, although not significant, decreased. Two other studies show similar results. One study found a strong correlation of SBP discrepancy with pulse pressure in patients with persistent unreliable oscillometric BP readings (device difference >10 mmHg in at least two clinic visits of an particular person) and there was a consistent trend for larger SBP differences across pulse pressure quintiles. Similar to our study, the differences in DBP decreased along pulse pressure quintiles [26]. In the other study an oscillometric Dinamap device overestimated SBP in patients with pulse pressures ≥60 mmHg (SBP difference 3.47 ± 11.15 mmHg) whereas in general SBP was slightly underestimated (-0.52 ± 9.84 mmHg) [54]. The magnitude of DBP difference was smaller in persons with pulse pressure ≥60 mmHg compared to the overall sample.

Moreover, two more studies support an effect of arterial stiffness on oscillometric BP measurement accuracy. Arterial stiffness was measured with carotid-femoral pulse wave velocity in one study and an increasing overestimation of SBP and DBP, obtained with a

Dinamap device in comparison to a random-zero sphygmomanometer, was found with increasing arterial stiffness [29]. The other study observed a more severe overestimation of SBP in a group of insulin-dependent diabetics, known to have stiffer arteries, but a less severe underestimation of DBP in comparison with a mercury sphygmomanometer [55].

A strength of this study is the relatively big sample size which exceeded the requirements set out in validation protocols (i.e. 85 subjects) and the well-balanced sample with regard to sex, age and BP distribution. Furthermore, the study design and standardization was compliant with the specifications of the ESH-IP2. Another positive finding was the large amount of explained variability. Accordingly, the conversion models operate well with just a few and easily available variables included.

However, the difficulties in recruiting participants with high BP, especially high DBP, represent a limitation of our study. The defined BP range of the ESH-IP2 was not fulfilled and the conversion models may be less robust in the hypertensive BP range.

However, the range close to the hypertension threshold (135-145/85-95 mmHg) is sufficiently reflected with our sample. Moreover, our results are not generalizable to children and adolescents since persons under 18 years were not included and also individuals with arrhythmia or a pacemaker were excluded and thus the device performance for these groups remains unclear.

Last but not least, the possible implications of our results are of interest. We found a mean systolic measurement difference exceeding 2 mmHg, which is of a magnitude that is relevant at the population level. It has been estimated that 2-3 mmHg lower mean population SBP could reduce mortality from coronary heart disease by 4% to 5% and stroke mortality could be even more reduced by 6 to 8% [56].

Furthermore, in our study the hypertension prevalence measured with the Omron device was twice as high as with Datascope. This large difference may be due to the fact that many people have BP levels that are only marginally above or below the hypertension threshold. However, SBP measurements differed by more than 10 mmHg in more than one third of those above the hypertension threshold and in 20% of the elderly as well as of those in the highest tertile of pulse pressure. Such larger differences may result in differential treatment decisions suggesting that differences between oscillometric devices may be of particular clinical relevance in specific patient groups, such as geriatric patients or patients with diabetes and end stage renal disease [28, 53, 55, 57-59].

In summary, our study suggests that BP values from different oscillometric devices may differ more than suggested by validation studies due to three reasons: (1) underestimation by one device and overestimation by the other device may add up, (2) manufacturer-provided cuffs may differ and lead to cuff-related BP measurement differences and (3) validation studies evaluate only overall agreement over a wide range of blood pressures and may mask more pronounced disagreement e.g. for measurements around and above hypertension threshold or measurements in patients with increased pulse pressure such as patients with diabetes or more generally in the elderly. This implies caution in the clinical care context when comparing measurements performed with different devices. In clinical as well as epidemiological studies cuff sizes and cuff selection rules should always be reported.

Acknowledgements

We thank the participants of the study, Julian Graef for programming the study software and the KORA study research team for providing an Omron device from their study equipment.

