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Validation and Compliance of a Home Monitoring Device in Pregnancy: Microlife WatchBP Home

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Objective. To assess the accuracy and patient compliance in using a novel home blood pressure monitoring device in high-risk pregnancy. *Methods.* Device accuracy was assessed according to the British Hypertension Society protocol in 45 pregnant women, including 15 with preeclampsia. Twenty-one high-risk pregnant women used the device in addition to their antenatal care. *Results.* The device achieved a mean difference ± SD of 0.4 ± 7.3/ –0.4 ± 5.5 mmHg (pregnancy) and –2.6 ± 7.0/0.8 ± 4.4 mmHg (preeclampsia) for systolic/ diastolic pressure. Eighty-one percent of women did at least 6 measurements/day and all women did at least 2 measurements/week. *Conclusion.* The Microlife WatchBP Home is accurate for use in pregnancy and increases surveillance in compliant patients.

Keywords Blood pressure, Home monitoring, Preeclampsia, Pregnancy, Validation.

INTRODUCTION

Home blood pressure monitoring (HBPM) has superior reproducibility to clinic measurements (1), can detect white coat/masked hypertension and is associated with improved hypertension control (2,3). In addition, it is a more acceptable and practical way of measuring BP, especially when compared to ambulatory blood pressure monitoring (ABPM).

The reliability of HBPM however, has been hampered by patient recording bias (4,5), device accuracy limitations, no agreement on the optimal blood pressure (BP) measurement schedule or the interpretation of the data collected (6,7). Fortunately, emerging technologies have more recently provided devices with a memory function, personal computer (PC) interfaces and increased accuracy (8,9) to overcome these drawbacks. In addition, an optimal

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HBPM schedule has been recommended by the European Society of Hypertension (ESH) Working Group on Blood Pressure Monitoring (10,11).

HBPM is increasingly being adopted in pregnancy, with a recent survey (12) reporting that in some populations, more than two thirds of non-proteinuric hypertensive women are already using HBPM in addition to their routine antenatal care.

In the pregnant hypertensive population, the unpredictable and heterogeneous nature of preeclampsia currently necessitates all hypertensive women to be subjected to increased antenatal visits and admissions for surveillance of BP and urine protein level. In fact, antenatal hypertension accounts for up to 24% of all admission to maternity units in the UK (13). Despite such measures, the current evidence suggests that conventional antenatal care is still not adequate in detecting disease deterioration of which inadequate identification of hypertension is likely to contribute (14). Therefore HBPM, particularly in women at risk of preeclampsia, offers the potential of being more than just a superior diagnostic method, through facilitation of maximal surveillance outside of the clinical environment.

Few automated BP devices are accurate compared to auscultation using a recognised validation protocol (9,15) and no studies have evaluated patient compliance to measurement schedules, which is key to the safety of introducing HBPM if it is to replace standard antenatal visits.

The Microlife WatchBP Home is a novel device that has specifically been designed according to the current ESH home monitoring guidelines to promote optimal application of HBPM (16). Its dual mode design allows both scheduled (diagnostic mode) and patient initiated (usual mode) BP measurements. The device allows automatic storage and ESH recommended average calculation of the data as well as a PC interface. It has been validated in an adult population (17) according to International protocol of the ESH (18). However, its accuracy in pregnancy and preeclampsia is yet to be established, as the majority of devices underestimate BP by clinically significant amounts, especially in preeclampsia (19), despite passing an adult validation.

METHODS

The study was performed at St. Thomas' Hospital (London, UK). Ethical permission was obtained from the local research ethics committee and all subjects were required to give written informed consent for validation of the device.

Accuracy Assessment

The Microlife WatchBP Home device was evaluated according to the British Hypertension Society (BHS) protocol (15). Although the protocol only stipulates

the need for 30 pregnant women, we recruited an additional 15 women with preeclampsia. Preeclampsia was defined as a diastolic blood pressure of ≥90 mmHg on two separate occasions more than 4 hours apart or a single reading >110 mmHg accompanied by proteinuria of >0.3 g on a 24 hour collection (20).

Measurements were taken while women were seated with their arm supported at heart level using a table or the arm of a chair. Arm circumference was measured at the approximate midpoint of the upper arm to determine the appropriate cuff size to be used. Two cuff sizes were available: Standard (22–32 cm) and Large (32–42 cm) and therefore any woman with an arm circumference outside 22–42 cm was excluded from the study. In addition, any woman with an arrhythmia or unclear Korotkoff sounds was also excluded from the study.

