Evaluation of interarm blood pressure differences using the Microlife WatchBP Office in a clinical setting

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Objective **The aim of this study was to evaluate the usefulness of Microlife WatchBP Office and the effect of increasing the number of measurements in the clinical evaluation of systolic interarm difference (IAD).**

Patients and methods **Office blood pressure was measured simultaneously on both arms in 339 patients (85% diabetic) using the Microlife WatchBP Office, a fully automatic, oscillometric device. The patients included were all scheduled for ambulatory blood pressure measurement at the outpatient clinic of endocrinology at Silkeborg Regional Hospital, Denmark. Two successive sets of three individual measurements were made. A statistical analysis of variance was carried out on the measurements.**

Results **In the first set of measurements, the mean IAD was −0.3 mmHg and the prevalence of IAD greater than or equal to 10 mmHg was 9.1%. Only 7.6% of the patients with an IAD less than 10 mmHg in the first set of measurements had an IAD greater than or equal to 10 mmHg in the second set of measurements. The 95% limits of agreement for the mean IAD for a single set of three measurements were ±13.16 mmHg. The probability of detecting an IAD more than 10 mmHg only increased slightly with an increasing number of measurements.**

Conclusion **A single set of triplicate measurements using Microlife WatchBP is an acceptable method for evaluating IAD as more measurements do little to improve the probability of detecting an IAD more than 10 mmHg because of high intraindividual variation.** ***Blood Press Monit*** **00:000–000**

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Introduction

Bilateral measurements at the initial blood pressure (BP) evaluation are recommended by current guidelines to identify a possible significant interarm difference (IAD) in BP [1,2]. A systolic IAD less than 10 mmHg is widely considered a normal physiological variation. Several studies have shown a high prevalence (9.5–19.6%) in IAD greater than or equal to 10 mmHg [3,4]. If significant IAD is detected, the arm with the highest BP should be used for future evaluation, both at home and for ambulatory blood pressure monitoring (ABPM) [1,5,6]. However, IAD measurements are characterized by poor reproducibility both between measurements performed at the same visit and for measurements performed on separate days [7,8]. Although guidelines of international hypertension societies recommend bilateral measurements, there is no consensus with respect to which technique should be used for IAD assessment [1]. Two different automated devices are used widely for simultaneous BP measurements in clinical studies [9–11]. However, even the use of two different devices may introduce bias because of interdevice differences or measurement delays, and also if the two devices are of the same type. Moreover, it is time-consuming and cumbersome to use two monitors simultaneously or a single monitor sequentially. The current guidelines recommending bilateral measurements are therefore widely disregarded in clinical practice. Recently, the Microlife WatchBP Office device was introduced. This device is capable of performing simultaneous, triplicate BP measurements in both arms using a single BP monitor [12,13].

As Microlife WatchBP Office is a single device capable of measuring BP simultaneously in both arms, the risk of bias is reduced. The aim of this study was therefore to evaluate the usefulness of Microlife WatchBP Office to detect systolic IAD in a clinical setting and the effect of increasing the number of measurements.

Patients and methods

Office BP was measured simultaneously on both arms in 339 patients using Microlife WatchBP Office (Microlife

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AG, Widnau, Switzerland). The patients included were all scheduled for ABPM at the outpatient clinic of endocrinology at Silkeborg Regional Hospital, Denmark. The BP was measured just before mounting the ABPM monitor as part of the routine clinical set-up. Five experienced clinical nurses performed the measurements. The circumferences of the upper arms were measured and the appropriate cuff-sizes were selected according to the manufacturer's instructions. Both arms were placed on armrests at the same horizontal level and the cuffs were attached. Before the measurements commenced, the patient sat in a chair in a quiet room with both feet on the ground. Then, the device measured three simultaneous BPs in both arms at 15 s intervals. The device provided the mean of three systolic and diastolic BPs separately for both arms. After the first set of measurements, the device was activated again and a new set of three measurements was obtained. We present data from 339 consecutive patients investigated in the period from 1 April 2013 to 31 March 2015. As the investigation formed part of a routine clinical set-up, and the study is based on retrospective chart reviews, no patient consent was required before performing the measurements.

