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How should we measure blood pressure? Implications of the fourth blood pressure measurement in office blood pressure

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Abstract

According to the European Hypertension Guidelines regarding office blood pressure measurements (OBPMs), the mean between second/third or third/fourth OBPM should be taken if the first two readings differ by ≤10 or >10 mmHg, respectively. Our aim was to explore the value of the fourth OBPM and determine whether a simplified OBPM procedure is feasible without loss of quality. In this cross-sectional study, four standard OBPMs were taken. The mean of the second/third OBPM (S2S3/D2D3) and third/fourth OBPM (S3S4/D3D4) for systolic/diastolic values was calculated. Correlation, agreement, and differences regarding BP classification were explored for the entire cohort and subsets with a difference between the first/second OBPM (S1S2/D1D2) ≤10 and >10 mmHg. Overall (n = 802) and for the subsets with an S1S2 (n = 596) and D1D2 (n = 742) difference ≤10 mmHg, S3S4/D3D4 was in median 0.5 mmHg lower than S2S3/D2D3, respectively (p < .0005 for all). In participants with an S1S2 (n = 206) and D1D2 (n = 60) difference >10 mmHg, S3S4/D3D4 differed numerically from S2S3/D2D3, respectively (p > .1 for all). Overall and for all subsets with an S1S2/D1D2 difference ≤10/>10 mmHg, less subjects were numerically classified as hypertensive with S3S4/D3D4 than with S2S3/D2D3 (p > .04), but BP reclassification occurred in both directions in 1.0%-10.0%, depending on the cohort. In conclusion, the third/fourth OBPM results in lower BP values than the second/third measurement, regardless of the difference between first/second OBPM, whereby BP reclassifications occurred in both directions. Therefore, the cutoff of >10 versus ≤10mmHg difference between first/second OBPM to implement a fourth BPM harbors the risk of distorted results. We therefore recommend using the second/third BPM for standardized OBPM.

Trial registration: Registered on clinicaltrials.gov (NCT02552030).

1 | INTRODUCTION

Worldwide, arterial hypertension (AHT) is the most prevalent modifiable risk factor for cardiovascular, cerebrovascular, and renal disease, as well as their associated morbidity and mortality.[1] Recently published guidelines allow the use of office blood pressure measurements (OBPM) for the diagnosis and therapy monitoring of AHT.[2,3] However, these guidelines differ largely in their proposed OBPM procedures.[4,5] In addition, different OBPM procedures have been used in previous clinical hypertension studies which in fact

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deviate from the recommended guidelines.[6] For both clinical and research purposes, the correct and comparable determination of blood pressure (BP) at the individual and the population level is crucial.[4-6] Further, it is important for both physicians and patients that the measurement method is easy to implement. Finally, the same OBPM method should be used in clinical practice as in the studies in which the evidence for diagnosis and treatment of AHT is generated.

According to the latest European Society of Cardiology/European Society of Hypertension (ESC/ESH) Guidelines, one has to decide upon the difference between a first and a second measurement (≤10 mmHg versus >10 mmHg) if the mean between the second and third or the third and fourth measurement should be used as OBPM, which may reduce longitudinal comparability and lead clinicians to misinterpretations.[2] The aim of the current study was to explore whether a fourth measurement adds any incremental value and to define a more easily applicable OBPM method based on the 2018 ESC/ESH Guidelines.[2]

2 | METHODS

2.1 | Patient recruitment and blood pressure measurement procedure

Between September 2015 and February 2016, patients at the Department of Internal Medicine and the Department of Obstetrics and Gynaecology at the University Hospital Basel (inpatient and outpatient units) were consecutively included for OBPM in the context of the iPARR Trial (iPhone App compared with standard RR measurement). This study was an observational cross-sectional, single-center trial, as described previously.[6] Standard operating procedures (SOPs) for OBPM were strictly applied in a single-visit setting. Participants rested in a sitting position with their back and arm supported, legs uncrossed, in a quiet room for five minutes. Then, four standard OBPMs were taken by an operator using an adequately sized upper arm cuff with an Omron-HBP-1300 device,[7] with two minutes between each measurement. Only participants with four complete measurements were included in the final analysis.

