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Calibration of blood pressure data after replacement of standard mercury sphygmomanometer by an oscillometric device and concurrent change of cuffs

Running title: Blood pressure calibration after device change

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Abstract

Objective(s): Oscillometric blood pressure (BP) measurement devices increasingly replace standard mercury sphygmomanometers and generalizability of validation studies to other environments, e.g. national survey environments, is assumed. We compared BP measurements according to two highly standardized German national survey BP protocols: a standard mercury sphygmomanometer and an oscillometric device, Datascope Accutorr Plus, each with specific manufacturer-provided cuffs and cuff-selection-rules.

Methods: A sample of 105 adults had alternate same-arm BP measurements according to the principles of the International Protocol revision 2010 for the validation of BP measuring devices in adults of the European Society of Hypertension. 315 BP measurement pairs were obtained.

Results: Mean systolic (SBP) and diastolic (DBP) BP were higher by the standard-mercury-old-protocol and increased with BP, age and pulse pressure and were associated with the ratios of the cuff width to the arm circumference. The mean systolic difference (Datascope-new-protocol minus standard-mercury-old-protocol) in participants with old-protocol-SBP<120 was -3.5±4.9 mmHg (n=162), -6.4±5.8 mmHg for SBP 120-139 (n=108) and -11.9±7.2 mmHg for SBP ≥140 (n=45). For DBP <80/80-89/≥90 in n=230/67/18 participants the differences were -1.9±5.0 mmHg/ -6.8±5.9 mmHg/ -7.6±5.2 mmHg. A calibration formula for SBP derived from linear regression modelling includes SBP, sex, age, pulse pressure and the difference of the cuff-width/arm-circumference ratios for the two devices (for DBP without age).

Conclusions: Our study suggests that even in a highly standardized national survey environment reported agreement from validation studies may not be replicable and comparisons in the specific clinical or research setting can be useful prior to replacing the mercury device completely.

Keywords: blood pressure; cuff size; measurement; oscillometric; arm circumference

Introduction

Detection of a population-wide blood pressure (BP) change of even 2 mmHg is important since it is associated with a change in stroke mortality of ten percent and coronary heart disease mortality of seven percent. [1] Therefore, it is important to differentiate real changes from measurement bias. One form of measurement bias, observer bias, can be avoided by replacing mercury sphygmomanometers by automated oscillometric devices but new measurement bias may arise depending on the agreement of the specific automated device with the standard mercury auscultatory method.

This study is a methodological study designed to evaluate comparability of BP data from two national health surveys in Germany after a change from the standard mercury sphygmomanometer (Erkameter 3000, Bad Tölz, Germany) to a validated automated oscillometric device, the Datascope Accutorr Plus (Datascope Corporation, Mahwah, NJ, USA) including a change of manufacturer-provided cuffs and cuff-selection rules.[2]

Methods

The study design followed the principles of the International Protocol revision 2010 for the validation of BP measuring devices in adults of the European Society of Hypertension (ESH-IP2).[3] The standardization of BP measurement was adopted from the two most recent German national examination surveys for adults conducted in 1998 (GNHIES89, old-protocol) and in 2008-11 (DEGS1, new-protocol).[2] The old and the new protocol differed however by the device, the cuffs and the instructions for selecting the cuffs (Table 1). Participants sat and relaxed for at least 5 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. The correct cuff size (Table 1) was identified by measuring the arm circumference (AC) between the acromion and the olecranon. The correct position of the cuff above the brachial artery was additionally checked with a mark on the cuff, which was in the middle of the inflatable bladder length. Deviations from the ESH-IP2 were relaxing time of five instead of 10-15 minutes and standard-mercury-old-protocol cuff length encircling 73%-127% of the arm circumference instead of 80%-100%.

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. Informed consent and assent were obtained from all participants.