Statistical analysis

Data distribution was tested using Q–Q plots. Differences between measurements were assessed using paired *t*-tests and are presented as mean values ± SD of the difference. A two-tailed *P*-value of less than 0.05 was considered significant. Agreement between IADs was assessed by Bland–Altman analysis [14].

Statistical analysis was carried out using the statistical software SPSS, version 20 (IBM Corp., Armonk, New York, USA).

To evaluate the association between the number of BP measurements and the accuracy of the IAD assessment, the BP data were analysed using a variance component model with side and time as fixed effects and three variance components plus one additional error (residual) component. The variance components were (a) random variation between the individual levels (interindividual variation), (b) random variation of repeated measurements over time for each individual and (c) random variation between the sides for each individual. From this variance component model, the SD on a single measurement of the IAD for a given individual can be computed as: $\mathrm{SD(IAD)}=\sqrt{2s_s^2+2s_E^2}$, where s_s denotes the SD on the random variation between sides and s_E denotes the SD on the error component. More generally, the SD on the average of k repeated measurements of the IAD for a given individual could be computed as: $\mathrm{SD}\overline{(\mathrm{IAD})}=\sqrt{2s_s^2+2s_E^2/k}$. From these SDs, 95% limits of agreement (LoA) on the IAD can be computed for different numbers of BP measurements.

Results

A total of 339 patients participated in this study. The patient characteristics are listed in Table 1. The majority of the patients were men with type 2 diabetes.

The mean BP and IAD are listed in Table 2. Systolic and diastolic BP was higher in the first than in the second set of measurements on both arms. No significant IADs were observed, except for the fact that diastolic BP was slightly higher on the right arm in the second set of measurements. Systolic IAD was not associated with mean BP (Fig. 1). As can be seen in Fig. 2, the difference between the first and the second assessment of IAD was not correlated to the mean difference.

Of the 339 patients investigated, 31/26/5 (9.1/9.0/9.8%) (overall/diabetics/nondiabetics) had a systolic IAD greater than or equal to 10 mmHg in the first set of measurements. Overall, 10/9/1 (2.9/3.1/2.0%) patients had a systolic IAD greater than or equal to 15 mmHg and 3/3/0 (0.9/1.0/0%) patients had a systolic IAD greater than or equal to 20 mmHg. The distribution of IADs for the first set of measurements is shown in the histogram in Fig. 3.

In the second set of measurements, 40/34/6 (11.8/11.8/11.8%) patients had a systolic IAD greater than or equal to 10 mmHg, 10/10/0 (2.9/3.5/0%) patients had a systolic IAD greater than or equal to 15 mmHg and 3/3/0 (0.9/1.0/0%) patients had a systolic IAD greater than or equal to 20 mmHg.

Of the 31 patients with a systolic IAD of 10 mmHg or more in the first set of measurements, 17/15/2 (5/5.2/3.9%) patients also had an IAD greater than or equal to 10 mmHg in the second set of measurements. Only one patient had an inverse IAD in the second set of measurements (−12 mmHg in the first set of measurement and 4 mmHg in the second set) (Fig. 4). Of the 308 patients with IAD less than 10 mmHg in the first set of measurements, 23/19/4 (7.5/7.3/8.7%) patients had a systolic IAD greater than or equal to 10 mmHg in the second set of measurements. The difference between the first

Table 1 Patient characteristics

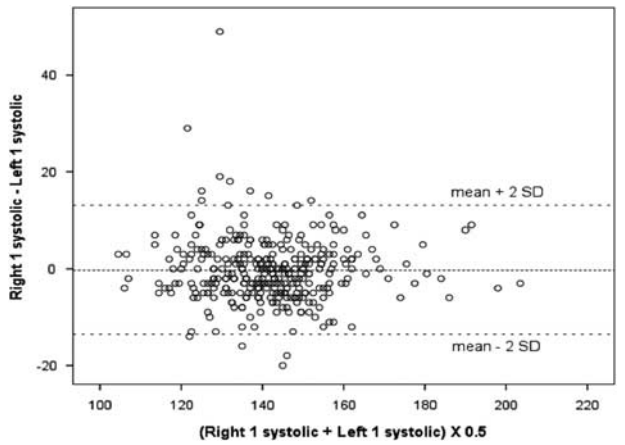
Variables	*n* (%)
n	339
Age [mean ± SD] (years)	58.8 ± 12.6
Male	224 (66.1)
Diabetes	288 (85)
No diabetes	51 (15)
Type 1	82 (24.2)
Type 2	200 (59.0)
Other types	6 (1.8)
Diabetes duration [mean ± SD] (years)	15.1 ± 12.4
Arm circumference [mean ± SD] (cm)	31.4 ± 4.2