2.2 | Calculation of blood pressure values

In the current analysis, we used the four BP measurements (BPMs) taken from each participant during the iPARR trial to calculate different systolic and diastolic BP values (Figure 1). These values consisted of the mean of the second BPM and the third BPM for systolic (S2S3) and diastolic (D2D3) values and the mean of the third BPM and fourth BPM for systolic (S3S4) and diastolic (D3D4) values. According to ESC/ESH, based on the absolute difference between the first and the second measurements (absolute S1S2 and D1D2 difference, respectively) ≤10 mmHg versus >10 mmHg the mean between second and third (S2S3/D2D3) or between third and fourth measurements (S3S4/D3D4) were designated as ESH-BP (Figure 1A,B).[2] Systolic and diastolic BP values were separately analyzed. Therefore, if a participant, for example, had a difference of >10 mmHg between S1S2 but ≤10 mmHg between D1D2, we designated S3S4 as the systolic ESH-BP (sESH) and D2D3 as the diastolic ESH-BP (dESH).

2.3 | Classification of arterial hypertension

All calculated BP values (S2S3, S3S4, D2D3, D3D4) were classified as normotensive or hypertensive. A systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg was regarded as hypertensive, all other values as normotensive.[2] Systolic and diastolic values were classified separately.

2.4 | Statistical analyses

Continuous data were reported as mean ± standard deviation (SD) if normally distributed or otherwise as median (interquartile range (IQR)). The Shapiro-Wilk test was used to test for normality. We tested for association using the related-samples Wilcoxon signed-rank test, for differences using the Bland-Altman plots, and for linearity by creating scatterplots. We ran an exact McNemar's test in case of ≤25 discordant pairs and a McNemar's test with continuity correction in case of >25 discordant pairs to determine whether there were differences in BP classifications with either procedure. An alpha level of 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 22 and R version 3.6.0.

2.5 | Ethical study approval and trial registration

This trial was approved by the local ethics committee (EKNZ 2015-287) and was compliant with the Declaration of Helsinki, and all participants provided written informed consent. The trial was registered on clinicaltrials.gov (NCT02552030). Anonymized data supporting the findings of this study are available from the corresponding author upon reasonable request.

3 | RESULTS

3.1 | Baseline characteristics

Complete measurements were available in 802 participants. Baseline characteristics are shown in Table 1.[5]

