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*** **00:000–000 © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

Blood Pressure Monitoring 2014, **00**:000–000

Keywords: blood pressure measurement, British Hypertension Society, International Organization for Standardization, low-resource setting, oscillometric, pre-eclampsia, pregnancy, validation, WHO

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Received 27 March 2014 **Revised** 13 August 2014 **Accepted** 19 August 2014

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,

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DOI: 10.1097/MBP.0000000000000086