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Baseline check of blood pressure readings of an automated device in severe pre-eclampsia and healthy normotensive pregnancy

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Abstract

Objective—The baseline blood pressure (BP) readings of an automated device that have not been validated in pregnancy require comparison with those from a reference standard before the device is utilized in pregnancy. We aimed to perform a baseline check of BP readings of an automated device, Mindray iMEC12 patient monitor, in severe pre-eclampsia and healthy pregnancy.

Study design—The BP of 50 severe pre-eclamptic and 90 normotensive pregnancies were measured using Mindray iMEC12 patient monitor (test device) and Welch Allyn 767 aneroid sphygmomanometer (reference device). A pass in either the International Organization for Standardization (ISO) or British Hypertension Society (BHS) rating was considered acceptable. The cumulative percentage of absolute BP difference between the test and reference devices within 5, 10 and 15mmHg were calculated to rate the test device according to the BHS grades (A, B, C or D). The ISO recommends that an accurate device should achieve a mean BP difference $\pm$ SD of 5 ± 8 mmHg.

Results—The mean BP difference between the test and reference devices were 1.27 ± 7.51 mmHg and 0.05 ± 6.09 mmHg for systolic and diastolic BPs respectively. The test device achieved the BHS grades B and A rating in systolic and diastolic BPs respectively. In each of the 2 groups (pre-eclamptic and normotensive pregnancies), the test device also satisfied the set pass criteria.

Conclusions—In settings that do not have a validated BP device, Mindray iMEC12 patient monitor may be used for BP measurement in normotensive and severe pre-eclamptic pregnancies.

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Conflicts of interest
None.

Keywords

Accuracy validation; Baseline check; Blood pressure device; iMEC12 patient monitor; Pre-eclampsia; Pregnancy

1. Introduction

A blood pressure (BP) monitoring device is an important tool in the management of hypertension. The accuracy of the device is usually established through approved validation processes [1–6]. Due to the hemodynamic changes in normal and pre-eclamptic pregnancies, automated BP devices also require validation in these patient populations. The hemodynamic changes in normal pregnancy include altered arterial wall compliance. This altered arterial wall compliance is much more pronounced in pre-eclampsia (PE) [7, 8] and may be worse in severe PE. Automated BP devices are therefore prone to inaccuracy because they utilize oscillometric pulses from the arterial wall which are dependent on the vessel wall reactivity [9].

Nonetheless, many of the available automated BP devices have not undergone any validation process [10, 11]. The lack of validation of these monitors is a major concern given that automated BP devices are replacing mercury sphygmomanometers. Therefore, automated devices that have not been validated in PE may underestimate [12] or overestimate BP recordings [13, 14].

The Royal College of Obstetricians and Gynaecologists (RCOG) recommends that when a non-validated automated BP device is used in women with PE, a baseline validation check should be performed using a mercury sphygmomanometer, or another automated device already validated for use in PE [15]. The Society of Obstetricians and Gynaecologist of Canada (SOGC) in their guidelines on management of PE also recommends that a non-validated BP device has to be compared at the outset with either the BP readings from an aneroid or mercury sphygmomanometer [14]. Unfortunately, neither the SOGC nor RCOG guidelines provide details on how to perform a baseline comparison between two BP devices. Additionally, there is scarcity of literature that explains how the baseline check should be performed. Due to the risk of mercury toxicity, the routine use of mercury-containing sphygmomanometers are no longer in favour [16]. Therefore, this type of device may not be available in some health facilities to be used as a reference device. On the other hand, an aneroid sphygmomanometer is a robust auscultatory device and a good replacement for the mercury-containing device but requires regular calibration [17]. Given that automated devices are prone to inaccuracy especially in PE [7], a new and calibrated aneroid sphygmomanometer is a good reference device that may be used for a baseline comparison. The aim of this study, therefore, was to perform a baseline check of BP readings of an automated device, iMEC12 patient monitor (Shenzhen Mindray Bio-Medical Electronics Co., Ltd) [18] in normotensive pregnancy and severe PE to assess the accuracy of the test device. The 767-series mobile aneroid sphygmomanometer (Welch Allyn® Inc) on a 5-leg stand [19] was used as the reference device. In this report, the authors also propose a guideline on how to conduct a baseline check of BP readings of an automated BP device.