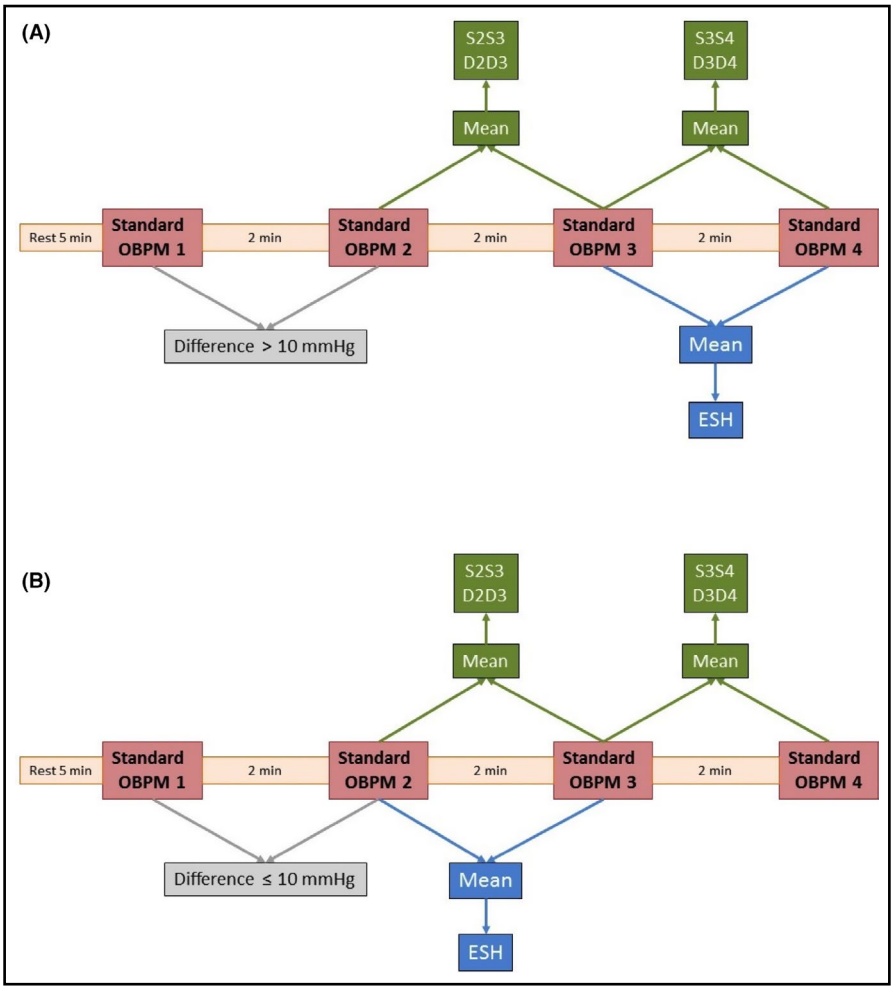

FIGURE 1 Procedure for calculation of BP values and labeling according to ESH: panel A: Difference between the first and second OBPMs >10 mmHg; panel B: difference between the first and second OBPMs ≤10 mmHg

3.2 | Office blood pressure measurements according to ESC/ESH Guidelines

3.2.1 | Systolic values

Overall, median sESH was 123.0 (IQR 112.5–134.5) mmHg. For those 206 participants with an absolute S1S2 difference >10 mmHg, median sESH was 124.5 (IQR 114.0–136.5) mmHg, and for the 596 participants with an absolute S1S2 difference ≤10 mmHg, median sESH was 122.5 (IQR 111.6–133.5) mmHg. Figure S1A shows a smooth density plot demonstrating sESH ranges for participants with an absolute S1S2 difference >10 mmHg (78–175 mmHg) and for participants with an absolute S1S2 difference ≤10 mmHg (86–201 mmHg), respectively.

3.2.2 | Diastolic values

Overall, median dESH was 79.0 (IQR 72.0–87.0) mmHg. For those 60 participants with an absolute D1D2 difference >10 mmHg, median dESH was 80.3 (IQR 73.1–87.5) mmHg, and for the other 742 participants with an absolute D1D2 difference ≤10 mmHg, median dESH was 78.5 (IQR 72.0–87.0) mmHg. Figure S1B shows a smooth

TABLE 1 Baseline characteristics

Parameter	Overall *n* = 802 (%)
Age, years (IQR)	46.5 (32.0–61.0)
Female sex	412 (51.4)
Arterial hypertension	261 (32.5)
Diabetes mellitus	88 (11.0)
Coronary artery disease	88 (11.0)
Congestive heart failure	40 (5.0)
Obstructive sleep apnea	33 (4.1)
Chronic kidney disease	52 (6.5)
Peripheral artery disease	14 (1.7)
TIA/stroke	34 (4.2)

Abbreviations: *N*, number of participants; IQR, interquartile range; TIA, transient ischemic attack.

TABLE 2 Median difference, median absolute difference, and number of participants with an absolute BP difference <5, <10, and <15 mmHg between S3S4 and S2S3, and D3D4 and D2D3, respectively, for the entire cohort, participants with an absolute S1S2 or D1D2 difference >10 mmHg, and an absolute S1S2 or D1D2 difference ≤10 mmHg

	S3S4 versus S2S3			D3D4 versus D2D3		
	Entire cohort (n = 802)	S1S2 difference >10 mmHg (n = 206)	S1S2 difference ≤10 mmHg (n = 596)	Entire cohort (n = 802)	D1D2 difference >10 mmHg (n = 60)	D1D2 difference ≤10 mmHg (n = 742)
Median difference, mmHg (IQR)	−0.5 (−3.0 to 1.5)	0.0 (−3.5 to 2.5)	−0.5 (−3.0 to 1.5)	−0.5 (−2.0 to 1.5)	−1.0 (−4.3 to 2.5)	−0.5 (−2.0 to 1.0)
Median absolute difference, mmHg (IQR)	2.5 (1.0–4.5)	3.0 (1.0–6.0)	2.0 (1.0–4.0)	1.5 (0.5–3.0)	3.3 (1.5–7.0)	1.5 (0.5–2.5)
Absolute difference <5 mmHg, n (%)	627 (78.2)	134 (65.0)	493 (82.7)	729 (90.9)	39 (65.0)	690 (93.0)
Absolute difference <10 mmHg, n (%)	775 (98.6)	195 (94.7)	580 (97.3)	785 (97.9)	50 (83.3)	735 (99.1)
Absolute difference <15 mmHg, n (%)	797 (99.4)	202 (98.1)	595 (99.8)	793 (98.9)	55 (91.7)	738 (99.5)

Abbreviations: BP, blood pressure; IQR, interquartile range.

density plot demonstrating dESH ranges for participants with an absolute D1D2 difference >10 mmHg (49–109 mmHg) and for participants with an absolute D1D2 difference ≤10 mmHg (49–126 mmHg), respectively.

