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An inaccurate automated device negatively impacts the diagnosis and treatment of gestational hypertension

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ABSTRACT

Objectives: Automated blood pressure devices are frequently introduced in maternity care without prior validation for their accuracy in pregnancy. Our objectives were to, firstly, establish the accuracy in pregnancy of a locally used device (Welch Allyn 300) and, secondly, to audit its impact on the diagnosis and treatment of hypertension.

Study design: Validation study: The device was evaluated using the grading criteria of the European Society of Hypertension International Protocol (ESH-IP) (2010). Two observers took nine same-arm measurements alternating between the Welch Allyn and the mercury sphygmomanometer. Thirty-three women of any gestation were included. Clinical audit: One observer took three same-arm measurements alternating between the Welch Allyn and the mercury sphygmomanometer. One hundred women of any gestation referred with suspected hypertension were included. The main outcome measures were the proportion diagnosed with hypertension or commenced on anti-hypertensive treatment on the presenting visit when using either the manual or the automated device.

Main outcome measures: Grading criteria of the ESH-IP (2010) and proportion of women diagnosed with hypertension or commenced on antihypertensive therapy at the presenting visit when using either manual sphygmomanometry or the Welch Allyn device.

Results: The Welch Allyn 300 series failed to meet the criteria of the ESH-IP (2010) for pregnancy. Compared to the mercury device, it under diagnosed hypertension by 48% and need for treatment by 80%.

Conclusions: The Welch Allyn 300 cannot be recommended for the measurement of blood pressure in pregnancy. Its use leads to the under-diagnosis and under-treatment of gestational hypertension.

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1. Introduction

Hypertensive disorders affect approximately 10 percent of women during pregnancy and are the second direct cause of maternal death worldwide [1]. The accurate measurement of blood pressure is integral to the diagnosis and management of hypertension in pregnancy.

The mercury sphygmomanometer, the gold standard for the measurement of blood pressure, is becoming obsolete due to concerns regarding mercury toxicity [2,3]. Automated devices are increasingly replacing mercury but their accuracy is disputed due to the empirical non-standardised algorithms used [4]. In attempt to address these concerns, validation protocols have been introduced and refined since the early 1990s [5–8]. The more recent version of the European Society of Hypertension International Protocol (ESH-IP) tightened the requirements for validation as a reflection of improvements in technology [7].

National guidelines do not state which method of blood pressure measurement should be used in pregnancy but only that it should be accurate and, if not mercury sphygmomanometry, validated [9]. To date, only 15 automated devices are validated for pregnancy of which five are accurate in preeclampsia [10–12]. Unfortunately, many hospitals use a centralised procurement system for blood pressure monitors and little attention is paid to their accuracy in different populations. At King's College Hospital, the Welch-Allyn Vital Signs 300 series has been centrally obtained and distributed to all maternity areas.

The two fundamental aspects of antenatal management of hypertension in pregnancy are, firstly, to be able to identify when a pregnant women becomes hypertensive and, secondly, to iden-

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tify whether the blood pressure is above a pre-determined threshold at which treatment is required. The impact of using an automated device that is inaccurate for use in pregnancy or preeclampsia has not been previously reported.

In this study, we used the ESH-IP 2010 to evaluate the accuracy of the Welch-Allyn Vital Signs 300 series in pregnancy and preeclampsia. In addition, as this device was already in clinical use in our unit, we sought to determine its impact on the diagnosis and decision for treatment of hypertension amongst women referred with suspected hypertension to our Maternal Assessment Unit (MAU). Finally, we evaluated the association between maternal characteristics and device agreement, in an attempt to define future strategies to improve the device performance.

2. Methods

2.1. Validation study

2.1.1. Procedure

Women of any gestation with an arm circumference of 25.3 to 34.4 cm were recruited from the maternity areas at Kings College Hospital (London, UK). Participants provided written consent at the time of recruitment. Women with unclear Korotkoff sounds (N = 5), arrhythmia (N = 1), or if unable to provide informed consent (N = 1), were excluded from the study. Thirty-eight participants were excluded due to blood pressure range completion (N = 28) or range adjustment (N = 10).

