An accurate semiautomated oscillometric blood pressure device for use in pregnancy (including pre-eclampsia) in a low-income and middle-income country population: the Microlife 3AS1-2

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Objectives **To assess the accuracy of the Microlife 3AS1-2 blood pressure device in pregnancy and pre-eclampsia in a low-resource setting.**

Methods **Prospective validation according to the British Hypertension Society protocol. A total of 45 pregnant women were recruited from Kimberley Hospital (South Africa), of whom 15 had pre-eclampsia.**

Results **The Microlife 3AS1-2 device achieved an overall B/A grade in pregnancy (including pre-eclampsia), passing the British Hypertension Society protocol requirements and achieving the International Organization for Standardization standard with a mean difference and SD of -3.8 ± 7.3 and -1.5 ± 6.2 mmHg for systolic and diastolic pressures, respectively.**

Conclusion **The Microlife 3AS1-2 device can be recommended for use in pregnancy, including pre-eclampsia. In addition, it fulfils the requirements stipulated by the WHO for an automated blood pressure device suitable for use in a low-resource setting. This makes it the ideal device for antenatal clinics and primary healthcare facilities in low-income and middle-income countries.** ***Blood Press Monit*** **20:52–55**

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Introduction

Hypertension in pregnancy complicates up to 10% of pregnancies [1]. Globally, pre-eclampsia is the second-leading cause of maternal mortality, resulting in an estimated 72 000 maternal deaths annually, 99% of which occur in low-income and middle-income countries (LMICs). The WHO estimates pre-eclampsia contributes to 500 000 perinatal deaths annually [2].

Accurate blood pressure (BP) measurement in pregnancy is essential for early identification and management of pre-eclampsia. Although mercury sphygmomanometry is the 'gold standard', it is subject to inaccuracies including misinterpretation of Korotkoff sounds and observer bias, and requires specific training and skill. In many LMICs, healthcare providers may have limited access to training in the conventional technique, and primary care relies increasingly on a cadre of 'community health workers' who have no formal medical training. Thus, use of automated devices is a more attractive option for many healthcare settings.

It is recommended that BP measurement devices be validated before introduction into clinical practice, to confirm their accuracy. Although more than 400 automated devices have been introduced commercially over the past 25 years, many have not been validated according to internationally recognized protocols. Far fewer have been validated for use in pregnancy and particularly in pre-eclampsia, where studies have shown that the underestimation of BP leads to clinically significant errors and underdetection of the disease [3]. In keeping with recommendations of the British Hypertension Society (BHS) protocol [4], the International Organization for Standardization (ISO) now recommends that devices intended for use in pregnancy should be separately validated [5].

Once validated, devices may still be unsuitable for use in a LMIC setting if they are expensive, fragile, have large power requirements and need to be frequently calibrated. Our group has previously validated the Microlife 3AS1-2, a hand-held, upper-arm, semiautomated oscillometric BP device, suitable for use in LMICs, in an adult nonpregnant population [6]. In this study, we describe the validation of the device in pregnancy and pre-eclampsia.

Methods

Women were recruited from the antenatal ward and clinics at Kimberley Hospital Complex (Kimberley, South Africa). Written informed consent was obtained

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and participants fulfilled the BHS protocol requirements in pregnancy. Fifteen additional pre-eclamptic women were recruited, as recommended by ISO. At least 10 women were in their second trimester, 10 in their third trimester and 12 women had an arm circumference greater than 35 cm. Women were excluded from the study if after three attempts the device failed to produce an oscillometric reading, if the participant had any arrhythmia or if the Korotkoff sounds were too weak to be accurately interpreted.

Three observers, experienced in the performance of validation studies, took nine sequential same-arm BP measurements for each participant using a double-headed teaching stethoscope and alternating between two calibrated mercury sphygmomanometers and the Microlife 3AS1-2 (Microlife Corporation, Taipei, Taiwan). Korotkoff V was used to identify diastolic BP. The observers were blinded to each other's auscultatory readings and to the device readings.

Data were then analysed according to the BHS protocol guidelines. Device readings were alternately compared with each of the observers' readings 'before' (difference backward) and 'after' (difference forward) for systolic and diastolic BPs, respectively, resulting in six calculable differences. The set of differences with the lowest absolute values for each participant was selected as the 'best difference'.

Results

A total of 47 pregnant women were recruited. The first 30 women to fulfil the BHS protocol criteria were selected for analysis, with a subsequent analysis also including 15 pre-eclamptic women. Two women were excluded to fulfil the distribution/BP range criteria. Mean demographic values were: age, 30 years; weight, 81 kg; arm circumference, 31 cm; gestation, 30 weeks; systolic BP, 138 mmHg; diastolic BP, 87 mmHg.