References

1. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, et al. Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension 2003;42:1206-1252
2. Feng JH, MacGregor A. Blood pressure is the most important cause of death and disability in the world. Eur Heart J Suppl 2011;9:B23-B28
3. Ostchega Y, Zhang G, Sorlie P, Hughes JP, Reed-Gillette DS, Nwankwo T, Yoon S. Blood Pressure Randomized Methodology Study Comparing Automatic Oscillometric and Mercury Sphygmomanometer Devices: National Health and Nutrition Examination Survey, 2009-2010. published by: U.S. Department of Health and Human Services, Centers for Disease Control, National Center for Health Statistics; Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr059.pdf
4. Meisinger C, Heier M, Volzke H, Lowel H, Mitusch R, Hense HW, Ludemann J. Regional disparities of hypertension prevalence and management within Germany. J Hypertens 2006;24:293-299
5. Dahlof B, Sever PS, Poulter NR, Wedel H, Beevers DG, Caulfield M, et al. Prevention of cardiovascular events with an antihypertensive regimen of amlodipine adding perindopril as required versus atenolol adding bendroflumethiazide as required, in the Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm (ASCOT-BPLA): a multicentre randomised controlled trial. Lancet 2005;366:895-906
6. Yusuf S, Teo KK, Pogue J, Dyal L, Copland I, Schumacher H, et al. Telmisartan, ramipril, or both in patients at high risk for vascular events. N Engl J Med 2008;358:1547-1559
7. Hansson L, Zanchetti A, Carruthers SG, Dahlof B, Elmfeldt D, Julius S, et al. Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. HOT Study Group. Lancet 1998;351:1755-1762
8. UNEP Chemicals. Global Mercury Assessment. 1. DRAFT. 25 April 2002; Available at: http://www.chem.unep.ch/mercury/Report/1stdraft-report.htm
9. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks). Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives. 23. September 2009; Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_025.pdf
10. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, et al. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. Blood Press Monit 2010;15:23-38
11. O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, et al. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. J Hypertens 1993;11:S43-S63
12. White WB, Berson AS, Robbins C, Jamieson MJ, Prisant LM, Roccella E, Sheps SG. National standard for measurement of resting and ambulatory blood pressures with automated sphygmomanometers. Hypertension 1993;21:504-509
13. Neuhauser H, Thamm M, Ellert U. Blood pressure in Germany 2008-2011: results of the German Health Interview and Examination Survey for Adults (DEGS1). Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2013;56:795-801
14. Neuhauser H, Thamm M. Blood pressure measurement in the German Health Interview and Examination Survey for Children and Adolescents (KiGGS). Methodology and initial results. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2007;50:728-735