The validation procedure recommended by the ESH-IP (2010) was followed [6]. Two observers were trained in blood pressure measurements using a CD-ROM programme produced by the British Hypertension Society. An independent supervisor assessed both observers individually prior to commencing the study to ensure correct blood pressure measurement technique.

The two observers took nine sequential same-arm measurements from each participant, alternating between the mercury sphygmomanometer and the Welch-Allyn Vital Signs 300 series device, using a double-headed stethoscope (Littman Class II Stethoscope). The participant was seated, legs uncrossed and arm supported at heart level. An independent supervisor would request the mercury measurement to be repeated if the inter-observer discrepancy exceeded 4 mmHg. A period of 30 s to 1 min was allowed between readings to avoid venous congestion.

The first measurement by the two observers using the mercury sphygmomanometer was the entry blood pressure and was used to categorise the participant into a blood pressure range as specified by the ESH-IP. The second measurement using the automated device was used to orientate the device to the participant. The subsequent seven measurements were used in the final analysis.

2.1.2. Analysis

The mean differences between the device and the observer measurements were calculated to determine the accuracy and a visual representation of this was provided in the form of Bland – Altman plots. Based on these results, the device will 'pass' only if it satisfies the validation requirements.

2.2. Audit on the diagnosis and treatment of hypertension

2.2.1. Procedure

This was a prospective observational audit, which was carried out in parallel with the validation. We measured blood pressure sequentially using the Welch-Allyn Vital Signs 300 series device, which was routinely used in the MAU, and a mercury sphygmomanometer. We aimed to assess the differences in the blood pressure readings between the two devices and the impact that this would have on the diagnosis of hypertension in pregnancy within the index visit. In addition, we aimed at assessing if maternal somatometric and demographic variables could explain potential differences between the two devices.

One hundred and fifteen women of any gestation who were referred with suspected hypertension were recruited from the MAU at Kings College Hospital. Verbal consent was obtained from each participant. Fifteen women were excluded due to unclear Korotkoff sounds (N = 5), arrhythmias (N = 2), incomplete outcome data (N = 4), or due to being unable to provide informed consent (N = 4).

The entry blood pressure was the blood pressure reading that prompted the referral. Each participant then had three sequential same-arm blood pressure readings with an interval of 30 s to one minute. A trained observer alternated between the mercury sphygmomanometer (first and third reading) and the Welch-Allyn Vital Signs 300 series test device (second reading). Three readings were taken to allow for two comparisons between the device and the manual sphygmomanometer and, thus, help limit bias.

2.2.2. Analysis

The outcome of each pregnancy was followed using our Maternity Database. Hypertension in pregnancy as defined by the American College of Obstetricians and Gynaecologists is blood pressure equal or greater than 140/90 mmHg on two occasions, four hours apart. Patients were classed as having chronic hypertension if this predated pregnancy or was prior to 20 weeks gestation. Hypertension occurring beyond 20 weeks gestation was defined as pregnancy-induced hypertension (PIH) or preeclampsia if in the presence of significant proteinuria (i.e. $\geq$0.3 g of protein in a 24-h urine collection) [13].

Based on the definitions stated, we determined the number of patients who would have been diagnosed with new-onset hypertension had the Welch-Allyn Vital Signs 300 series or the manual readings been used. To address the second issue of when to initiate anti-hypertensive treatment, again we looked at the number of patients who would have commenced medication based on either the Welch-Allyn Vital Signs 300 series or the mercury sphygmomanometer blood pressure readings. We used two thresholds for commencing treatment: 150/100 mmHg, as recommended by the National Institute of Health and Clinical Excellence (NICE) [13], and 140/90 mmHg, if tighter blood pressure control was to be achieved [9].

2.2.3. Statistics

As with the validation study, mean differences between the observer and the device were calculated and plotted on a Bland – Altman plot.

The normality of the distribution of the data was assessed by the Kolmogoroff-Smirnoff test. Univariate and multivariate linear and logistic regression were used to estimate and compare the magnitude of the effects of age, ethnicity, body mass index (BMI), gestational age, and systolic or diastolic blood pressure level (as measured by the mercury) on the differences between the two devices.

3. Results

3.1. Validation study

3.1.1. Study participants

Seventy-eight women were recruited in order to complete the blood pressure categories as specified in the ESH-IP (2010). Thirty-three women were included in the final analysis. The characteristics of the study participants along with the number of

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