

# Accuracy validation of the Microlife 3AS1-2 blood pressure device in a pregnant population with low blood pressure

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**Objective** To assess the accuracy of the Microlife 3AS1-2 blood pressure (BP) device in pregnant women with low BP to investigate suitability for hypotensive detection in low-income and middle-income countries.

**Methods** A prospective observational study was carried out evaluating the Microlife 3AS1-2, a hand-held, upper-arm, semiautomated BP device, according to British Hypertension Society (BHS) protocol methods. Thirty (stable) pregnant women with a clinical systolic BP less than 100 mmHg and/or diastolic BP less than 60 mmHg were recruited from antenatal wards and clinics and their BP was measured by three trained observers at a district-level hospital in South Africa. Accuracy was assessed according to the BHS grading criteria (A/B = pass) and the ANSI/AAMI/ISO standard for mean difference and SD ( $\leq 5 \pm 8$  mmHg).

**Results** The device achieved an A/A grade according to the BHS grading criteria. The mean difference  $\pm$  SD between the observer and the test device was  $0.5 \pm 6.2$  and  $1.3 \pm 5.4$  mmHg for systolic and diastolic BP, respectively, fulfilling the standard required by the ANSI/AAMI/ISO protocol. All observer differences were within 4 mmHg.

## Introduction

Annually, over 500 000 women die during pregnancy and childbirth worldwide [1], and 99% of these deaths occur in low-income and middle-income countries (LMICs) [2]. The four most important contributors to maternal death are obstetric haemorrhage, sepsis, unsafe termination of pregnancy and eclampsia; all except the latter are associated with clinical hypotension [3]. The assessment of each of these conditions is reliant on the measurement of vital signs, including blood pressure (BP), to determine the severity of haemodynamic compromise.

It is recommended that automated BP devices be validated according to a recognized protocol and in the specific populations for which they are intended. This includes pregnancy, a state of altered haemodynamics, upon which the accuracy of oscillometric devices is dependent [4]. The Microlife 3AS1-2 is a hand-held, upper-arm, semiautomated BP device that has been validated for use in a nonpregnant population [5] and in

**Conclusion** According to the BHS protocol, the Microlife 3AS1-2 BP device is accurate in pregnant women with low BP. The device has been validated previously in pregnancy and pre-eclampsia and also fulfils the criteria of the WHO for use in a low-resource setting. Although unstable women were not included in this validation (for safety and pragmatic reasons), this device could potentially improve the detection of shock secondary to obstetric haemorrhage or sepsis, as well as being used in pre-eclampsia, particularly in low-income and middle-income countries. *Blood Press Monit* 20:299–302 Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

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pregnancy (including pre-eclampsia) [6]. It also fulfils the WHO requirements for use in low-resource settings [5].

The British Hypertension Society (BHS) validation protocol for pregnancy requires 30 pregnant women with a wide range of BP, but none are required to have a BP less than 100/60 mmHg [7]. As oscillometry is dependent on arterial wall compliance, the detection of the oscillometric waveform by automated devices may change in altered haemodynamic states, well recognized in hypertension and potentially influenced by hypotension [8]. It is critical to detect low BP to escalate treatment where required, but it is unknown whether oscillometric devices are accurate in hypotension. This study aimed to validate the Microlife 3AS1-2 device in pregnant women with low BP, assessing its accuracy at low pressures such as those observed in obstetric haemorrhage and sepsis.

## Methods

Participants were recruited from the antenatal clinic and wards at Kimberley Hospital Complex (Kimberley, South Africa) over 34 weeks (17 April 2013–12 November 2013). Ethical approval was obtained from the University

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of the Free State Ethical Committee (ETOVS No.66/08) and all participants were required to provide written informed consent. Pregnant women with a clinical systolic BP less than 100 mmHg and/or a diastolic BP less than 60 mmHg and whose clinical situation allowed participation were approached. All participants had an arm circumference within the permitted range of the cuffs (22–42 cm). Any woman with a cardiac arrhythmia or unclear Korotkoff sounds was excluded. Korotkoff sound 5 was used for the identification of diastolic BP.

Participants were seated and allowed to rest for 5 min. The middle upper-arm circumference was measured to determine the correct cuff size to be used. The arm was supported at the woman's approximate heart level. The woman was advised not to talk or move during measurements, but to notify the observers if any symptoms such as arm discomfort were experienced. A gap of between 30 s and 1 min was allowed between readings to reduce venous congestion.

Three trained observers took nine sequential same-arm BP measurements from each participant, alternating between mercury sphygmomanometry and the device. Observers obtaining auscultatory readings used a double-headed teaching stethoscope and calibrated mercury sphygmomanometers and were blinded to each other's readings and to the device readings, obtained by the third observer.