15. Sung RY, Choi KC, So HK, Nelson EA, Li AM, Kwok CW, et al. Oscillometrically measured blood pressure in Hong Kong Chinese children and associations with anthropometric parameters. J Hypertens 2008;26:678-684
16. Kulaga Z, Litwin M, Grajda A, Kulaga K, Gurzkowska B, Gozdz M, Pan H. Oscillometric blood pressure percentiles for Polish normal-weight school-aged children and adolescents. J Hypertens 2012;30:1942-1954
17. Lowel H, Meisinger C, Heier M, Hymer H, Alte D, Volzke H. [Epidemiology of hypertension in Germany. Selected results of population-representative cross-sectional studies]. Dtsch Med Wochenschr 2006;131:2586-2591
18. Stang A, Moebus S, Mohlenkamp S, Dragano N, Schmermund A, Beck EM, et al. Algorithms for converting random-zero to automated oscillometric blood pressure values, and vice versa. Am J Epidemiol 2006;164:85-94
19. Greiser KH, Kluttig A, Schumann B, Kors JA, Swenne CA, Kuss O, et al. Cardiovascular disease, risk factors and heart rate variability in the elderly general population: design and objectives of the Cardiovascular disease, Living and Ageing in Halle (CARLA) Study. BMC Cardiovasc Disord 2005;5:33
20. Anwar YA, Tendler BE, McCabe EJ, Mansoor GA, White WB. Evaluation of the Datascope Accutorr Plus according to the recommendations of the Association for the Advancement of Medical Instrumentation. Blood Press Monit 1997;2:105-110
21. White WB, Herbst T, Thavarajah S, Giacco S. Clinical evaluation of the Trimline blood pressure cuffs with the Accutorr Plus Monitor. Blood Press Monit 2003;8:137-140
22. Wong SN, Tz Sung RY, Leung LC. Validation of three oscillometric blood pressure devices against auscultatory mercury sphygmomanometer in children. Blood Press Monit 2006;11:281-291
23. Coleman A, Freeman P, Steel S, Shennan A. Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol. Blood Press Monit 2006;11:27-32
24. El Assaad MA, Topouchian JA, Asmar RG. Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT. Blood Press Monit 2003;8:127-133
25. Stergiou GS, Yiannes NG, Rarra VC. Validation of the Omron 705 IT oscillometric device for home blood pressure measurement in children and adolescents: the Arsakion School Study. Blood Press Monit 2006;11:229-234
26. Stergiou GS, Lourida P, Tzamouranis D, Baibas NM. Unreliable oscillometric blood pressure measurement: prevalence, repeatability and characteristics of the phenomenon. J Hum Hypertens 2009;23:794-800
27. Amoore JN, Lemesre Y, Murray IC, Mieke S, King ST, Smith FE, Murray A. Automatic blood pressure measurement: the oscillometric waveform shape is a potential contributor to differences between oscillometric and auscultatory pressure measurements. J Hypertens 2008;26:35-43
28. Thompson AM, Eguchi K, Reznik ME, Shah SS, Pickering TG. Validation of an oscillometric home blood pressure monitor in an end-stage renal disease population and the effect of arterial stiffness on its accuracy. Blood Press Monit 2007;12:227-232
29. van Popele NM, Bos WJW, de Beer NAM, van der Kuip DAM, Hofman A, Grobbee DE, Witteman JCM. Arterial Stiffness as Underlying Mechanism of Disagreement Between an Oscillometric Blood Pressure Monitor and a Sphygmomanometer. Hypertension 2000;36:484-488
30. Marks LA, Groch A. Optimizing cuff width for noninvasive measurement of blood pressure. Blood Press Monit 2000;5:153-158

31. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, et al. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Hypertension 2005;45:142-161
32. Maxwell MH, Waks AU, Schroth PC, Karam M, Dornfeld LP. Error in blood-pressure measurement due to incorrect cuff size in obese patients. Lancet 1982;2:33-36
33. Bovet P, Hungerbuhler P, Quilindo J, Grettve ML, Waeber B, Burnand B. Systematic difference between blood pressure readings caused by cuff type. Hypertension 1994;24:786-792
34. Rastam L, Prineas RJ, Gomez-Marin O. Ratio of cuff width/arm circumference as a determinant of arterial blood pressure measurements in adults. J Intern Med 1990;227:225-232
35. O'Brien E. Review: a century of confusion; which bladder for accurate blood pressure measurement? J Hum Hypertens 1996;10:565-572
36. Aylett M, Marples G, Jones K, Rhodes D. Evaluation of normal and large sphygmomanometer cuffs using the Omron 705CP. J Hum Hypertens 2001;15:131-134
37. Sphygmomanometers for Self-measurement of Blood Pressure (SBPM). Upper Arm Devices for Self-measurement of Blood Pressure. Available at: http://www.dableducational.org/sphygmomanometers/devices_2_sbpm.html
38. Topouchian JA, El Assaad MA, Orobinskaia LV, El Feghali RN, Asmar RG. Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT). Blood Press Monit 2006;11:165-171
39. Altunkan S, Iliman N, Altunkan E. Validation of the Omron M6 (HEM-7001-E) upper arm blood pressure measuring device according to the International Protocol in elderly patients. Blood Press Monit 2008;13:117-122
40. Altunkan S, Ilman N, Kayaturk N, Altunkan E. Validation of the Omron M6 (HEM-7001-E) upper-arm blood pressure measuring device according to the International Protocol in adults and obese adults. Blood Press Monit 2007;12:219-225
41. O'Brien E, Mee F, Atkins N, Thomas M. Evaluation of three devices for self-measurement of blood pressure according to the revised British Hypertension Society Protocol: the Omron HEM-705CP, Philips HP5332, and Nissei DS-175. Blood Press Monit 1996;1:55-61
42. Furusawa EA, Ruiz MF, Saito MI, Koch VH. Evaluation of the Omron 705-CP blood pressure measuring device for use in adolescents and young adults. Arq Bras Cardiol 2005;84:367-370
43. Iglesias Bonilla P, Mayoral Sanchez E, Lapetra Peralta J, Iborra Oquendo M, Villalba Alcala F, Cayuela Dominguez A. Validation of two systems of self-measurement of blood pressure, the OMRON HEM-705 CP and OMRON M1 (HEM 422C2-E) models. Aten Primaria 2002;30:22-28
44. Vera-Cala LM, Orostegui M, Valencia-Angel LI, Lopez N, Bautista LE. Accuracy of the Omron HEM-705 CP for blood pressure measurement in large epidemiologic studies. Arq Bras Cardiol 2011;96:393-398
45. Lewis JE, Boyle E, Magharious L, Myers MG. Evaluation of a community-based automated blood pressure measuring device. CMAJ 2002;166:1145-1148
46. Markandu ND, Duneclift S, Carney C, Arnold A. Further validation of a semi-automatic blood pressure machine (OMRON HEM-705CP) with an assessment of its use in a hypertension unit and preliminary findings in a general medical ward. Journal of Human Hypertension; 2001:357-358