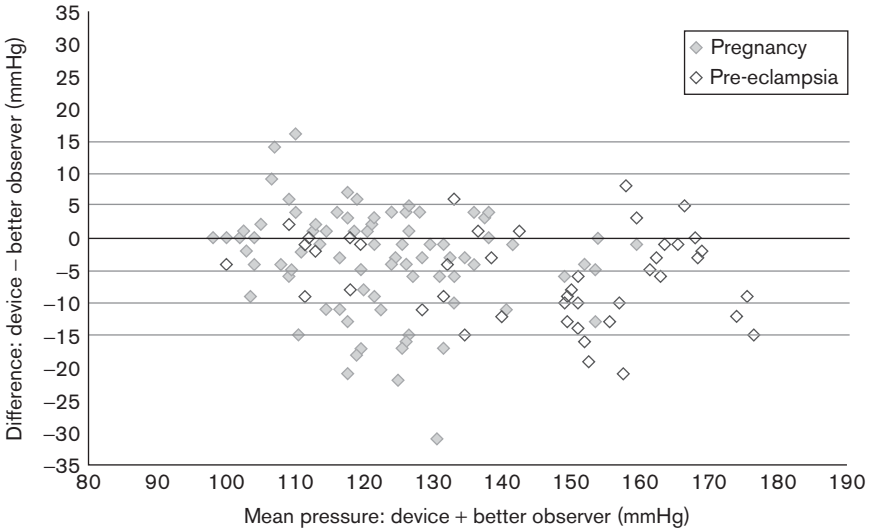
The Microlife 3AS1-2 achieved an overall B/A grade ($n = 45$), with an A/A grade in pregnancy alone ($n = 30$). Mean against difference plots are shown in Figs 1 and 2. The device also achieved the ISO standard for mean difference ± SD ($\leq 5 \pm 8$ mmHg) in pregnancy, including pre-eclampsia (Table 1).

Discussion

The Microlife 3AS1-2 is a semiautomated BP device that can be recommended for use in pregnancy, including pre-eclampsia, according to the BHS protocol. To our knowledge it is the first device to be validated as accurate in pregnancy and to fulfil the WHO requirements for use in low-resource settings. It has low power requirements (because of the manual inflation feature), a large and easily legible LCD display, and can function at extremes of temperatures and high humidity. Its dual function as an auscultatory and oscillometric device allows for accurate use by staff with minimal training while its durability, long battery life and minimal calibration requirements ensure longevity of use. Costing less than 20 Euros, it is comparatively cheap compared with others on the market.

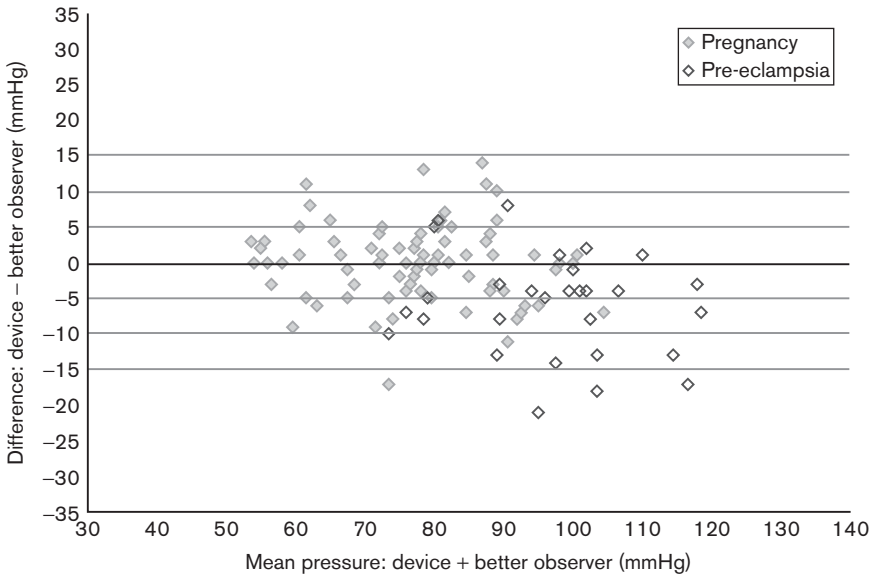
Impaired accuracy of some automated devices at higher BPs, particularly in pre-eclamptic women, may be because of the pathophysiological changes of the disease, including decreased arterial compliance and increased interstitial oedema; these are thought to alter the transmission of the oscillometric waveform, thereby underestimating the true BP. The Microlife 3AS1-2, however

Fig. 1



Mean against difference plot for systolic pressure in pregnancy and pre-eclampsia ($n = 45$).

Fig. 2



Mean against difference plot for diastolic pressure in pregnancy and pre-eclampsia ($n = 45$).

Table 1 Results according to the BHS protocol

	Grade	≤5 mmHg	≤10 mmHg	≤15 mmHg	Mean difference ± SD (mmHg)
Pregnancy ($n = 30$)					
Systolic BP	A	63	86	96	−2.9 ± 7.4
Diastolic BP	A	81	93	99	0.3 ± 5.0
Pregnancy (including pre-eclampsia) ($n = 45$)					
Systolic BP	B	58	82	95	−3.8 ± 7.3
Diastolic BP	A	70	90	97	−1.5 ± 6.2

BHS, British Hypertension Society; BP, blood pressure.

achieves the BHS and ISO protocols standard for use in pre-eclampsia, and therefore can be recommended for use in this high-risk group.

In a high-income setting, most pre-eclamptic women are diagnosed early, through regular antenatal monitoring, allowing them to be managed in an appropriate and timely manner. However, in LMICs, pre-eclampsia is often detected at a late stage because of infrequent antenatal attendance and inaccurate BP monitoring. Research has repeatedly linked adverse outcome to the late detection of hypertensive disorders of pregnancy [7]. The Microlife 3AS1-2 is an ideal device for use in LMICs; further design adaptations currently underway include a traffic light warning system to indicate extremes of BP, and a rechargeability function.

Conclusion

The Microlife 3AS1-2 device can be recommended for use in pregnancy, including pre-eclampsia, according to the BHS protocol. It also fulfils the WHO requirements for an automated device suitable for use in a low-resource setting.

Acknowledgements

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Conflicts of interest

There are no conflicts of interest.

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