Nine sequential same arm blood pressure measurements were taken from each woman, alternating between the reference device (mercury sphygmomanometer) and the test device (Microlife WatchBP Home). Two mercury columns were joined via a Y connector to an upper arm cuff and a bulb. This enabled the trained observers to take simultaneous auscultatory measurements while being blinded to each other's readings and to the device reading. Device readings were retrieved from the device memory after completing all 9 measurements, which could then be reviewed independently of the observers. At least 30 seconds to 1 minute was allowed between measurements to avoid venous congestion and to minimise variability in blood pressure. The first reading by observer 1 was used to classify subjects into groups specified by the protocol (Table 1) and only the last 7 readings were used in the analysis.

The three sequential mercury measurements with the smallest absolute difference compared to the three device measurements *before* or *after* were chosen for the final analysis. The percentage of differences within 5, 10 and 15mmHg was calculated separately for systolic and diastolic pressure (and for each observer) to determine the grading (A-D grade) according to the BHS criteria (Table 2). The device had to achieve percentages greater than or equal to those in the table to achieve a particular grade. Data was entered and analysed using Excel (Microsoft Office) software. A visual representation of the device accuracy is provided using mean-against-difference plots (21).

Table 1: Recruitment criteria.

Criteria	Requirement
Arm circumference >35cm	8–10
Second Trimester	10
Third Trimester	10
SBP range: 100–115, 116–130, 131–145, 146–160 mmHg	5 in each
DBP range: 70–80, 81–90, 91–105 mmHg	5 in each

Table 2: Grading criteria according to the British Hypertension Society protocol.

	Absolute pressure difference between standard and test device (mmHg)		
Grade	**≤5**	**≤10**	**≤15**
Cumulative percentage of readings (%)			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Home Monitoring

A total of 8 Microlife WatchBP Home devices were available and used in this part of the study and loaned to women for use in addition to their current antenatal care. Pregnant women were recruited from the Day Assessment Unit (DAU) and antenatal clinics at St Thomas' Hospital. On recruitment, they were classified into four distinct categories based on the reasons for home monitoring and to allow for customised instructions depending on patient classification (Table 3). Hypertension was defined as BP of ≥90 mmHg on two occasions that were at least four hours apart or a single diastolic reading of >110 mmHg. Proteinuria was defined as >0.3 g on a 24-hr collection. Preeclampsia was defined as confirmed hypertension and proteinuria (20).

Table 3: Summary of patient classification.

Classification	Definition	Monitor	Seek Advice if:
Hypertension Alone / High Risk Patients	Hypertension (chronic or gestational) + No Protein OR High Risk for PET	DIAG & USUAL & Urine Dipstick	BP ≥140/90 mmHg AND ≥1+ Protein OR BP ≥160/100 mmHg
Proteinuria Alone	No Hypertension + Protein (≥0.3g/dL)*	DIAG & USUAL	BP ≥140/90 mmHg
Mild Preeclampsia	Hypertension + Protein (0.3–0.5g/dL)*	DIAG & USUAL	BP ≥160/100 mmHg
Uncertain BP	To improve BP characterisation (e.g. to exclude white coat hypertension).	DIAG only	BP ≥160/100 mmHg

DIAG = Diagnostic mode: 2 consequtive readings between 6 am–12 pm and 6 pm–12 am.
USUAL = Usual mode: Patient initiated single readings at 10 am, 12 pm and 2 pm.
PET = Preeclampsia.
*24-hour urine collection.

Verbal consent was obtained and demographic information such as age, gravidity, parity and gestation were recorded. The patient, health care professionals in charge of management and maternity notes were consulted to obtain the relevant clinical details required for correct categorisation. All patients were loaned a HBPM device with an appropriately sized cuff, based on a measurement of their arm circumference at the approximate mid point of the upper arm. Any woman in the 'Hypertension only or High Risk' group was also given urine dipsticks and a urine sample collection bottle. Training was then given for approximately 15 min on how to use the HBPM device; how to obtain a midstream urine sample and how to use the urine dipstick (if indicated). Women were asked to call the DAU if a specified BP threshold was reached. A typed summary of instructions and telephone numbers for the Day Assessment Unit (DAU), Birth Centre and for the research office was provided.

All women were asked to use the diagnostic (DIAG) function of the device. In this function, two BP measurements were taken consecutively at a patient initiated time between 6 am–12 pm and again between 6 pm–12 am. Women were encouraged to do this for 7 consecutive days to fulfil the ESH guidelines. In addition, some women were also asked to take a single BP measurement at 10 am, 12 pm and 2 pm using the USUAL mode.