A convenience sample of 105 adults aged 21 to 64 years (65 women, 40 men, age 41±12 years years (mean ± standard deviation, SD), mainly white collar workers) was included into the study, providing a total of 315 BP measurement pairs from alternate serial same-arm BP measurements with the two devices. Persons with arrhythmia or a pacemaker (ascertained by personal interview and pulse palpation) as well as pregnant women were excluded from the study.

Observer training for the auscultatory method included British Hypertension Society (BHS) interactive tutorials and tests (http://www.bhsoc.org/resources/bhs-dvd/), other audiovisual training materials and supervised training. Auscultatory readings were obtained by two independent observers simultaneously by using a Y-tube-stethoscope and were recorded to the nearest 2 mmHg. The two observers were blinded to each other's readings and entered the auscultatory readings independently into an electronic form. An alarm was set in the electronic form when observer disagreement from the simultaneous auscultatory reading exceeded 4 mmHg and the measurement had to be repeated. The maximum number of measurement repetitions due to observer disagreement was two, otherwise measurements in that particular participant had to be discontinued. A series of 9 sequential same-arm BP measurements was aimed for in each participant starting with the standard mercury sphygmomanometer. 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 and these time limits were monitored with a software programmed for this study.

The analysis was based on BP measurement pairs as outlined in the ESH-IP2 protocol.[3] Each Datascope measurement was compared to the nearest of the previous and next mercury sphygmomanometer measurement (mean from the two simultaneous observer readings). Only participants with three valid measurement pairs were included. IBM SPSS Statistics version 20, SPSS Inc. was used for analyses.

Results

The analysis was based on 315 measurement pairs from 105 participants (Table 1). The mean observer difference for auscultatory BP was -0.08±1.8 mmHg for SBP and -0.13±2.0 mmHg for DBP. Mean SBP and DBP were higher by the old-protocol than by the new-protocol and the difference increased with BP and AC (Table 2). Mean systolic difference (Datascope-new-protocol minus standard-mercury-old-protocol) was -3.50±4.91 mmHg for optimal SBP, -6.38±5.78 mmHg for prehypertensive SBP and -11.89±7.23 mmHg for hypertensive SBP (diastolic -1.91±5.03 mmHg, -6.75±5.93 mmHg and -7.61±5.20 mmHg). More than one third of hypertensive study participants had device differences in SBP of more than 15 mmHg.

A calibration formula was derived to predict new-protocol SBP and DBP values from old-protocol SBP and DBP values with linear regression models. Parameters considered for the model were old-protocol SBP and DBP respectively, age, sex, pulse pressure (SBP minus DBP) and variables relating to cuffs and AC (cuffs, AC, cuff-width/arm-circumference-ratio CWACR and cuff-length/arm-circumference-ratio CLACR for both devices and their differences (Datascope minus standard mercury)). Parameters with $p<0.05$ were retained in the model. The final models were:

Predicted new-protocol SBP = 17.842 + 0.904*old-protocol-SBP - 1.503*sex – 0.058*age - 0.159*pulse-pressure + 0.230*CWACR-difference (R^2=0.865)

Predicted new-protocol DBP = 5.401 + 0.749*old-protocol-DBP + 1.415*sex + 0.189*pulse-pressure + 0.189*CWACR-difference (R^2=0.742)

Discussion

This study shows that after replacing a standard mercury sphygmomanometer with an automatic oscillometric device in a highly standardized national survey environment disagreement of BP measurement may be much larger than expected from published validation studies.

A validation study of the Datascope Accutorr Plus from 1997 [4] had shown an observer-device agreement of -0.04±7.93 mmHg for SBP and 0.35±5.75 mmHg for DBP. The criteria of the Association for the Advancement of Medical Instrumentation (AAMI, mean difference ≤5 mmHg and SD ≤8 mmHg) and BHS criteria (Grade A both for SBP and DBP, i.e. absolute difference within 5 mmHg in ≥60% of measurement pairs, within 10 mmHg in ≥85% and within 15 mmHg in ≥95%) were fulfilled. A second validation study in adults from 2003, [5] focused on hypertensive and hypotensive subjects and on subjects with small ACs had largely similar results to the first one. The device was chosen for national health surveys in Germany in 2002 based on a clinical review with recommendatios of the European Society of Hypertension.[6]