3.3 | Correlation of blood pressure values

3.3.1 | Systolic values

We compared the S3S4 BP values to the S2S3 BP values in all participants (n = 802). Overall, the S3S4 BP value (median 122.0 mmHg, IQR 112.0–134.5 mmHg) was in median 0.5 mmHg lower compared to S2S3 (median 123.0 mmHg, IQR 112.5–135.0 mmHg) (z = −4.517, P < .0005). The number of participants with an absolute BP difference between S3S4 and S2S3 of <5, <10 and <15 mmHg is shown in Table 2.

Regarding the 206 participants with an absolute S1S2 difference >10 mmHg, the S3S4 BP value (median 124.5 mmHg, IQR 114.0–136.5 mmHg) did not differ significantly from S2S3 (median 125.0 mmHg, IQR 112.5–137.6 mmHg) (z = −1.36, P = .174).

In the 596 participants with an absolute S1S2 difference ≤10 mmHg, the S3S4 value (median 121.5 mmHg, IQR 111.1–133.5 mmHg) was in median 0.5 mmHg lower compared to S2S3 (median 122.5 mmHg, IQR 111.6–133.5 mmHg) (z = −4.59, P < .0005).

3.3.2 | Diastolic values

We compared the D3D4 BP values to the D2D3 BP values in all participants (n = 802). Overall, the D3D4 BP value (median 78.5 mmHg, IQR 72.0–86.5 mmHg) was in median 0.5 mmHg lower than with D2D3 (median 78.8 mmHg, IQR 72.0–87.1 mmHg), z = −3.76, P < .0005. The number of participants with an absolute difference between D3D4 and D2D3 <5, <10 and <15 mmHg can be found in Table 2.

Regarding the 60 participants with an absolute D1D2 difference >10 mmHg, D3D4 BP value (median 80.3 mmHg, IQR 73.1–87.5 mmHg) did not differ significantly from D2D3 (median 80.3 mmHg, IQR 72.1–91.0 mmHg), z = −1.11, p = .269.

In the 742 participants with an absolute D1D2 difference ≤10 mmHg, the D3D4 BP value (median 78.5 mmHg, IQR 72.0–86.1 mmHg) was in median 0.5 mmHg lower compared to D2D3 (median 78.5 mmHg, IQR 72.0–87.0 mmHg), z = −3.68, p < .0005.

3.4 | Difference between S2S3/D2D3 and S3S4/D3D4

The Bland-Altman plots of both systolic and diastolic procedures, stratified for the absolute S1S2 difference, are shown in Figure 2. Mean difference and 95% limits of agreement were comparable except for those participants with an absolute D1D2 difference

>10 mmHg, where the limits of agreement were larger (mean difference 1.6 mmHg, 95% limits of agreement mean ± 14.8 mmHg) (Figure 2).

3.5 | Linear relationship between blood pressure values

Scatterplots show a linear relationship between S3S4 and S2S3 in all participants (R^2 = 0.944, p < .0005; Figure S2A), in participants with an absolute S1S2 difference >10 mmHg (R^2 = 0.918, p < .0005; Figure S2B), and in participants with an absolute S1S2 difference ≤10 mmHg (R^2 = 0.953, P < .0005; Figure S2C), and further between D3D4 and D2D3 over the entire cohort (R^2 = 0.911, p < .0005; Figure S2D), over those with an absolute D1D2 difference >10 mmHg (R^2 = 0.694, p < .0005; Figure S2E) and over those with an absolute D1D2 difference ≤10 mmHg (R^2 = 0.968, p < .0005; Figure S2F).

3.6 | Blood pressure classification

3.6.1 | Systolic values

Of a total of 802 participants, 150 (18.7%) were classified as hypertensive based on S2S3. Using S3S4 reduced the number of participants classified as hypertensive to 137 (17.1%) (p = .043) due to 11 participants (1.4%), who were classified as normotensive with but hypertensive with S3S4, and 24 participants (3.0%) classified as hypertensive with S2S3 but normotensive using S3S4 (Figure 3A, column 1).