47. Kaufmann MA, Pargger H, Drop LJ. Oscillometric blood pressure measurements by different devices are not interchangeable. Anesth Analg 1996;82:377-381
48. O'Brien E, Atkins N, Mee F, O'Malley K. Comparative accuracy of six ambulatory devices according to blood pressure levels. J Hypertens 1993;11:673-675
49. Bhatt SD, Hinderliter AL, Stouffer GA. Influence of sex on the accuracy of oscillometric-derived blood pressures. J Clin Hypertens 2011;13:112-119
50. Baulmann J, Nurnberger J, Slany J, Schmieder R, Schmidt-Trucksass A, Baumgart D, et al. Arterial stiffness and pulse wave analysis. Dtsch Med Wochenschr 2010;135:Suppl S4-14
51. Ursino M, Cristalli C. A mathematical study of some biomechanical factors affecting the oscillometric blood pressure measurement. IEEE Trans Biomed Eng 1996;43:761-778
52. Raptis AE, Spring MW, Viberti G. Comparison of blood pressure measurement methods in adult diabetics. Lancet 1997;349:175-176
53. SunTech Medical Inc. Rationale for Non-Invasive Blood Pressure Research on Dialysis Patients. ; Available at: http://www.suntechmed.com/downloads/OEM/white_papers/OEM_Whitepaper_0003.pdf [Accessed 10 May 2013]
54. Ni H, Wu C, Prineas R, Shea S, Liu K, Kronmal R, Bild D. Comparison of Dinamap PRO-100 and mercury sphygmomanometer blood pressure measurements in a population-based study. Am J Hypertens 2006;19:353-360
55. van Ittersum FJ, Wijering RM, Lambert J, Donker AJ, Stehouwer CD. Determinants of the limits of agreement between the sphygmomanometer and the SpaceLabs 90207 device for blood pressure measurement in health volunteers and insulin-dependent diabetic patients. J Hypertens 1998;16:1125-1130
56. Stamler R. Implications of the INTERSALT study. Hypertension 1991;17:I16-20
57. Cavalcanti S, Marchesi G, Ghidini C. Validation of automated oscillometric sphygmomanometer (HDBPM) for arterial pressure measurement during haemodialysis. Med Biol Eng Comput 2000;38:98-101
58. Akpolat T, Erdem E, Aydogdu T. Validation of the Omron M3 Intellisense (HEM-7051-E) Upper Arm Blood Pressure Monitor, for Self-Measurement, according to the European Society of Hypertension International Protocol Revision 2010 in a Stage 3–5 Chronic Kidney Disease Population. Kidney Blood Press Res 2012;35:82-88
59. Semret M, Zidehsarai M, Agarwal R. Accuracy of oscillometric blood pressure monitoring with concurrent auscultatory blood pressure in hemodialysis patients. Blood Press Monit 2005;10:249-255

