

Agreement of aneroid and oscillometric blood pressure devices used in pregnancy



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ABSTRACT

Objectives: The objective of this study was to compare three automated blood pressure devices (Microlife VSA, Uscom BP+ and Tensiomed Arteriograph) with an aneroid device in an Australian antenatal population to determine an accurate and reliable alternative method of measuring blood pressure in pregnant women.

Study design: This observational, prospective study recruited a random sample of 200 pregnant women of any gestation attending an antenatal clinic in an Australian hospital. Each participant had two peripheral blood pressure measurements per instrument performed, resulting in eight measurements per participant.

Main outcome measurements: Intra- and inter-device reliability of peripheral blood pressure measurements made by the aneroid device and the three automated brachial-cuff oscillometric devices were assessed. The agreement between devices was graded according to standardised criteria.

Results: Both intra- and inter-device reliability of blood pressure measurements of the four devices in this study were found to be 'excellent' (ICCs > 0.75). Microlife VSA and Uscom BP+ showed acceptable levels of agreement (± 5 mmHg) when compared to the aneroid device. Arteriograph did not show an acceptable level of agreement with the aneroid device for systolic blood pressure, but did for diastolic blood pressure.

Conclusion: Accurate automated devices may ensure consistent assessment of blood pressure in the antenatal setting. Our results suggest that Microlife VSA and Uscom BP+ may be suitable alternatives to the aneroid device for use in the antenatal setting. Further studies assessing both auscultatory and oscillometric blood pressure devices in pregnancy, and especially in hypertensive cohorts, are required.

1. Introduction

Blood pressure (BP) measurements are a vital component of antenatal care, where relatively subtle changes in BP may result in significant alterations to clinical management. Accurate peripheral blood pressure (pBP) measurements are especially important for the timely detection and treatment of hypertensive disorders of pregnancy (HDP), such as gestational hypertension and preeclampsia [1].

The auscultatory technique, using auscultation with a stethoscope, with an aneroid sphygmomanometer remains the usual method for performing pBP measurements and remains the most commonly used method in the antenatal clinic [2]. However, this technique is user-

dependent and therefore susceptible to inaccuracies including inadequate deflation rate, inability to clearly hear and interpret the Korotkoff sounds, reading parallax error or subjective bias [3,4]. It can also be time-consuming, an issue particularly relevant to very busy clinics.

There are now a number of automatic BP devices that have been developed for use in clinical and research settings. The Microlife CRADLE Vital Signs Alert (VSA) [Microlife, Taipei, Taiwan] has been validated for particular use in pregnant populations, including in both preeclamptic and hypotensive cohorts [5–7]. Its simplicity makes it ideal for use in low-resource healthcare settings and in pregnancy [8].

Other devices, such as Uscom BP+ [USCOM, Sydney, Australia] and Arteriograph [Tensiomed, Budapest, Hungary] perform the additional

Abbreviations: AAMI, Association for the Advancement of Medical Instrumentation; BHS, British Hypertension Society; BP, Blood pressure; cBP, Central blood pressure; HDP, Hypertensive disorders of pregnancy; ICC, Intraclass Correlation Coefficients; pBP, Peripheral blood pressure

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measurements of central BP (cBP) and augmentation index. cBP has been shown to be a better predictor of future cardiovascular events and is more closely related to vascular hypertrophy and extent of atherosclerosis than pBP [9,10]. Augmentation index, a marker of vascular tone and stiffness, is also an independent predictor of future cardiovascular events and all-cause mortality [11] and has been shown to be elevated in women with HDP [12–14].

Despite the emergence of numerous automated BP devices, some of which are validated for use in pregnancy, aneroid devices remain the most commonly used tool for measuring BP in the antenatal setting internationally. The objective of this study was to compare three BP devices (Microlife VSA, Uscom BP+ and Tensiomed Arteriograph) with an aneroid device to determine their reliability and accuracy in an Australian single-centre antenatal population.