In the 206 participants with an absolute S1S2 difference >10 mmHg, 47 (22.8%) were classified as hypertensive using S2S3. Using S3S4, the number of participants classified as hypertensive decreased to 41 (19.9%) (p = .210) due to 5 participants (2.4%) who were classified as normotensive with S2S3 but hypertensive with S3S4, and 11 participants (5.3%) classified as hypertensive with S2S3 but normotensive using S3S4 (Figure 3A, column 2).

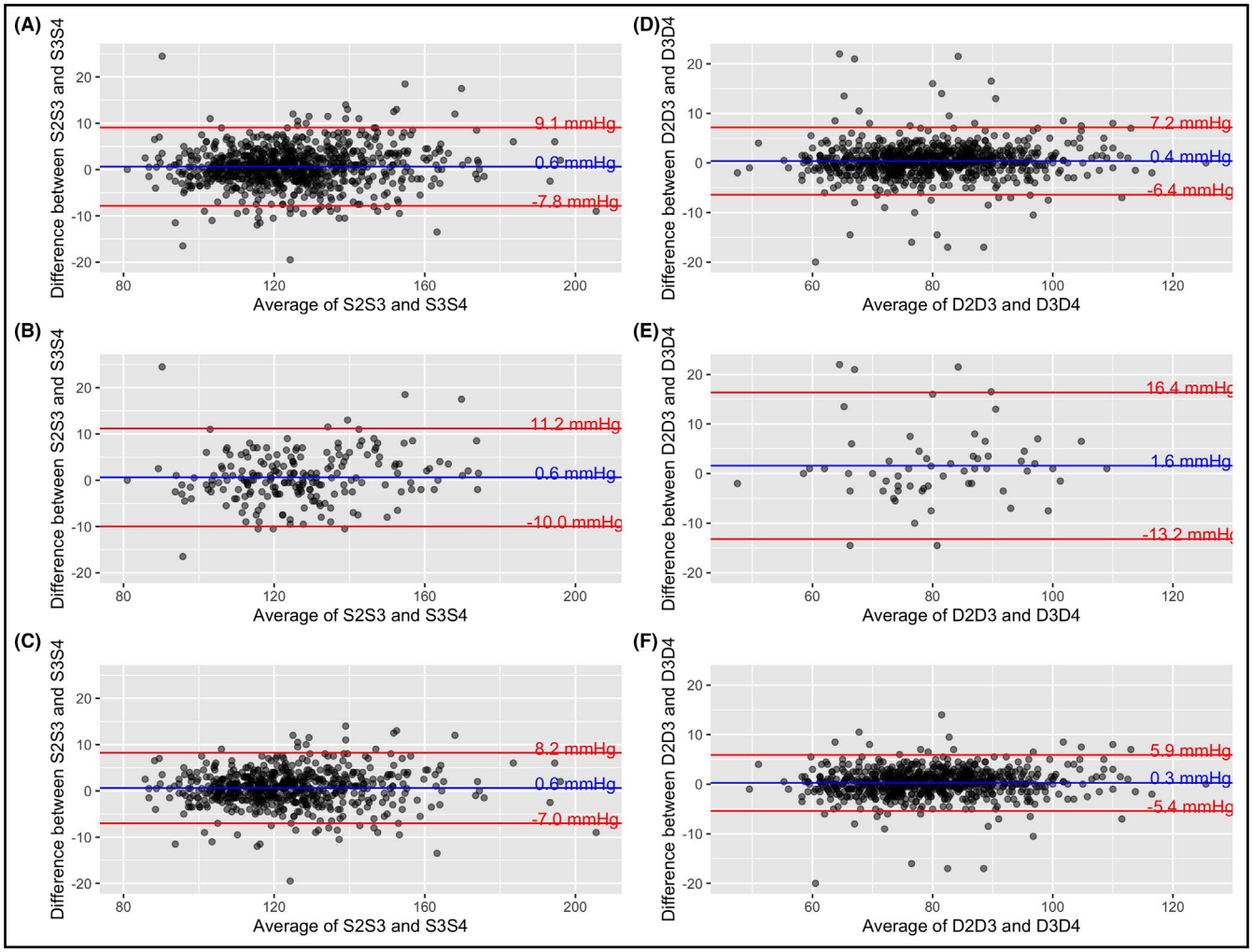

FIGURE 2 Bland-Altman plots comparing the difference between S3S4 and S2S3 (panels A–C) and D3D4 and D2D34 (panels D–F). Displayed are comparisons of S3S4 and S2S3 for the entire cohort (panels A), for participants with an absolute S1S2 difference >10 mmHg (panel B), for participants with an absolute S1S2 difference ≤10 mmHg (panel C), comparisons of D3D4 and D2D3 for the entire cohort (panel D), for participants with an absolute D1D2 difference >10 mmHg (panel E), and for participants with an absolute D1D2 difference ≤10 mmHg (panel F)

