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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 15 mmHg 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 ± 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.

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

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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 ≥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 ≥110 mmHg, systolic BP ≥160 mmHg, HELLP syndrome, platelet count < 100,000/μl, impending eclampsia, pulmonary oedema, cardiac failure, fetal growth restriction, 24 h proteinuria ≥3 g/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 s apart but did not exceed one minute. This 30–60 s 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 33 cm [25,26,28]. The position of the cuff on the arm was at the level of the heart [15,29]. Korotkoff phases 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 min in severe PE (to aid patient management), and after 15 min in normotensive women that had baseline BP elevation above hypertension threshold. To avoid misclassification error, "normotensive" women that had sustained hypertension (BP ≥140/90 mmHg) after a 15 min 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 5 mmHg, 10 mmHg and 15 mmHg 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 ± SD of ≤5 ± 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 ≥ 140/90 mmHg (≥15 min) 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 15 mmHg according to the BHS grades is shown in Table 4. The iMEC12 patient monitor achieved a grade B in

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 ≤5 mmHg	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.