In our study, which replicates our national health survey environment and follows the ESH-IP2 protocol, mean measurement difference increased with BP from 3.5 mmHg in normotensive to 12 mmHg in hypertensive participants. Several reasons may have contributed to this surprising disagreement: 1) differences between the device-specific cuffs, 2) residual differences between the standardization in a validation laboratory and a highly-

standardized national survey environment and 3) difficulties in replicating validation results from one and a half decades ago. Of note, in previous validation studies only mean agreement was very good but SDs were large. Agreement was not presented stratified by BP and Bland-Altman plots suggested higher disagreement with higher BP.

One difference of our study and previous validation studies is the use of different cuff sizes for each device. Maintaining identical bladder sizes and identical cuff-selection-rules over decades of national health surveys has proved impossible since manufacturer-provided cuff-sizes changed frequently and cuff-selection rules had to be adjusted to current guidelines. However, the main contributors to measurement disagreement were BP level and pulse pressure. This has been reported before [7, 8] but it is not pointed out in validation studies. Protocols for validation studies do not require reporting of stratified results for different BP levels.

A major limitation of our study is that recruitment in the high BP and high age range was difficult and did not reach ESH-IP2 recommendations. Therefore, calibration of severely hypertensive measurements (≥160/110 mmHg) with the calibration formula from this study relies on fewer measurements and is likely to be less robust than calibration of lower BPs. In addition, the correction formulas presented here are only valid for the device studied in combination with the cuff studied, which is a rare combination. However, the variables in the formulas are likely to be relevant for similar studies, in particular cuff-related variables and

pulse pressure, which have not been considered in the development of previous correction formulas.[9, 10] Of note, validation studies have shown that oscillometric devices can over- or underestimate BP depending on the specific device (www.dableducational.org). The influence of device-related and cuff-related measurement differences can add or can attenuate each other.

In summary, our study reaffirms that prior to replacing the mercury device completely old mercury readings and new oscillometric readings should be compared in the specific setting.[11] Lower agreement may be suspected in particular if there is a concurrent change of cuffs, if the validation studies are older (i.e. the device algorithm could have changed in the meantime), as well as in populations with hypertension and with comorbidities associated with increased pulse pressure like diabetes or renal insufficiency.

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Table 1 Characteristics of the study population

	n unless stated otherwise	% of measurement pairs
Total screened	110	
Measurement series incomplete	5	
Observer disagreement	0	
Recruitment in low BP range complete	0	
Arrhythmias	0	
Withdrawal of informed consent	0	
Total completed (Total/Women/Men)	105 / 65 / 40	
Total measurement pairs (Total/Women/Men)	315 / 195 / 120	100 / 62 / 38
Age 20-40/40-60/60+ years	48 / 50 / 7	46 / 47 / 7
Proportion with BP lowering drugs	15	14.3
Arm circumference (mean ± SD)	29.3 ± 3.6	
Old-protocol-mercury		
small bladder 8x20 cm for AC < 20 cm	0	0
medium bladder 12x28 cm for AC 20-40 cm	103	98.1
large bladder 14x40 cm for AC > 40 cm	2	1.9
AC small bladder group (mean ± SD)	0	
AC medium bladder group (mean ± SD)	29.1 ± 3.2	
AC large bladder group (mean ± SD)	40.8 ± 3.0	
SBP mean ± SD	121.7 ± 16.1	
DBP mean ± SD	72.7 ± 10.4	
Pulse pressure min/max/mean ± SD	26 / 78 / 49.0 ± 10.8	
CWACR (in %) min / max / mean ± SD	31 / 55 / 42 ± 5	
CLACR (in %) min / max / mean ± SD	73 / 127 / 97 ± 11	
New-protocol-Datascope		
small bladder 10.6x23.9 cm for AC 21.0- 27.9 cm	22	21.0
medium bladder 13.5x30.7 cm for AC 28.0- 35.9 cm	79	75.2
large bladder 17.0x38.6 cm) for AC 36.0-46.0 cm	4	3.8
AC small bladder group (mean ± SD)	25.1 ± 1.5	
AC medium bladder group (mean ± SD)	30.0 ± 2.3	
AC large bladder group (mean ± SD)	39.3 ± 1.7	
SBP mean ± SD	116.1 ± 14.0	
DBP mean ± SD	69.4 ± 9.2	
Pulse pressure min/max/mean ± SD	18 / 74 / 46.6 ± 9.3	
CWACR (in %) min / max / mean	36 / 53 / 45 ± 3	
CLACR (in %) min / max / mean ± SD	82 / 120 / 101 ± 8	