In the 596 participants with an absolute S1S2 difference ≤10 mmHg, 103 (17.3%) were classified as hypertensive using S2S3. Using S3S4, the number of participants classified as hypertensive decreased to 96 (16.1%) (p = .167) due to 6 participants (1.0%) who were classified as normotensive with S2S3 but hypertensive with S3S4, and 13 participants (2.2%) classified as hypertensive with S2S3 but normotensive using S3S4 (Figure 3A, column 3).

3.6.2 | Diastolic values

Of a total of 802 participants, 146 participants (18.2%) were classified as hypertensive based on D2D3. Using D3D4 reduced the number of participants classified as to 139 (17.3%) (p = .324) due to 15 participants (1.9%) who were classified as normotensive with the D2D3 but hypertensive with D3D4, and 22 participants (2.7%) classified as hypertensive with D2D3 but normotensive using D3D4 (Figure 3B, column 1).

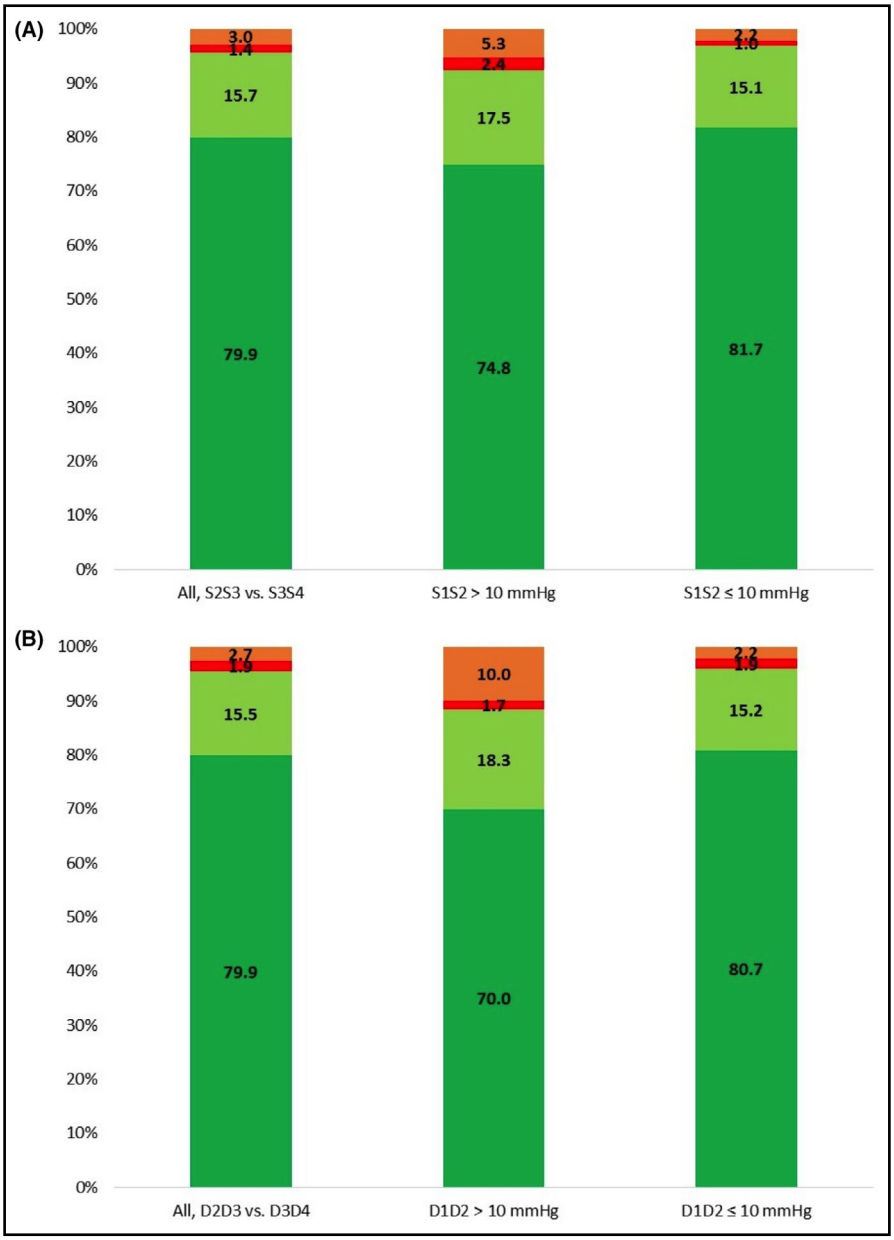

FIGURE 3 BP classifications in % for systolic (panel A) and diastolic (panel B) BP values. Dark green: S2S3/D2D3 and S3S4/D3D4 classified as normotensive; light green: corresponding S2S3/D2D3 and S3S4/D3D4 classified as hypertensive; red: S2S3/D2D3 classified as normotensive and corresponding S3S4/D3D4 classified as hypertensive; and orange: S2S3/D2D3 classified as hypertensive and corresponding S3S4/D3D4 classified as normotensive. S1S2: absolute difference between first and second systolic blood pressure measurements. D1D2: absolute difference between first and second diastolic blood pressure measurements. BP: blood pressure

In the 60 participants with an absolute D1D2 difference >10 mmHg, 17 participants (28.3%) were classified as hypertensive using D2D3. Using D3D4, the number of participants classified as hypertensive decreased to 12 (20.0%) (p = .125) due to 1 patient (1.7%) who was classified as normotensive with D2D3 but hypertensive with D3D4, and 6 participants (10.0%) classified as hypertensive with D2D3 but normotensive using D3D4 (Figure 3B, column 2).

In the 742 participants with an absolute D1D2 difference ≤10 mmHg, 129 participants (17.4%) were classified as hypertensive using D2D3. Using D3D4, the number of participants classified as hypertensive decreased to 127 participants (17.1%) (p = .855) due to 14 participants (1.9%) who were classified as normotensive with D2D3 but hypertensive with D3D4, and 16 participants (2.2%) classified as hypertensive with D2D3 but normotensive using D3D4 (Figure 3B, column 3).