This study aimed to assess intra- and inter-device reliability of pBP measurements made by the aneroid device and the three automated, brachial-cuff oscillometric devices, and to grade the agreement between devices according to standardised criteria.

2. Methods

2.1. Design and participants

This observational, prospective study recruited a random sample of 200 pregnant women of any gestation during their antenatal visit at a tertiary hospital between June and August 2017. Patients with known cardiac arrhythmias were excluded due to the potential of these conditions to result in unreliable and/or inaccurate measurements. Written informed consent was obtained from all participants. Each set of patient measurements were performed by one of two trained research personnel to ensure the technique was standardised. The auscultatory technique was conducted according to American Heart Association recommendations [15]. This study was approved by the TQEH/LMH/MH Human Research Ethics Committee [HREC/17/TQEH/15].

2.2. Study protocol

Participants were rested for five minutes prior to the BP measurements. Arm circumference was measured to ensure the correct cuff for each device was used (see Table I in Appendix for cuff sizes available for use in this study). Cuffs were placed 2 cm above the cubital fossa. Auscultatory BP was measured first to prevent observer bias, followed by the oscillometric devices in randomised order. Measurements on each device were performed twice with a one-minute break between each measurement, resulting in eight measurements per participant.

The auscultatory BP measurement was performed using an aneroid wall-mounted sphygmomanometer (Riester Big Ben). The auscultatory method was used as the ‘standard,’ against which the three automatic devices tested in this study were compared.

The aneroid device measurements were conducted by inflating the cuff to above systolic pressure to occlude the brachial artery. The cuff was then slowly deflated and sounds accompanying the return of pulsatile blood flow was detected by a stethoscope held over the artery at a point just below the cuff. The Korotkoff phase I and phase V sounds corresponded to systolic and diastolic BP values, respectively.

The Microlife VSA is a semi-automated oscillometric BP device that measures pBP and heart rate. It is a simple operator-independent device with indicator lights to provide inexperienced users with assistance in interpreting the results.

The Uscom BP+ is an automated oscillometric BP device that measures pBP and cBP, heart rate and augmentation index. During the initial inflation and deflation period, the device records the pBP. The cuff reinflates approximately 30 mmHg higher than the pBP, occluding the brachial artery. This inflation holds for 10 s while the device records the suprasystolic BP waves and calculates cBP [16–18]. The quality of the measurements were secured by an inbuilt quality control, expressed

as signal-to-noise ratio. Measurements with a signal-to-noise ratio of < 6 were considered unacceptable quality.

The Arteriograph is an automated oscillometric pulse wave analysis device that measures pBP and cBP, heart rate and augmentation index. During the initial inflation phase, the pBP is measured. The cuff then deflates for 10 s, followed by inflation to diastolic BP for 10 s. Finally, the cuff inflates to the suprasystolic pressure for 10 s, occluding the brachial artery, whereby the local influence of the brachial artery wall is eliminated. The signals conveyed to the cuff represent the cBP using the late systolic wave amplitude. The BP measuring algorithm in Arteriograph has been previously validated against invasive measures [19] and used in pregnancy [12,14,20].

Arteriograph provides immediate feedback on the accuracy of its measurement. The software warns the user of a possible inaccurate measurement and provides quantitative quality control scores.

2.2.1. Statistical analysis

Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA), Stata 14.1 (StataCorp 1985–2015) and R 3.3.0 (R Core Team, Vienna, Austria).

2.2.1.1. Power calculations. Post-hoc power calculations confirmed statistical power was greater than 99% for all measurements.

2.2.1.2. Intra- and inter-device reliability. Intraclass Correlation Coefficients (ICCs) were used to test intra-device reliability of two repeated measurements for each device. A two-way mixed-effects model was used looking at consistency of agreement and average ICCs.

ICCs were also calculated to assess inter-device reliability of the variables measured using the four different devices. A two-way mixed-effects model was used to observe consistency of agreement. Average ICCs were used to estimate correlations between average measurements made on the same participant (the mean rating over four (or two) devices).