AC: arm circumference; CWACR: cuff-width to arm-circumference ratio;
CLACR: cuff-length to arm-circumference ratio

Table 2 Agreement between old-protocol-standard-mercury and new-protocol Datascope measurements

			Difference old-protocol-mercury minus new-protocol-Datascope (mmHg)				
	n	(%)	mean +- SD (mmHg)	p	% with ≤5 mmHg	% with ≤10 mmHg	% with ≤15 mmHg
SBP old-protocol-mercury	315		-5.7 ± 6.3	0.000	52.1	78.1	92.4
optimal (<120 mmHg)	162	51	-3.5 ± 4.9	0.000	66.7	90.7	98.8
prehypertensive (120-139 mmHg)	108	34	-6.4 ± 5.8	0.000	44.4	75.9	94.4
hypertensive (>=140 mmHg)	45	14	-11.9 ± 7.2	0.000	17.8	37.8	64.4
close to hypertension threshold (135-145 mmHg)	40	13	-7.8 ± 6.2	0.000	37.5	65.0	90.0
DBP old-protocol-mercury	315		-3.3 ± 5.7	0.000	65.7	89.2	96.2
optimal (<80 mmHg)	230	73	-1.9 ± 5.0	0.000	73.9	95.2	98.3
prehypertensive (80-89 mmHg)	67	21	-6.8 ± 5.9	0.000	44.8	74.6	91.0
hypertensive (>=90 mmHg)	18	6	-7.6 ± 5.2	0.000	38.9	66.7	88.9
close to hypertension threshold (85-95 mmHg)	37	12	-6.2 ± 5.9	0.000	48.6	73.0	94.6
SBP by arm circumference	66	21	-1.5 ± 3.6	0.002	84.8	98.5	100
< 28 cm	237	75	-6.8 ± 6.3	0.000	43.5	73.0	90.7
28-35.9 cm	12	4	-7.6 ± 7.5	0.011	41.7	66.7	83.3
>36 cm							
DBP by arm circumference	66	21	-1.3 ± 5.4	0.055	80.3	93.9	97.0
< 28 cm	237	75	-3.7 ± 5.7	0.000	62.9	88.2	96.2
28-35.9 cm	12	4	-5.9 ± 5.5	0.007	41.7	83.3	91.7
>36 cm							
SBP by old-protocol-mercury pulse pressure							
1st tertile pulse pressure (<45 mmHg)	129	41	-3.2 ± 5.1	0.000	65.1	89.9	99.2
2nd tertile pulse pressure (45-56 mmHg)	113	36	-5.1 ± 5.2	0.000	57.5	84.1	97.3
3rd tertile pulse pressure (>56 mmHg)	73	23	-10.9 ± 6.6	0.000	41414	47.9	72.6
DBP by old-protocol-mercury pulse pressure							
1st tertile pulse pressure (<45 mmHg)	129	41	-4.2 ± 5.4	0.000	62.0	89.1	95.3
2nd tertile pulse pressure (45-56 mmHg)	113	36	-3.4 ± 5.5	0.000	67.3	90.3	95.6
3rd tertile pulse pressure (>56 mmHg)	73	23	-1.4 ± 6.0	0.060	69.9	87.7	98.6