4 | DISCUSSION

In the age of evidence-based medicine, both BPM procedures and BP thresholds used in daily clinical practice should ideally be derived from clinical trials. Likewise, a uniform, easily applicable, and highly reproducible BPM procedure should be used in clinical trials, which is easily transferable into clinical practice.[8] Examples of highly reproducible forms of BPM are ambulatory blood pressure measurements (ABPMs) and automated office blood pressure measurements (AOBPMs). However, for practical reasons standard OBPM will continue to be used in clinical trials and clinical medicine over the next years. The two most important current guidelines for arterial hypertension, the ESC/ESH Guidelines and the ACC/AHA Guidelines, recommend clear procedures for OBPM; however, they lack data on which these procedures are based on.[2,3]

The 2018 ESC/ESH Guidelines recommend the following procedure: "Three BP measurements should be recorded, 1–2 min apart, and additional measurements only if the first two readings differ by >10 mmHg. BP is recorded as the average of the last two BP readings".[2] The ESC/ESH recommendation leaves several questions unanswered. If there is a difference >10 mmHg in either the first or the second systolic or diastolic measurement, but not both, which mean should be used, that is, the mean of the second and third or the mean of the third and fourth measurements? If a patient shows a difference >10 mmHg only inconsistently over several consultations, should we use one calculation method over all consultations, or should we switch between the mean of a second and third and a third and fourth measurements on basis of each measurement session? To our knowledge, this question has never been studied, and this ESC/ESH procedure has never been used in a study setting.

The alternative ACC/AHA Guidelines state "use an average of ≥2 readings obtained on ≥2 occasions to estimate the individual's level of BP."[3] Comparing these two procedures results in largely different BP values and classifications, as we have previously shown.[5] We are only aware of one study having applied the ACC/AHA procedure, the Systolic Hypertension in the Elderly Program (SHEP) trial.[9] As this procedure is hard to implement in studies or clinical practice as it is very time-consuming, we focused on the ESC/ESH procedure.[2]