2. Methods

The study was conducted in 2015 in a regional hospital in South Africa and received regulatory (ethical and institutional) approval (reference BE236/14). Written informed consent was obtained from each participant prior to recruitment. During the data collection period, one of the most commonly used automated BP devices at the study site was the Mindray iMEC12 patient monitor, and the authors decided to perform a baseline check of the BP readings from the device. The Mindray iMEC12 patient monitor (test device) had a valid calibration status according to the manufacturer's recommendations [18]. A new and calibrated 767-series mobile aneroid sphygmomanometer (Welch Allyn® Inc) on a 5-leg stand was used as the reference device. The aneroid device maintained its calibration at the end of the study. Importantly, the accuracy of 767-series mobile aneroid sphygmomanometer has been confirmed in previous studies [20, 21].

Women with severe PE and healthy normotensive pregnancies were included in the study. PE was defined as new-onset hypertension (BP $\geq$ 140/90 mmHg) after 20 weeks gestational age with significant proteinuria, and or either maternal organ dysfunction or uteroplacental insufficiency [22]. Severe PE were cases complicated by any of diastolic BP $\geq$ 110mmHg, systolic BP $\geq$ 160 mmHg, HELLP syndrome, platelet count $<$ 100 000/ μ l, impending eclampsia, pulmonary oedema, cardiac failure, fetal growth restriction, 24 hours proteinuria $\geq$ 3g/dl, more than twice the normal values of serum liver enzymes (transaminases) and or serum creatinine [23, 24].

The BP of each research participant was measured using the Mindray iMEC12 and the aneroid sphygmomanometer. Each device was used to measure the BP of a participant twice, and the average of both measurements recorded as the BP of the patient according to the South African guidelines on hypertension [25]. The sequence of use of the BP devices in successive participants was alternated. In all even numbered participants, the BP was measured firstly using the automated device and later with the aneroid machine. In all odd numbered participants, BP was measured initially with the aneroid sphygmomanometer and subsequently with the automated device. Each participant's BPs were measured from the same arm preferably the left, in a sitting position with the feet resting on the floor. The time interval between the BP measurements was at least 30 seconds apart but did not exceed one minute. This 30 to 60 seconds interval between successive BP measurements prevents venous congestion and BP variability [26]. The mid-upper arm circumference was measured using standard technique [27]. The length of the BP cuff used for each participant was at least 1.5 times the patient's mid-upper arm circumference [14]. A large cuff was used for the BP measurement if the mid-upper arm circumference exceeded 33cm [25, 26, 28]. The position of the cuff on the arm was at the level of the heart [15, 29]. Korotkoff phase 1 and 5 of the aneroid device were used to denote the systolic and diastolic BPs respectively [14]. Two trained medical practitioners measured the BP of the participants. This approach may prevent a recurrent pattern of terminal digit preference error which may occur if a single medical practitioner measures all the BPs. Briefly, this error arises when a medical practitioner that is using an auscultatory device to measure BP unconsciously prefers a particular terminal digit while reading the graduation marks to determine the systolic and diastolic BPs [30]. The BP measurement was repeated after 15 minutes in severe PE (to aid

patient management), and after 15 minutes in normotensive women that had baseline BP elevation above hypertension threshold. To avoid misclassification error, “normotensive” women that had sustained hypertension (BP $\geq 140/90$ mmHg) after a 15 minutes interval were excluded from the study. Women with multiple pregnancies, chronic and gestational hypertension, as well as eclampsia, were also excluded.

2.1. Data analysis

The participants (50 severe PE and 90 normotensive pregnancy) were recruited in a parent study, yet to be published, but aimed at assessing the pre-delivery serum levels of angiogenic factors and BP patterns of the same women. Given that normotensive pregnancy occur more frequently than severe PE, an unbalanced recruitment of 50 severe PE and 90 normotensive participants were calculated to be adequate to detect a medium effect size (Cohen’s $d = 0.50$) [31, 32] difference in BP or angiogenic factor level between the two groups using a student t-test (80% power, 95% confidence interval and 5% α).

Data analysis was performed using IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. In each participant, the systolic BP (SBP) obtained using the Mindray iMEC12 was subtracted from the SBP obtained with the aneroid device. The diastolic BP (DBP) was also subjected to similar analysis. The agreement between the test and reference devices was then assessed by two methods. In the first method, the cumulative percentage of absolute BP difference within 5mmHg, 10mmHg and 15mmHg were calculated to assess SBP and DBP grading of the device according to British Hypertension Society (BHS) guidelines Table 1 [2]. In the second method, all the SBP differences were added together, and the mean of the sum was then calculated. Similar analysis was performed on DBP. The mean differences were interpreted based on the International Organization for Standardization (ISO) recommendation [1] to ascertain if Mindray iMEC12 BP readings are comparable to the aneroid device. The ISO recommends that an accurate device should have a mean difference $\pm$ SD of $\pm 5 \pm 8$ mmHg [1]. Bland Altman plots of the SBP and DBP were constructed to aid visual assessment of the agreement.