List of tables / figures

Table 1: Characteristics of the study population

	N unless stated otherwise	% of measurement pairs
Total completed (Total/Women/Men)	109 / 70 / 39	
Total measurement pairs (Total/Women/Men)	327 / 210 / 117	100 / 64 / 36
Age <40/40-60/>60 years	49 / 48 / 12	45 / 44 / 11
Proportion on BP lowering drugs	17	15.6
Arm circumference mean ± SD (cm)	29.2 ± 3.6	
Omron HEM-705 CP II		
Arm circumference: cuff bladder sizes		
AC 22-31.9 cm: bladder 14x45 cm	89	81.7
AC 32-42 cm: bladder 16x65 cm	20	18.3
SBP mean ± SD (mmHg)	117.6 ± 15.5	
DBP mean ± SD (mmHg)	70.1 ± 10.1	
pulse pressure min / max / mean ± SD (mmHg)	23 / 87 / 47.6 ± 9.5	
CW/AC-R min / max / mean ± SD (%)	40 / 61 / 49.8 ± 4.8	
CL/AC-R min / max / mean ± SD (%)	71 / 100 / 83.3 ± 7.5	
Datascope Accutorr Plus		
Arm circumference: cuff bladder sizes		
AC 21 – 27.9: bladder 10.6x23.9 cm	34	31.2
AC 28 – 35.9 cm: bladder 13.5x30.7 cm	71	65.1
AC 36 – 46 cm: bladder 17.0x38.6 cm	4	3.7
SBP mean ± SD (mmHg)	115.1 ± 13.9	
DBP mean ± SD (mmHg)	69.3 ± 9.4	
pulse pressure min / max / mean ± SD (mmHg)	27 / 78 / 45.8 ± 8.3	
CW/AC-R min / max / mean ± SD (%)	38 / 48 / 43.7 ± 3.0	
CL/AC-R min / max / mean ± SD (%)	87 / 110 / 99.2 ± 7.1	
CW/AC-R difference Omron - Datascope min / max / mean ± SD (%)	-3 / 15 / 6.1 ± 5.5	
CL/AC-R difference Omron - Datascope min / max / mean ± SD (%)	-28 / -3 / -15.9 ± 11.0	

CW/AC-R: cuff-width to arm-circumference ratio; CL/AC-R: cuff-length to arm-circumference ratio

Table 2: Agreement between Omron HEM-705CP II and Datascope Accutorr Plus

			Difference Omron HEM-705 CP II – Datascope Accutorr Plus				
	N pairs	% of pairs	Mean ± SD (mmHg)	≤5 mmHg (%)	≤10 mmHg (%)	≤15 mmHg (%)	p
SBP	327		2.5 ± 5.7	66	91	98	0.000
DBP	327		0.7 ± 3.5	89	99	100	0.000
Sex							
SBP							
men	117	35.8	4.0 ± 6.1	56	87	97	0.000
women	210	64.2	1.7 ± 5.3	72	93	99	0.000
DBP							
men	117	35.8	1.3 ± 3.4	88	99	100	0.000
women	210	64.2	0.4 ± 3.6	90	98	100	0.077
Age							
SBP							
<40 years	147	45.0	2.4 ± 4.7	70	95	100	0.000
40-60 years	144	44.0	2.2 ± 5.9	66	90	98	0.000
>60 years	36	11.0	4.7 ± 8.0	53	81	89	0.003
DBP							
<40 years	147	45.0	1.0 ± 3.8	87	99	100	0.001
40-60 years	144	44.0	0.6 ± 3.4	91	98	100	0.054
>60 years	36	11.0	0.0 ± 3.0	89	100	100	0.599
Blood pressure (Omron)							
SBP							
Optimal: ≤120 mmHg	188	57.5	1.1 ± 4.7	75	96	100	0.001
Prehypertensive: 120-139 mmHg)	107	32.7	3.0 ± 5.5	65	90	98	0.000
Hypertensive: ≥140 mmHg	32	9.8	9.3 ± 6.7	25	63	84	0.000
Close to hypertension threshold: 135-145 mmHg	35	10.7	5.3± 6.6	46	77	94	0.000
DBP							
Optimal: ≤80 mmHg	261	79.8	0.2 ± 3.3	91	99	100	0.253
Prehypertensive: 80-89 mmHg	57	17.4	2.3 ± 3.4	83	100	100	0.000
Hypertensive: ≥90 mmHg	9	2.8	5.1 ± 3.9	78	89	100	0.008
Close to hypertension threshold: 85-95 mmHg	30	9.2	3.4 ± 3.6	80	97	100	0.000
Pulse pressure (Omron)							
SBP							
<43 mmHg	116	35.5	0.2 ± 4.8	74	97	100	0.457
43 – 50 mmHg	107	32.7	2.1 ± 4.6	74	94	100	0.000

