Background

Globally, pre-eclampsia is the second-leading cause of maternal mortality, resulting in 500,000 maternal deaths annually\(^1\), 99% of which occur in low- and middle-income countries (LMICs)\(^3\). Accurate blood pressure (BP) measurement is essential for early identification and management of pre-eclampsia.

In LMICs, antenatal care increasingly relies on ‘community health workers’ who have no formal medical training. In this setting, the use of automated BP devices is a more attractive option than conventional auscultation of BP.

Few automated devices have been validated for use in pregnancy and those that have, tend to fail in pre-eclampsia, as they underestimate BP in these women. The Microlife 3AS1-2 is a semi-automated oscillometric BP device suitable for use in a low resource setting (insert ref of low resource req).

Aims

To assess the accuracy of the Microlife 3AS1-2 in pregnancy and pre-eclampsia in a low resource setting, according to the British Hypertension Society (BHS) Protocol\(^2\) and the International Organization of Standardization (ISO)\(^4\).

Methods

- 45 pregnant women were recruited from Kimberley Hospital (South Africa), fulfilling the BHS protocol requirements
- 15 of the women were pre-eclamptic, fulfilling ISO recommendations
- Three observers took 9 sequential same-arm BP measurements from each subject using a double-headed stethoscope and alternating between two calibrated mercury sphygmomanometers (Fig 1) and the Microlife 3AS1-2 (Fig 2). The observers were blinded to each other’s readings and to the device readings
- Device readings were alternately compared to each of the observers’ readings ‘before’ and ‘after’, giving two sets of 3 differences each for systolic and diastolic BP respectively.
- The set of differences with the lowest absolute values was selected as the ‘best difference’ and analysed according to the BHS and ISO protocol criteria.

Results

Table 1. Results according to the BHS protocol

<table>
<thead>
<tr>
<th>Grade</th>
<th>20mmHg</th>
<th>10mmHg</th>
<th>5mmHg Mean difference ± SD (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy (n=30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>A</td>
<td>63</td>
<td>86</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>A</td>
<td>81</td>
<td>93</td>
</tr>
<tr>
<td>Pregnancy (incl. pre-eclampsia (n=45)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>B</td>
<td>58</td>
<td>82</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>A</td>
<td>70</td>
<td>90</td>
</tr>
</tbody>
</table>

SD – standard deviation

Mean demographic values: 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) (table 1). The device also achieved the ISO standard for mean difference ± standard deviation (± 5 ± 8 mmHg) in pregnancy, including pre-eclampsia. Mean against difference plots are shown in Figures 3 and 4.

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Conclusion

The Microlife 3AS1-2 BP device can be recommended for use in pregnancy, including pre-eclampsia, according to BHS and ISO protocols.

In LMICs, pre-eclampsia is often detected late due to infrequent antenatal attendance and inaccurate BP monitoring.

To our knowledge this is the first BP device to be validated as accurate in pregnancy and to fulfill the WHO requirements for use in low-resource settings\(^5\), making it the ideal device for use in antenatal clinics and primary health-care facilities in LMICs. We are further modifying the device to include a traffic light warning system to indicate extremes of BP for unskilled health workers.

References


Acknowledgements

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