Data were entered on Microsoft Excel (Microsoft Office, Redmond, Washington, USA) and analysed according to the BHS protocol guidelines. The first reading of the mercury sphygmomanometry and device was discarded and the first reading of the first observer was used for classification purposes according to the specified BP range requirements of the protocol, that is, systolic BP less than 100 mmHg or diastolic BP less than 60 mmHg. The subsequent three device readings were then alternately compared with each of the observer's readings 'before' (difference backward) and 'after' (difference forward) for systolic and diastolic pressures, respectively. The best set of differences (lowest absolute values) for each participant was selected, that is, either the set of 'differences forward' or the set of 'differences backward'.

A sample size of 30 women was required, yielding 90 'best' differences for further analysis. To determine whether the device passed the protocol, the percentage of differences in each of three categories specified by the BHS protocol ( $\leq 5$ ,  $\leq 10$  and  $\leq 15$  mmHg) was calculated. The device was required to achieve an A or B grade for both systolic and diastolic BP to be recommended for clinical use (Table S1, Supplemental digital content 1, <http://links.lww.com/BPMJ/A10>) [7]. The device was also required to achieve the standard required by the Association for the Advancement of Medical Instrumentation (ANSI/AAMI/ISO) of having a mean difference  $\pm$ SD of less than or equal to  $5 \pm 8$  mmHg [9,10].

## Results

Thirty women were recruited, of whom 16 were in their second trimester ( $< 27$  weeks' gestation) and 14 were in their third trimester. Each woman completed the study without untoward symptoms. Demographic data are shown in Table 1. All observer measurements agreed within 4 mmHg. The mean difference  $\pm$ SD for observer agreement was  $-0.3 \pm 1.8$  and  $-0.3 \pm 1.7$  mmHg for systolic and diastolic BP, respectively.

The Microlife 3AS1-2 device (Microlife Corp., Taipei, Taiwan) achieved an A/A grade (Table 2), with a mean difference  $\pm$ SD of  $0.5 \pm 6.2$  and  $1.3 \pm 5.4$  mmHg for systolic and diastolic BP, respectively, thereby achieving the BHS protocol and the ANSI/AAMI/ISO protocol standard in pregnant women with a low BP. Mean-against-difference plots are used to graphically illustrate device accuracy by plotting the mean pressure of the better observer and the test device against the difference (Fig. 1) [11].

## Discussion

The Microlife 3AS1-2 BP device achieved an A/A grade, according to the BHS protocol criteria, and fulfilled the ANSI/AAMI/ISO protocol standard for mean difference and SD ( $\leq 5 \pm 8$  mmHg) in pregnant women with low BP. This is the first study to validate a BP device for use at low BP as well as specifically in pregnant women with low BP.

Haemodynamically unstable women were not included in the study as their clinical condition precluded involvement according to the BHS protocol. However, it is likely that those who are clinically shocked will have altered vascular characteristics that may influence the detection of the oscillometric waveform by the BP device. Furthermore, BP measurement may be difficult if the shocked woman is lying supine and is perhaps uncooperative because of poor central perfusion. Thus, although we are reassured about the accuracy of the device in stable women, we cannot be certain of the accuracy in severely compromised women. This limitation is also encountered when validating devices in pre-eclampsia; women for whom severe hypertension must be urgently controlled cannot participate in a validation study, and thus the accuracy of devices at extremes of BP cannot be ensured/guaranteed. It is accepted that pragmatic validation in less severe cases is sufficient to recommend use [7,9]. Furthermore, our intention is for

**Table 1 Demographics of the study population at enrolment**

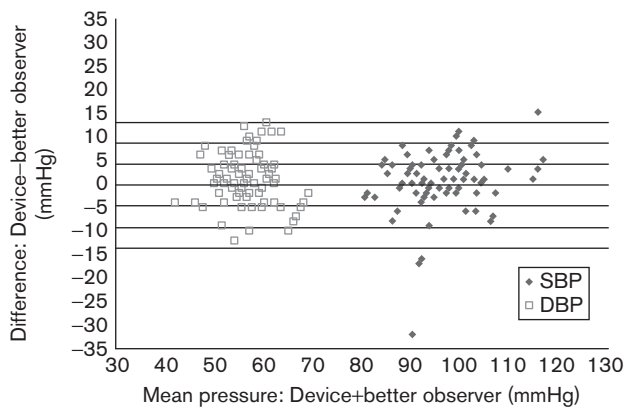
	Mean $\pm$ SD [range]
Age (years)	28 $\pm$ 7 [18–45]
Arm circumference (cm)	25 $\pm$ 4 [22–36]
Systolic blood pressure (mmHg)	98 $\pm$ 8 [86–122]
Diastolic blood pressure (mmHg)	57 $\pm$ 7 [40–72]
Gestational age (weeks)	27 $\pm$ 7 [12–38]
Second trimester : third trimester (n)	16 : 14
Medium cuff : large cuff (n)	27 : 3