Interpretation for ICCs for intra- and inter-device analyses was based on agreement measures determined by Cicchetti [21]. A poor agreement was defined as an ICC of < 0.40, fair ICC 0.40–0.59, good ICC 0.60–0.74 and excellent ICC 0.75–1.00.

2.2.1.3. Agreement between devices. Bland-Altman plots were constructed to further evaluate the level of agreement between the mean individual measurements across the devices. The mean difference and 95% limits of agreement (± 1.96 standard deviations of the mean difference) were given on each plot. Clinically relevant and acceptable mean differences were chosen to be ± 5 mmHg for both pBP and cBP, based on the first criterion of the Association for the Advancement of Medical Instrumentation (AAMI) [22].

2.2.1.4. Grading of peripheral blood pressure. Peripheral systolic and diastolic BP values were rated using British Hypertension Society (BHS) and AAMI criteria. The criteria for fulfilling the BHS protocol state that devices must achieve at least grade B (where A denotes greatest agreement with mercury standard and D denotes least agreement) for peripheral systolic and diastolic BP [23]. The criteria for fulfilling the AAMI provision state that the test device must not differ from the mercury standard by a mean difference of > 5 mmHg or a SD > 8 mmHg [22]. In the absence of a mercury standard in Australian hospitals, this study used the aneroid auscultatory method as the standard when applying these criteria to the results. A device was deemed ‘recommended’ if both peripheral systolic and diastolic pressures received an ‘A’ or ‘B’ grades according to the BHS protocol and passed the AAMI criteria.

Table 1
Participant characteristics.

| Patient characteristics (n = 200) | Mean (± SD) or N (%) |
|--|--|
| Age, years | 30 ± 5 (range: 17–49) |
| Height, m | 1.63 ± 0.07 |
| Weight at first antenatal visit, kg | 77.3 ± 21.5 (med: 72.9) |
| BMI at booking, kg/m ² | 29.0 ± 7.4 (range: 15.8–52.6, med: 27.1) |
| Upper arm circumference, cm | 29.8 ± 5.1 (med: 28.1) |
| Ethnicity | |
| Caucasian | 152 (76.0) |
| Indian Subcontinent | 11 (5.5) |
| Middle-Eastern | 5 (2.5) |
| Aboriginal | 3 (1.5) |
| South East & Far East | 11 (5.5) |
| African Subcontinent | 11 (5.5) |
| Other | 7 (3.5) |
| Gestational age at measurement, weeks | 24 ± 10 (range: 7.7–39.7) |
| First trimester | 48 (24.0) |
| Second trimester | 61 (30.5) |
| Third trimester | 91 (45.5) |
| Nulliparous | 69 (34.5) |
| Singleton | 191 (95.5) |
| Self-reported drug-use at time of measurement: | |
| Smoking | 10 (5.0) |
| Regular caffeine intake | 115 (58.1) |
| Alcohol | 0 (0.0) |
| Recreational drugs | 0 (0.0) |

3. Results

3.1. Study characteristics

The majority of the cohort was Caucasian (76%), with a mean age of 30 years and mean BMI of 29 kg/m² (Table 1). The majority of women were multiparous (65.5%) and carrying a singleton (95.5%). The mean gestation at time of measurement was 24 weeks. In total, 1,466 measurements were performed. Ninety Microlife VSA and 6 Arteriograph measurements could not be obtained due to cuff size limitations. All aneroid and Uscom BP+ measurements were obtained.

4. Characteristics of haemodynamic measurements

4.1. Intra- and inter-device reliability

Both intra- and inter-device reliability of pBP measurements of the four devices in this study were found to be ‘Excellent’ (all ICC > 0.75) (Tables 2 and 3) according to Cicchetti criteria for interpretation of ICCs [21].