Table 2 Blood pressure and interarm differences in the two sets of measurements

	Right (mmHg)	Left	Right−left	*P*
Systolic blood pressure				
First	141.7±15.0	142.0±15.2	−0.3±6.6	0.47
Second	137.2±14.3	137.1±15.1	0.1±6.8	0.73
First−second	4.5±5.4*	4.8±5.3*	−0.4±4.9	0.14
Diastolic blood pressure				
First	82.9±10.2	82.5±10.0	0.3±4.4	0.17
Second	81.7±10.5	80.8±10.5	0.9±4.9	0.001
First−second	1.2±3.8*	1.7±4.5*	−0.5±4.5	0.03

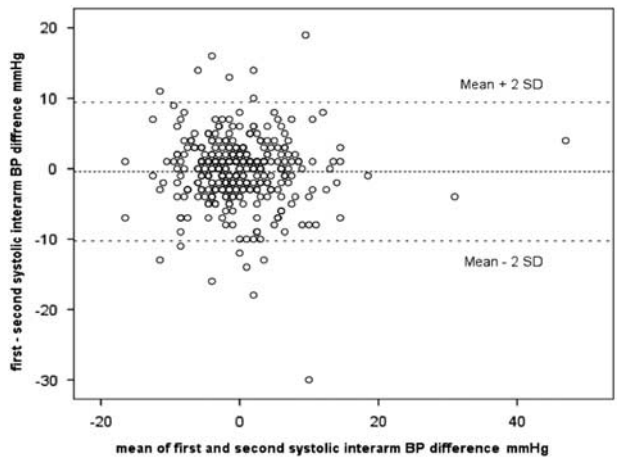
*First–second, $P < 0.001$.

Fig. 1



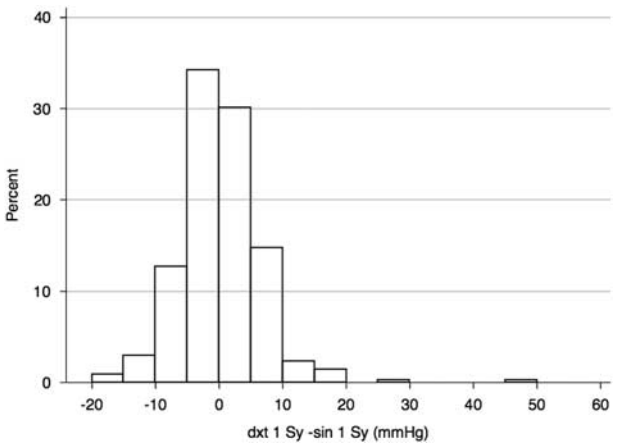
Bland–Altman plot of the interarm difference versus the mean systolic blood pressure. The horizontal lines represent the mean difference −0.26±13.3 mmHg.

Fig. 2



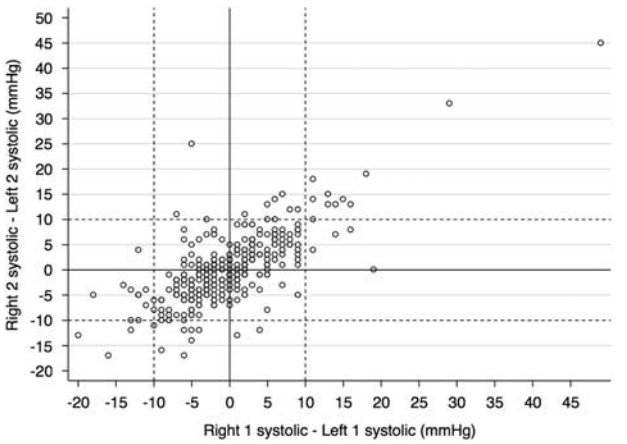
Bland–Altman of plot of the difference between the first and the second interarm difference in systolic blood pressure versus the mean difference. The horizontal lines represent the mean difference −0.39±9.85 mmHg.