**Table 2 Results presented according to the British Hypertension Society protocol (n = 90)**

Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Mean difference ± SD (mmHg)
Cumulative percentage of readings [n/N (%)]				
Observer 1				
SBP	A 65/90 (72)	85/90 (94)	87/90 (97)	0.5 ± 6.2
DBP	A 63/90 (70)	83/90 (92)	90/90 (100)	1.6 ± 5.2
Observer 2				
SBP	A 66/90 (73)	83/90 (92)	89/90 (99)	0.4 ± 6.5
DBP	A 63/90 (70)	83/90 (92)	90/90 (100)	1.3 ± 5.4
Final result				
SBP	A 65/90 (72)	85/90 (94)	87/90 (97)	0.5 ± 6.2
DBP	A 63/90 (70)	83/90 (92)	90/90 (100)	1.3 ± 5.4

Absolute difference between standard and test device.

DBP, diastolic blood pressure; SBP, systolic blood pressure.

**Fig. 1**

Mean-against-difference plot for systolic and diastolic pressures (n = 90). DBP, diastolic blood pressure; SBP, systolic blood pressure.

this device to alert the clinician to initiate management before severe compromise.

Validation protocols stipulate that devices intended for use in pregnancy should be validated in a pregnant population and include a specific number of women who are either hypertensive or pre-eclamptic [7,9,10]. Protocols do not make specific requirements for the inclusion of a certain number of patients with low BP (systolic BP < 100 mmHg or diastolic BP < 60 mmHg) [7,9,10]. It is recognized that pregnant women tend to have lower BP than the general population; a UK prospective longitudinal study reported BP to be lowest at 22 weeks, with a mean systolic BP of 105 mmHg and diastolic BP of 61.3 mmHg [12]. Our validation addresses these lower pressure ranges often encountered in healthy pregnancy, which a standard pregnancy validation would not.

Important contributors towards maternal death are obstetric haemorrhage, sepsis and unsafe abortion, all of which can present with haemodynamic compromise either through hypovolaemic or septic shock [3]. Accurate BP measurement, as well as other vital signs, is crucial for

their timely recognition and management. However, in LMICs, where the majority of maternal deaths occur, healthcare providers may not have access to functioning, let alone accurate BP devices.

Very few automated devices have been validated for use in pregnancy, including pre-eclampsia, and no device has been validated in a population with low BP, particularly low BP in pregnancy. The Microlife 3AS1-2 device has been validated successfully in a nonpregnant population [5], a pregnant population, including pre-eclampsia [6], and now also in pregnant women with low BP. To our knowledge, it is also the first device to be both accurate in pregnancy and suitable for use in low-resource settings [5,6]. Considering the maintained accuracy of Microlife 3AS1-2 over a range of BP in pregnant women and its suitability for use in a low-resource setting, this device would be ideal for LMICs as a vital tool in the drive to prevent maternal mortality.

It is not known whether all validated devices remain accurate at lower BPs. As it is our intention to specifically target women with low BP, given that hypotension is a major contributor to global maternal mortality, we believed it necessary to specifically validate in this population. The principle of validating in any specific population that theoretically may have altered oscillometric characteristics is important. Further work would be needed to establish whether this should be a generic requirement in validation protocols. It is reassuring that the Microlife 3AS1-2 device remains accurate at a low BP.

We are further modifying the Microlife 3AS1-2 device by incorporating a traffic-light early-warning system that alerts community healthcare providers (who may have little formal training) to both hypertension and shock, indicating the need for treatment and/or referral. Shock index, the ratio of heart rate to systolic BP, has been shown to be an earlier predictor of haemodynamic compromise than conventional vital signs in cases of obstetric haemorrhage [13]. Evidence-based shock index thresholds will be used as triggers for the early-warning system [14]. The final device will then be evaluated in a clinical LMIC setting.

## Conclusion

According to the BHS protocol, the Microlife 3AS1-2 BP device is accurate in pregnant women with low BP. The device has been validated previously in pregnancy and pre-eclampsia and also fulfils the criteria of the WHO for use in a low-resource setting. Therefore, this device could potentially improve the detection of shock secondary to obstetric haemorrhage or sepsis, as well as being used in pre-eclampsia, particularly in LMICs.

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### Conflicts of interest

There are no conflicts of interest.

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