4.2. Agreement between devices

Both Microlife VSA and Uscom BP+ demonstrated good agreement for mean peripheral systolic and diastolic BP measurements compared to the aneroid device (Figs. 1 and 2). Arteriograph showed a poor agreement for peripheral systolic BP, but a good agreement for peripheral diastolic BP, compared to the aneroid device.

Table 2
Maternal haemodynamics assessed by different devices.

| | N | Mean Systolic BP (SD) (mmHg) | ICC | Mean Diastolic BP (SD) (mmHg) | ICC | Hypertensive measurements* (n) (%) |
|---------------|-----|------------------------------|------|-------------------------------|------|------------------------------------|
| Aneroid | 400 | 113 (11.6) | 0.97 | 67 (9.2) | 0.97 | 5 (2.5) |
| Microlife VSA | 310 | 114 (11.7) | 0.91 | 70 (8.1) | 0.90 | 6 (3.9) |
| Uscom BP+ | 400 | 115 (11.5) | 0.93 | 66 (8.8) | 0.94 | 4 (2) |
| Arteriograph | 392 | 121 (14.0) | 0.97 | 66 (11.3) | 0.94 | 18 (9.2) |

* Hypertensive measurements are defined as sBP ≥ 140 mmHg and/or dBP ≥ 90 mmHg.

Table 3
Inter-device reliability.

| Devices | Mean Systolic BP ICC | Mean Diastolic BP ICC |
|--------------------------|----------------------|-----------------------|
| Aneroid vs Microlife VSA | 0.92 | 0.90 |
| Aneroid vs Uscom BP+ | 0.90 | 0.86 |
| Aneroid vs Arteriograph | 0.86 | 0.82 |

4.3. Measurement grading according to BHS and AAMI criteria

Comparisons between the pBP measurements of the aneroid device, Microlife VSA and Uscom BP+ scored a ‘B’ grade according to the BHS criteria, and additionally passed the AAMI criteria (Table 4). Comparisons between the pBP measurements of the aneroid device and Arteriograph scored a ‘D’ grade, and failed the AAMI criteria.

5. Discussion

This is the first study to compare BP measurements performed by an aneroid device with the Microlife VSA, Uscom BP+ and Arteriograph. Both intra- and inter-device reliability of pBP measurements of the four devices in this study were found to be excellent.

Microlife VSA and Uscom BP+ both showed good levels of agreement across pBP when compared to the auscultatory method. These two devices also fulfilled the BHS and AAMI criteria for acceptable use in the clinical setting. The Arteriograph did not show an acceptable level of agreement with the aneroid device for systolic BP, but did for diastolic BP. These data indicate that Microlife VSA and Uscom BP+ may be acceptable alternatives to the aneroid device.

Other studies have reported poor limits of agreement when comparing Arteriograph to gold-standard measures [24,25]. Recent literature, however, has promoted the feasibility of using the Arteriograph in the general population clinical setting. Jekell & Kahan (2017) found no significant difference between peripheral systolic BP measured by Arteriograph when compared to the Sphygmocor Tonometer (applanation tonometry), although reported high standard deviations [26]. Another study also reported good agreement between Arteriograph cBP and catheterisation, although the results suggested that these data would likely not meet grading criteria for BHS and AAMI [27]. Confidence intervals for peripheral systolic and diastolic BP were unfortunately not reported [27]. In light of these previous reported results, this study performed robust and comprehensive data analyses to observe both statistical and clinical significance. Our results indicate that Arteriograph may not be an accurate and feasible device for clinical use in a pregnant population.

This study is the first to investigate all four specific devices in a pregnant population and include a large enough study population to compare measurements of these devices (power > 99% for all measurements). This varied cohort is representative of an Australian antenatal population and the results are therefore applicable to real antenatal clinical scenarios.