Fig. 3



Histogram showing the frequency of differences in systolic blood pressure between the right and the left arm in the first set of measurements.

Fig. 4



Scatterplot of interarm differences in the two sets of blood pressure measurements.

and the second systolic IAD (first difference − second difference) was not significant (−0.39±4.93 mmHg, $P = 0.13$). The difference between the patient groups has not been tested as the study is not powered to investigate any difference between groups.

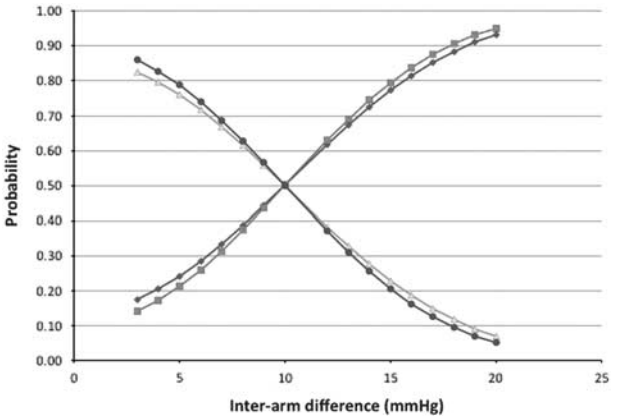
The 95% LoA for the mean IAD was determined for different numbers of measurements. As can be seen from Table 3, increasing the number of measurements had only a limited effect on the 95% LoA.

Figure 5 shows the probability of observing an IAD greater than or equal to 10 mmHg for a range of different fixed 'true IADs' as well as the probability of measuring an IAD less than 10 mmHg, given a fixed 'true' IAD.

Table 3 SD and 95% limits of agreement in relation to different numbers of blood pressure measurements

Number of measurements, Microlife	Number of individual measurements	SD	95% limits of agreement (1.96 × SD)
1	3	6.71	13.16
2	6	6.24	12.24
3	9	6.08	11.91
4	12	5.99	11.75
5	15	5.94	11.65
6	18	5.91	11.58
7	21	5.89	11.53

Fig. 5



The graph presents the probability of finding an IAD more than 10 mmHg (◆ = one set of measurements, ■ = three repeated sets of measurements) and the probability of finding an IAD between −10 and 10 mmHg (▲ = one set of measurements, ● = three repeated sets of measurements), given a fixed 'true IAD'. Example: If the 'true' IAD is 7 mmHg, the probability that the measured IAD is more than 10 mmHg or less than −10 mmHg is 33% for one comparison and 31% for three comparisons measured. The probability that a measured IAD is in the interval between −10 and 10 mmHg is 67 and 69%, respectively.

Curves for both a single set of triplicate measurements as well as for three repeated sets of triplicate measurements are shown. As can be seen, the curves are almost identical. Tables showing the probabilities used in Fig. 5 are provided in the Supplementary Data, (Supplemental digital content 1, *http://links.lww.com/BPMJ/A30*).

Discussion

Correct techniques for measuring BP are essential for the diagnosis and treatment of hypertension. International guidelines recommend using the arm with the highest BP for future BP measurements if an IAD of 10 mmHg or more exist. Furthermore, it is recommended to refer patients with IAD of 20 mmHg to evaluation for vascular abnormalities. In our study, we have evaluated a technique for detecting an IAD. Detection of an IAD of 10 mmHg or more is important to ensure that the correct arm is being used for BP measurements. Using the wrong arm, that is, the arm with the lowest BP could result in misclassification of hypertensive patients as normotensive or result in insufficient pharmacological treatment and vice versa.

