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 ± SD between the observer and the test device was 0.5 ± 6.2 and 1.3 ± 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.**

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*** **00:000–000**

Blood Pressure Monitoring 2015, **00**:000–000

Keywords: blood pressure measurement, hypotension, low-resource setting, pregnancy, validation

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Received 19 August 2014 **Revised** 15 April 2015 **Accepted** 18 April 2015

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 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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DOI: 10.1097/MBP.0000000000000134