A limitation of this study is that a mercury sphygmomanometer was not used as the standard. Hospitals in Australia no longer allow mercury devices to be used clinically due to the occupational hazards and toxicity of mercury. Aneroid devices are the standard alternative for mercury

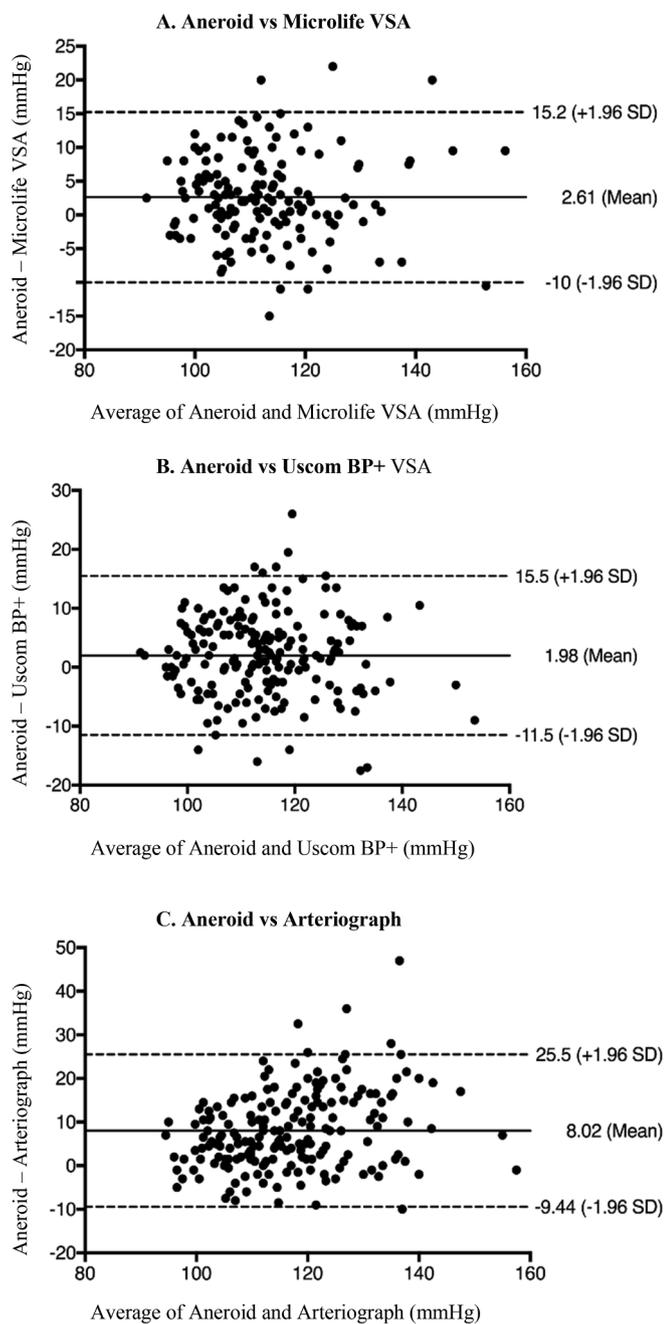


Fig. 1. Agreement of systolic blood pressure. Each dot represents mean difference between devices for one participant.

auscultatory BP measurements in Australian hospitals. The Riester Big Ben aneroid sphygmomanometers used in this study were pressured-checked upon installation, but do not undergo any ongoing or regular calibration. This is standard hospital practice for these devices.

Aneroid devices have been shown to be more reliable than many automated BP devices [2] and are commonly used in Australia and internationally due to the environmental issues associated with mercury devices [15]. Despite their ubiquity, aneroid sphygmomanometers have been shown to be inaccurate when compared to mercury devices [28] and are not recommended by the International Society for the study of Hypertension in Pregnancy (ISSHP) [29]. Another non-mercury auscultatory device, the liquid crystal sphygmomanometer, has been successfully tested in hypertensive pregnant women [30]; however, these devices are not widely available and may require further investigation.