In the current study, we found that S3S4/D3D4 results in lower BP values than S2S3/D2D3. This held true across the entire cohort and—at least numerically—for both subgroups, that is, for participants with an absolute difference >10 mmHg as well for participants with an absolute difference ≤10 mmHg between the first and second BP measurements. The systematic difference between BP values calculated as S2S3/D2D3 and S3S4/D3D4 is further highlighted by the clear linear relationship between S2S3/D2D3- and S3S4/D3D4-derived values. Application of S3S4/D3D4 instead of S2S3/D2D3 resulted in a relevant number of BP reclassifications in both directions, meaning that participants who were hypertensive with S2S3 could become normotensive with S3S4 and vice versa. This again applied to the whole cohort, as did to the two subgroups with an absolute S1S2/D1D2 difference of >10 mmHg and ≤10 mmHg, although, due to the small number of cases, the difference was partly only numerically ascertainable.

S3S4/D3D4 is on average systematically lower than S2S3/D2D3, as our data showed. This fact leads to bias, if S3S4/D3D4 is only used in specific situations, that is, if there is an absolute difference of >10 mmHg between the first and the second OBPMs as proposed by the ESC/ESH Guidelines.[2] Strictly speaking would a patient with an S2S3/D2D3 of 141/91 mmHg and an S3S4/D3D4 of 138/88 mmHg receive a diagnose of hypertension, or an adaption of treatment, as applicable, if his S1S2/D1D2 difference was ≤10 mmHg, but not if it were >10 mmHg, though the difference between S2S3/D2D3 and S3S4/D3D4 is equally likely in both situations. This potential bias may arise in every clinical visit mixing up both forms of calculation.

In clinical trials, the implementation of the ESC/ESH procedure would lead to bias in longitudinal and cross-sectional settings as the use of S3S4/D3D4 leads with a certain probability to a lower BP value regardless of the arbitrary threshold of an absolute S1S2/D1D2 difference ≤10 and >10 mmHg and both measurements would be mixed up in the study population.

In conclusion, the use of two different BP mean values based on an arbitrary algorithm makes it difficult to interpret the data both in a cross-sectional and particularly in a longitudinal setting.

The next question that arises is whether we should systematically use S2S3/D2D3 or S3S4/D3D4 as the documented OBPM? This question is still unanswered and outcome data are lacking. Clearly, the difference between S2S3/D2D3 and S3S4/D3D4 may be relevant in an individual patient. However, over the entire cohort the difference is clinically only marginally significant, with a median difference of 0.5 mmHg for both systolic and diastolic values.

The available data do not justify deciding whether S2S3/D2D3 or S3S4/D3D4 should be used based on an absolute S1S2/D1D2 difference of >10 versus ≤10 mmHg. The current guidelines may lead to distortion of hypertensive grades on an individual and population level

without recognizable benefit. Therefore, we recommend using BP values based on S2S3/D2D3 in all patients. This procedure is easy to implement, to standardize in everyday clinical practice, and ensures good comparability of the generated data at the individual and the population level as well between clinical studies. This is also supported by the fact that this suggested OBPM procedure has already been used in several recent clinical trials[10-14] and large epidemiological studies[15,16] and has been recommended in a recent hypertension guideline.[17]

4.1 | Limitation

There is no longitudinal data that could show us what influence the differently obtained data have on the outcome. This applies to both our study and the ESC/ESH Guidelines due to the lack of epidemiological or clinical study data.

5 | CONCLUSION

We propose using the mean of a second and third standardized OBPMs as a universal BPM procedure for use in clinical trials and daily clinical practice if OBPM is preferred over automated or ambulatory blood pressure measurements.

DECLARATION OF INTERESTS

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Dr AS Vischer contributed to the conception and design of the study; acquisition, analysis, and interpretation of the data; drafted the manuscript; critically revised the manuscript; and gave final approval for the manuscript. Dr T. Socrates contributed to the acquisition and analysis of the data; drafted the manuscript, critically revised the manuscript; and gave final approval for the manuscript. Dr C. Winterhalder contributed to the acquisition of the data; critically revised the manuscript; and gave final approval for the manuscript. Dr J. Eckstein contributed to the design of the study; acquisition of the data; drafted the manuscript; critically revised the manuscript; and gave final approval for the manuscript. Dr M. Mayr contributed to the acquisition, analysis, and interpretation of the data; critically revised the manuscript; and gave final approval for the manuscript. Dr T. Burkard contributed to the conception and design of the study; acquisition, analysis, and interpretation of the data; drafted the manuscript; critically revised the manuscript; and gave final approval for the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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