3. Results

The clinical details of the participants at recruitment are shown in Table 2. None of the participants had hypotension. Also, none of the normotensive women had a sustained BP $\geq 140/90$ mmHg (≥ 15 minutes) nor did any of them receive antihypertensive therapy. The mean difference in the SBP and DBP are shown in Table 3. The cumulative percentage of absolute BP difference between the test and reference devices within 5, 10 and 15mmHg according to the BHS grades is shown in Table 4. The iMEC12 patient monitor achieved a grade B in systolic BP and a grade A in diastolic BP. Bland Altman plots of the difference in BP (test minus reference device) versus the mean BP of the two devices are shown in Figure 1 (SBP) and Figure 2 (DBP) to depict the agreement between the two measurements.

4. Discussion

The Mindray iMEC12 patient monitor fulfilled the pass criteria derived from both the ISO and BHS. A major implication of this finding is that iMEC12 may be used to monitor BP in

severe PE and healthy normotensive pregnancy in settings that do not have BP devices validated in pregnancy and pre-eclampsia. The hemodynamic changes caused by PE is arguably worse in severe than mild-moderate PE, therefore, the test device may also be accurate in the later. By achieving an overall BHS grades A and B in the SBP and DBP respectively suggest that the device may have higher accuracy in measuring SBP than DBP.

The Food and Drug Administration approved the Mindray iMEC12 patient monitor [33]. The device is an automated device developed based on a technical platform similar to Mindray BeneView T Series patient monitors [33] which the British and Irish Hypertension Society (BIHS) validation services have tested and approved its BP function [34]. Because Mindray iMEC12 is derived from Mindray BeneView T5, the former has been equivalently listed as a device validated for clinical use [34]. Nonetheless, to the best of our knowledge, Mindray iMEC12 is yet to be validated in pregnancy and pre-eclampsia.

Only a few automated BP devices have been validated and approved for use in pregnancy and PE, and examples such as Microlife BP 3AS1-2, Microlife WatchBP Home (BP3MX1-1) and Omron MIT Elite (HEM-7300-WE) are listed in dabl Educational Trust website [35]. The methodology of existing organizational protocols [36] used for validation of BP device are prone to protocol violation [37], complex, and may not be easy to administer in an office setting by a sole medical practitioner that wants to check a non-validated BP device. Regardless, it is appropriate to validate the accuracy of BP devices in different patient population prior to their usage. Manufacturers are therefore strongly advised to support independent validation of their products (BP monitors). Irrespective, many medical practitioners utilize BP devices that are yet to be validated and that have not undergone a baseline check. Possible reason for the use of such devices may include inadequate knowledge about validated BP devices appropriate for a particular patient group, unavailability of a validated device, lack of capacity to subject their device to a validation protocol, and lack of a simple clear-cut instruction on how to conduct a baseline check. Therefore, a simple method on how to perform a baseline check is needed. This is crucial given that complex guidelines are difficult to be implemented. An example of such “complex” guideline that relates to BP measurement which medical practitioners do not adhere to is the use of an average of two to three BP readings to establish the BP level of a patient. While the authors recommend such an approach during BP measurement, it is important to note laudably that approximately 96% of medical practitioners use only a single measurement to determine the BP level [38].

Again, two medical practitioners measured the BP of the participants in the present study. Some investigators justify the use of three medical practitioners to measure the BPs in a validation study [11]. Understandably, the use of more than two medical practitioners to measure the BPs results in additional BP measurements and may improve the opportunity to determine an accurate BP. Nonetheless, one medical practitioner may also measure the BP in a validation study but this may lead to observer bias as well as a pattern of terminal digit preference (when reading the BP values of an auscultatory device) and will also not allow the accuracy of the test device to be assessed with multiple users [26]. However, the effectiveness of using one medical practitioner is that it replicates the approach to BP measurement in a clinic setting [26], and ensures that the same measurement technique will

be applied on every research participant preventing error due to interobserver variability [26, 39]. The later is an argument that supports that a baseline check of BP readings of a device may be undertaken by a single medical practitioner, and this approach have been utilized by other investigators including experts that validated an auscultatory hybrid sphygmomanometer (A&D UM-101) that has a digital display as well as a vertical column displaying mercury-free liquid crystal [26]. The UM-101 (A&D Company, Ltd., Toshima-ku, Tokyo, Japan) [40] has been found to be accurate in normal pregnancy and PE, and may also be a good replacement for mercury sphygmomanometer [26].