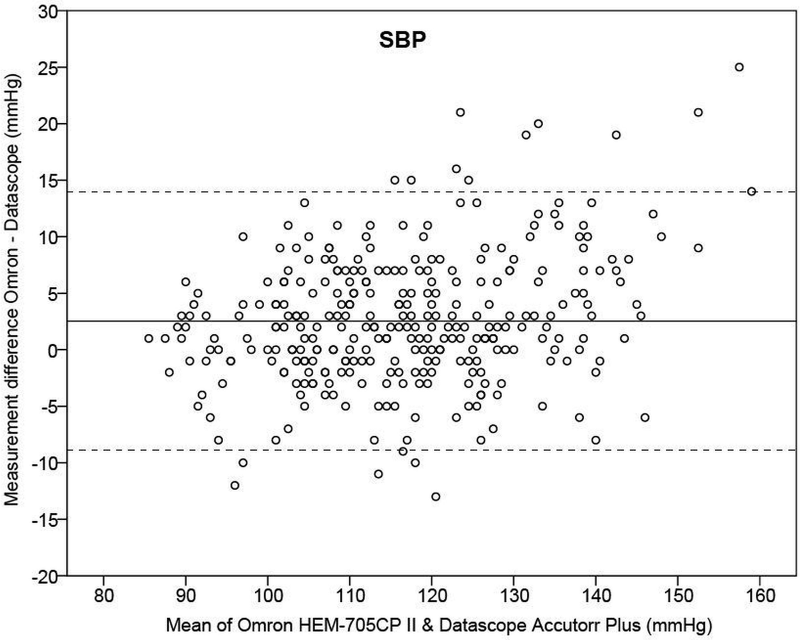
>50 mmHg	104	31.8	5.6 ± 6.3	50	81	93	0.000
DBP							
<43 mmHg	116	35.5	1.1 ± 3.4	90	98	100	0.000
43 – 50 mmHg	107	32.7	0.6 ± 3.9	87	97	100	0.074
>50 mmHg	104	31.8	0.4 ± 3.3	90	100	100	0.497
Arm circumference							
SBP							
<28 cm	102	31.2	1.9 ± 6.2	68	89	96	0.008
28-35.9 cm	213	65.1	2.8 ± 5.6	65	91	99	0.000
>36 cm	12	3.7	3.0 ± 3.7	75	100	100	0.016
DBP							
<28 cm	102	31.2	-0.6 ± 3.4	91	98	100	0.170
28-35.9 cm	213	65.1	1.1 ± 3.3	89	99	100	0.000
>36 cm	12	3.7	4.1 ± 4.3	67	100	100	0.011
CW/AC-R difference							
SBP							
≤0%	12	3.7	3.0 ± 3.7	75	100	100	0.016
>0%	315	96.3	2.5 ± 5.8	66	91	98	0.000
DBP							
≤0%	12	3.7	4.1 ± 4.3	67	100	100	0.011
>0%	315	96.3	0.6 ± 3.4	90	98	100	0.022