The main findings in the present study are a prevalence of 9.1% for systolic IAD greater than or equal to 10 mmHg in the first set of measurements and a prevalence of 7.6% of patients with an IAD less than 10 mmHg in the first set of measurement with an IAD greater than or equal to 10 mmHg in the second set of measurements. There is no apparent difference between patients with diabetes and patients without diabetes; however, no test of significance was performed.

Another main finding was that increasing the number of measurements does not improve the probability of finding an IAD greater than or equal to 10 mmHg.

The overall IAD prevalence is in agreement with the previously reported prevalence in both diabetic and nondiabetic patients [4,9].

To the best of our knowledge, we are the first to use a statistical model to estimate the probability of finding an IAD greater than or equal to 10 mmHg and to investigate how that probability changes with an increasing number of repeated measurements. Even with simultaneous, automated BP measurements, a wide LoA was observed. Increasing the number of measurements (k) only results in a minor improvement in the LoA as the intraindividual variance component is unrelated to k, which is evident from the formula $\mathrm{SD}(\overline{\mathrm{IAD}}) = \sqrt{2s_s^2 + 2s_E^2 / k}$. A single set of triplicate bilateral measurements using Microlife WatchBP Office therefore seems to be an appropriate method for the initial evaluation of IAD.

The suggestion of using a single set of measurements is in agreement with Clark *et al.* [10], who suggested an initial set of sequential measurements to screen for IAD in diabetic patients. In their study, Clark and colleagues used two different devices to obtain four sets of simultaneous measurements. We used a single device for our simultaneous measurements and we incorporated a statistical model that we believe increases the level of confidence with which this recommendation can be provided.

In previous studies investigating IAD, manual and automated devices, as well as simultaneous and sequential measurements have been used [15,16]. A recent meta-analysis comparing automated and manual devices as well as simultaneous and sequential measurements [15] found a higher prevalence of IAD more than 10 mmHg when manual devices (relative risk 4.4 vs. 2.1) were used than when automated devices were used. The study also found a higher prevalence of IAD more than 10 mmHg with sequential measurements than with simultaneous measurements (relative risk 4.4 vs. 2.2). Another study comparing the Microlife WatchBP Office

with a manual device [16] found a higher mean IAD (4.9 vs. 3.8 mmHg), a higher SD (4.1 vs. 3.1 mmHg) and a higher prevalence of IAD more than 20 mmHg (9 vs. 3%) when the manual device was used; all differences were statistically significant.

Therefore, the method used in this study, a single device capable of performing automated, simultaneous measurements, seems to be the most accurate method for evaluating IAD.

We observed a significant difference between the first and the second set of measurements on both arms. This is consistent with previous studies [8], and could be a result of a white-coat effect and adaptation to measurements. However, IAD did not relate to the level of BP and the difference between repeated measurements of IAD was unrelated to the level of the difference.

Strengths and limitations

One strength of the present study was the use of a device capable of performing simultaneous measurements automatically, whereby operator bias was eliminated. Another strength is the number of patients included in our study.

In the present study, we performed two sets of three bilateral measurements. The number of measurements could potentially be a source of concern. It has been shown previously that the IAD prevalence decreases with increasing number of measurements [7]. However, our calculations show that increasing the number of measurements does little to improve the probability of detecting an IAD more than 10 mmHg.

The vast majority of our patients had diabetes. The results therefore may not be applicable in other populations.

The measurements were performed in immediate succession in line with a typical clinical set-up. Therefore, the day-to-day variation and reproducibility could not be determined in the present study.

This study showed a consistent, low mean IAD in the two sets of measurements, and it showed that IAD was unrelated to the level of BP. We also showed that repeated measurements improved the probability of detecting an IAD more than 10 mmHg only marginally because of the intraindividual variation in BP between sides. Therefore, the use of a single automatic device capable of performing bilateral measurements simultaneously is a clinically feasible approach for detecting a difference in systolic BP between arms more than 10 mmHg, and for informing the clinician's choice of arm to be used for BP measurement in a routine clinical setting.

Acknowledgements

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Conflicts of interest

There are no conflicts of interest.

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