Notably, auscultatory BP devices are affected by wear and tear [26]. This is of particular importance in aneroid sphygmomanometers because they measure BP using a lever and bellow system [41]. The bellow has been reported to be made from a thin corrugated brass [42]. The inflation of the cuff expands the bellow and moves the pin/pointer (which rests on the bellow) along the pressure scale [17, 42]. The functioning of these parts may be easily affected by mechanical trauma facilitating loss of calibration over time particularly among portable hand-held aneroid sphygmomanometers. We avoided this limitation by using a new aneroid sphygmomanometer on a 5-leg stand with a valid calibration status at inception and at the end of the study.

The present study has limitations such as unavailability of protocol for conducting a baseline check of BP readings of a device. However, our study design is pragmatic despite the limited availability of comparative literature. Notably, the methods employed in the present study should not be misconstrued as a duplication of existing BP device validation protocols. Rather it is a simple and easy approach that can be utilized to assess a BP device in a setting that do not have validated devices. This approach assists with the provision of quality care to pregnant women. Where resources are available, the authors recommend the use of approved protocols to validate a BP device. Additionally, the effect of antihypertensive therapy on the BP of women with severe PE is an indicated cofounder, and it will be unjust to withhold such treatment.

4.1. Recommendations on how to conduct a baseline BP check of a device

The following is a pragmatic approach on how to conduct the baseline BP check.

- a. Decide on the category of patients/individuals that will be the participants.
- b. Obtain all necessary permissions for the investigation. This is to avoid the use of participants' information for a study without approval.
- c. Explain the methods and obtain consent from each participant.
- d. Recruit as many participants (15) as convenient in each group of patients where the accuracy of the device is to be assessed. Assign a study number to each participant for proper documentation. Notably, the ISO protocol for validation of a BP device in pregnancy/pre-eclampsia recommends that 15 of the participants required in their validation protocol in pregnancy should be pre-eclamptic patients [1]. Similarly, a minimum of 15 participants (from a specific group of patients) for the baseline check may be acceptable. This number of participants may be debatable but pragmatic in the authors' opinion, given that a baseline

check is a simplified “screening” assessment of a BP measuring device. The 15 participants should be representative of the group of patients used for the assessment of the BP device. The classification of BP in pregnancy into normal BP, mild to moderate hypertension (BP 140–159/90–109 mmHg) and severe hypertension (BP > 160/110 mmHg) [22] is simple, known to most obstetricians and should be used as the main basis for participants’ selection during the baseline check of BP device in pregnant women with a hypertensive disorder.

- e. Determine the arm circumference of each participant and select a large BP cuff if the mid-arm circumference is >33cm.
- f. Measure the BP of each participant with the test and reference devices using the selected cuff.
- g. Alternate the order of use of the test and reference devices during BP measurement in each subsequent participant. For instance, measure the BP using the reference device followed by the test device in the first participant. In the second participant, measure the BP with the test device and followed by the reference device, etc.
- h. For each pair of BP (test and reference) obtained from each participant, subtract the reading of the test device from that of the reference device. (a) The difference obtained in the SBP from all participants should be summed up. Calculate the mean and the standard deviation of the differences. Do the same calculation for the DBP. The mean difference should be 5 ± 8 mmHg for the test device to be considered to have passed the baseline BP check. This criterion is derived from the ISO rating [1]. (b) Alternatively, the cumulative percentage of the absolute difference between each pair of measurement (reference and test devices) should at least meet the grade C criteria stated in BHS protocol [2]. A pass in either ISO or BHS rating is acceptable to avoid unwitty declaration that a device is inaccurate before subjecting it to a validation protocol. To ensure brevity and encourage practitioners to check their BP devices before usage, the plotting of Bland-Altman curve is not mandatory.
- i. A device that do not meet the recommended pass criteria may not be used for BP monitoring until it has passed a validation protocol. Devices that pass the baseline check test may be used for BP monitoring in the interim but still has to pass a validation protocol.
- j. Give feedback to the participants and other role players.