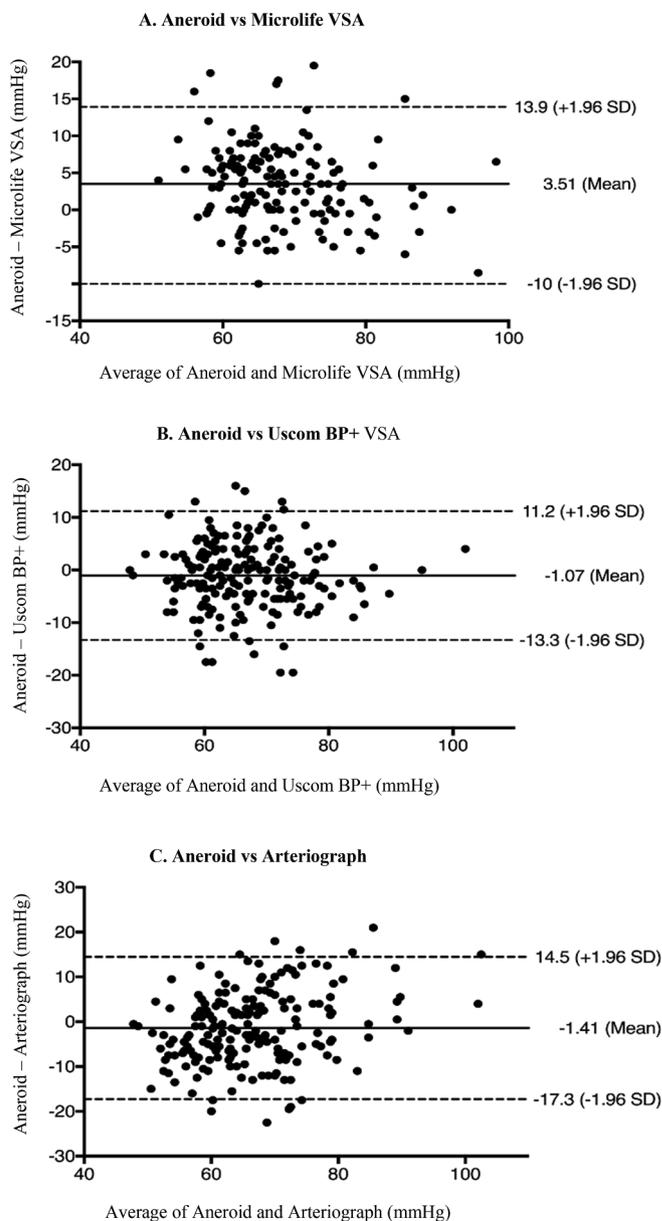


Fig. 2. Agreement of diastolic blood pressure. Each dot represents mean difference between devices for one participant.

Auscultatory techniques are also operator-dependent and therefore susceptible to inaccuracies [3] and an automated alternative may be preferable to increase efficiency and accuracy in a busy clinical setting. ISSHP have also recommended use of automated devices that have been found to be reliable in both antenatal and preeclamptic cohorts [29].

The measurements in this study were consistently performed under standardised conditions in the antenatal setting; however, we did not use a single observer for all auscultatory measurements. The two observers in this study were trained in measuring auscultatory measurements, but inter-observer difference testing was not undertaken.

At the time of the study, the larger cuff size for Microlife VSA was unavailable for purchase (although this cuff is now available) and so 45 participants with arm circumferences > 32 cm were unable to have measurements performed on this device. Furthermore, 6 participants' Arteriograph readings were excluded or unobtainable due to either technical difficulties, poor signal readings or having an arm circumference > 42 cm, the upper limit on the largest cuff for this device. Cuff-size limitations are specifically problematic in obese women, who are at increased risk of developing HDP.