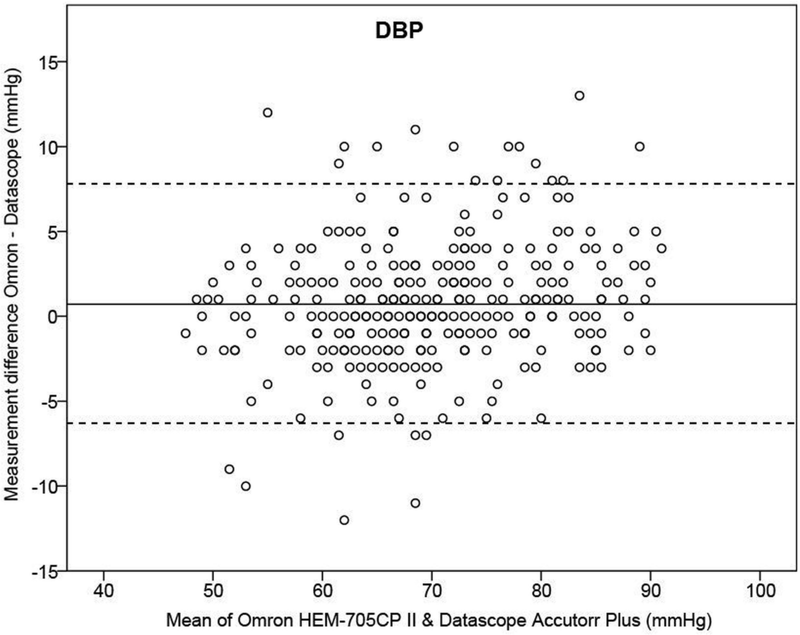
CW/AC-R: cuff-width to arm-circumference ratio; CW/AC-R difference: CW/AC-R Omron HEM-705CP II – CW/AC-R Datascope Accutorr Plus

Table 3: Linear regression models for the conversion of BP from Omron HEM-705CP II to Datascope Accutorr Plus and vice versa

	Regression coefficient	95% CI for regression coefficient		Standardized coefficient	p	R^2
		Lower Limit	Upper Limit			
Model 1: Prediction of Omron SBP from Datascope SBP						
Intercept	5.966	-0.551	12.482		0.073	
Datascope SBP	1.050	0.980	1.119	0.942	0.000	
Datascope pulse pressure	-0.150	-0.263	-0.037	-0.081	0.009	0.872
Female sex	-2.742	-4.204	-1.281	-0.085	0.000	
CW/AC-R difference	-0.089	-0.203	0.025	-0.031	0.128	
Model 2: Prediction of Omron DBP from Datascope DBP						
Intercept	-0.300	-3.518	2.917		0.854	
Datascope DBP	0.953	0.913	0.993	0.889	0.000	0.896
Datascope pulse pressure	0.117	0.074	0.161	0.097	0.000	
CW/AC-R difference	-0.180	-0.248	-0.113	0.098	0.000	
Model 3: Prediction of Datascope SBP from Omron SBP						
Intercept	3.046	-3.717	9.808		0.376	
Omron SBP	0.975	0.919	1.032	1.087	0.000	
Omron pulse pressure	-0.305	-0.392	-0.217	-0.209	0.000	0.885
Arm circumference	0.036	0.017	0.054	0.093	0.000	
CW/AC-R difference	0.225	0.102	0.349	0.089	0.000	
Model 4: Prediction of Datascope DBP from Omron DBP						
Intercept	4.088	1.134	7.042		0.007	
Omron DBP	0.859	0.819	0.898	0.920	0.000	
Omron pulse pressure	0.043	0.006	0.081	0.044	0.022	0.888
Age	0.056	0.029	0.083	0.081	0.000	
CW/AC-R difference	0.111	0.044	0.177	0.065	0.001	

CW/AC-R: cuff-width to arm-circumference ratio; CW/AC-R difference: CW/AC-R Omron HEM-705CP II – CW/AC-R Datascope Accutorr Plus


SBP
Measurement difference Omron - Datascope (mmHg)
Mean of Omron HEM-705CP II & Datascope Accutorr Plus (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
80
90
100
110
120
130
140
150
160


DBP
Measurement difference Omron - Datascope (mmHg)
Mean of Omron HEM-705CP II & Datascope Accutorr Plus (mmHg)
15
10
5
0
-5
-10
-15
40
50
60
70
80
90
100