5. Conclusion

Among normotensive and pre-eclamptic pregnant women, the BP recordings obtained with the Mindray iMEC12 patient monitor demonstrated agreement with those of the Welch Allyn 767 aneroid sphygmomanometer. Therefore, the Mindray iMEC12 patient monitor may be used to measure the BP of severe pre-eclamptic and healthy normotensive pregnant women if a BP device already validated in these groups is unavailable. Our

recommendations on how to conduct a baseline check of a BP device is pragmatic and a good foundation for future research on this crucial topic.

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Highlights

- Non-validated automated BP monitor require baseline check before usage in pregnancy
- Details of how to conduct a baseline check of a BP monitor are lacking
- Mindray iMEC12 patient monitor is yet to be validated in pregnancy/pre-eclampsia
- Pragmatic and simple method of baseline check of a BP device is proposed
- Mindray iMEC12 patient monitor passed baseline check in pregnancy/pre-eclampsia

Y-axis is difference in SBP (test - reference device); X-axis is mean SBP (test and reference devices)

Fig. 1.
Bland-Altman plot of systolic blood pressure (SBP) in mmHg

Y-axis is difference in DBP (test - reference device); X-axis is mean DBP (test and reference devices)

Fig. 2.
Bland-Altman plot of diastolic blood pressure (DBP) in mmHg

Table 1

Criteria for grading blood pressure measuring devices according to the British Hypertension Society

Grade	Cumulative percentage of the absolute blood pressure (BP) difference between the test and reference device		
	BP difference 5mmHg	BP difference 10	BP difference 15
A	60%	85%	95%
B	50%	75%	90%
C	40%	65%	85%
D	< 40%	< 65%	< 85%

To achieve a particular grade, all the three criteria stipulated in the corresponding row of the BP difference must be attained or exceeded.

Table 2

Profile of the participants at recruitment

Variables	Value	
	Normotensive, n=90	Pre-eclampsia, n=50
Age (years)		
Mean (SD)	28.30 (5.47)	24.86 (6.60)
Gestational age		
Mean (SD)	38.54 (1.54)	34.78(4.76)
Second trimester (13–24 weeks), n	0	2
Second trimester range (low:high)	Nil	(23:24)
Third trimester (> 24 weeks), n	90	48
Third trimester range (low:high)	(35:42)	(24:42)
Body mass index (kgm ⁻²)		
Mean (SD)	33.63 (7.30)	32.22 (6.55)
Mid-upper arm circumference (cm)		
Mean (SD)	31.80 (4.55)	30.39 (4.76)
^a Systolic blood pressure (mmHg), n		
Mean (SD)	113.79 (14.51)	144.40 (18.89)
<139	85	14
140–159	5	23
160	Nil	13
^a Diastolic blood pressure (mmHg), n		
Mean (SD)	69.99 (10.98)	94.64 (13.62)
<89	84	12
90–109	6	28
>110	Nil	10

^a Blood pressure were those obtained with the reference device. The blood pressure groups were based on classification of hypertension in pregnancy into mild to moderate (BP = 140-159/90-109 mmHg) and severe hypertension (BP 160/110 mmHg).

Table 3

Mean difference in blood pressure (test device minus reference device)

Variables	Mean BP difference (standard deviation) in mmHg
All participants (n = 140)	
Automated SBP minus aneroid SBP	1.27 (7.51)
Automated DBP minus aneroid DBP	0.05 (6.09)
Normotensive women (n = 90)	
Automated SBP minus aneroid SBP	1.94 (7.57)
Automated DBP minus aneroid DBP	0.91 (5.89)
Pre-eclamptic women (n=50)	
Automated SBP minus aneroid SBP	0.06 (7.31)
Automated DBP minus aneroid DBP	1.50 (6.19)

Table 4

Cumulative percentage of absolute blood pressure (BP) difference between the test and reference devices that are within 5, 10 and 15mmHg

Patient group	BP difference (mmHg)	Cumulative percentage of absolute BP difference	
		Systolic BP	Diastolic BP
All participants	5	62.14	62.86
	10	85.71	93.57
	15	90.00	97.14
Normotensive	5	56.67	61.10
	10	86.67	94.44
	15	92.22	97.78
Severe preeclampsia	5	72.00	70.00
	10	86.00	92.00
	15	90.00	96.00