Table 4
Measurement grades according to BHS and AAMI criteria.

| | Aneroid vs Microlife VSA | | | Aneroid vs Uscom BP + | | | Aneroid vs Arteriograph | | |
|--|--------------------------|--------------|-------|-----------------------|--------------|-------|-------------------------|--------------|-------|
| | Systolic BP | Diastolic BP | Grade | Systolic BP | Diastolic BP | Grade | Systolic BP | Diastolic BP | Grade |
| <i>BHS criteria</i> | | | | | | | | | |
| Measurements within $\leq \pm 5$ mmHg (%) | 57% | 57% | | 54% | 61% | | 41% | 48% | |
| Measurements within $\leq \pm 10$ mmHg (%) | 86% | 92% | | 87% | 91% | | 63% | 78% | |
| Measurements within $\leq \pm 15$ mmHg (%) | 98% | 97% | | 96% | 97% | | 79% | 94% | |
| 95% of data ± 15 mmHg Grade | Yes B | Yes B | | Yes B | Yes A | | No D | No C | |
| Overall grade | B* | | | B* | | | D | | |
| <i>AAMI criteria</i> | | | | | | | | | |
| Mean difference ≤ 5 mmHg | 2.61 | 3.51 | Pass* | 1.98 | −1.07 | Pass* | 8.02 | −1.41 | Fail |
| SD of mean difference ≤ 8 mmHg | 6.44 | 5.31 | Pass* | 6.88 | 6.25 | Pass* | 8.91 | 8.10 | Fail |

* denotes acceptable score according to grading.

The Microlife VSA is an inexpensive, easy-to-use device for pBP measurement with acceptable intra- and inter-device reliability in this study. Uscom BP+ and Arteriograph are able to perform additional haemodynamic measures, which may be of use in populations at risk of developing HDP. However, the Arteriograph is sensitive and was unable to detect the pulse wave to calculate cBP and augmentation index in 30% of measurements. In almost 10% of this cohort, Arteriograph reported hypertensive measurements, whilst the other devices reported only 2–4% as hypertensive. This overestimation could lead to a false diagnosis of hypertension and changes to medical care in pregnant patients.

The accuracy of the devices may be in part influenced by the fact that the cohort in this study was predominantly normotensive. The number of errors could potentially be greater in a hypertensive cohort and further investigation of Uscom BP+ and Arteriograph in these populations is warranted. The Microlife VSA has been previously validated in preeclamptic populations [5].

Although Microlife VSA and Uscom BP+ ‘passed’ both AAMI and BHS requirements, only 54–61% of readings on Microlife VSA and

Uscom BP+ fell within 5 mmHg. This discrepancy may have important clinical implications and may be even higher in hypertensive cohorts. This highlights the need for further research assessing appropriate devices for use in pregnant cohorts, as well as the need to assess both statistical and clinical accuracy of BP devices.

Accurate automated BP devices in pregnancy may ensure consistent assessment and reduce subjective observer errors that accompany auscultatory techniques. Our results suggest that Microlife VSA and Uscom BP+ may be suitable alternatives to the aneroid device for use in the antenatal setting, and have potential to improve consistency in the quality of measurements and maximise efficiency. The Microlife VSA likely has additional benefits to low income countries specifically, due to its ease of use and low purchase cost. Future studies should focus on assessing the accuracy and reliability of these devices, and others, in both obese pregnant and hypertensive pregnant cohorts.

Declaration of Competing Interest

None.

Appendix A

Appendix Table 5

| Device | Cuff Name | Arm Circumference (cm) |
|------------------------|-------------------|------------------------|
| Aneroid | Thigh | 40–55 |
| | Large Adult | 32–43 |
| | Adult | 25–34 |
| | Small Adult | 20–26 |
| Microlife VSA | M-L | 22–32 |
| Uscom BP + | Large | 33–47 |
| | Adult | 25–35 |
| | Paediatric | 18–26 |
| Tensiomed Arteriograph | Alternative Adult | 34–42 |
| | Child (/Adult) | 20–30 |
| | New Size Child | 15–25 |

Appendix B. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.preghy.2019.05.005>.