A schedule of review was agreed with each individual woman according to her scheduled antenatal appointments. All the BP measurements were recorded in the memory storage system of the device and were subsequently downloaded and saved onto a PC from the device at every patient review. At every review, feedback from the patient was recorded, especially with regard to any incidences of high BP reading (above the instructed threshold) and subsequent actions taken or not taken by the patient. Any problems that the patient faced during HBPM (i.e. technical difficulties such as device malfunction) and factors that could have influenced the readings or measurements were also recorded. Each patient carried on using the HBPM device until home monitoring was no longer clinically indicated or the patient decided to withdraw from the study or i.e. delivery or admittance to hospital.

RESULTS

Validation

Demographics of the subjects recruited were similar for pregnancy and preeclampsia (Table 4). The mean systolic and diastolic blood pressures were higher in the preeclamptic population compared to normotensive pregnancy: 135/82 mmHg vs. 119/75 mmHg. The mean value for proteinuria on 24-hr collection in preeclamptic women was 1.1 ± 1.4 g/dL.

Table 4: Demographics of study population for validation.

	Age	Height	Weight	Arm circumference	Gestation
	(yrs)	(cm)	(kg)	(cm)	(weeks)
Pregnancy (n = 30)	33 ± 5	165 ± 7	76 ± 16	31 ± 4	32 ± *7 days*
Preeclampsia (n = 15)	32 ± 6	165 ± 5	73 ± 9	31 ± 4	36 ± *3 days*

*Values stated are mean ± standard deviation.

In pregnancy (excluding preeclampsia), the Microlife WatchBP Home device achieved an A/A grade with a mean difference ± SD of 0.4 ± 7.3 mmHg for systolic and –0.4 ± 5.5 mmHg for diastolic pressure (Table 5). In preeclampsia the device achieved an overall B/A grade with a mean difference ± SD of –2.6 ± 7.0 mmHg and –0.8 ± 4.4 mmHg for systolic and diastolic pressures respectively (Table 5). The device therefore also passed the AAMI criteria, which stipulates a mean difference ± SD of ≤5 ± 8 mmHg (62). Mean-against-difference plots are shown in Figures 1 and 2.

The inter-observer comparison fulfilled the accuracy criteria stipulated in the BHS protocol with 97% of readings within 5 mmHg and 100% of readings within 10 mmHg for both systolic and diastolic pressures.

During the validation study one woman was excluded, because the device failed to produce a measurement. This was suspected to be due to excess hanging skin folds on the posterior aspect of the upper arm, which may have interfered with correct application of the cuff and subsequent signal acquisition.

Home Monitoring

In all, 21 patients used the 8 home monitoring devices available to take a total of 1141 BP measurements. The average gestation of patients at recruitment

Table 5: Device accuracy in pregnancy and preeclampsia according to BHS criteria.

		Differences between standard and test device (mmHg)			
	Grade	≤5	≤10	≤15	Mean ± *SD* mmHg
Pregnancy (n = 90)					
Systolic BP	A	61%	87%	96%	0.4 ± 7.3
Diastolic BP	A	74%	93%	98%	–0.4 ± 5.5
Preeclampsia (n = 45)					
Systolic BP	B	67%	89%	93%	–2.6 ± 7.0
Diastolic BP	A	76%	100%	100%	–0.8 ± 4.4

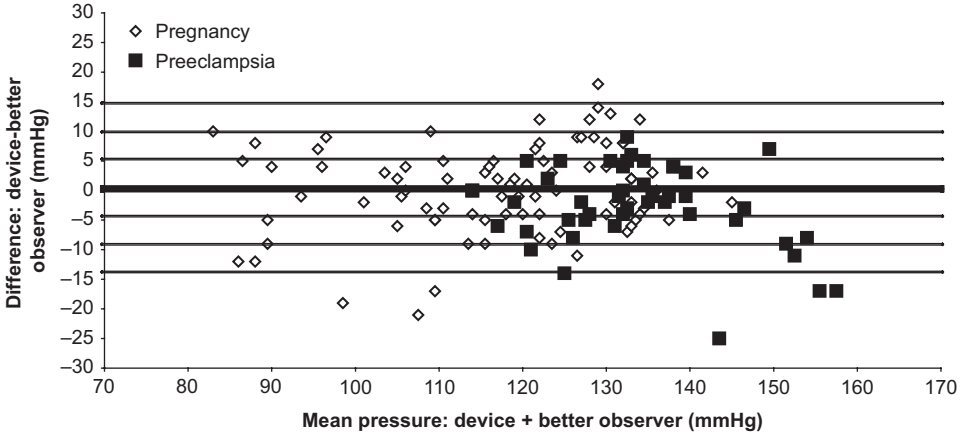

Figure 1: Bland-Altman plot presenting the differences in blood pressure between the better observer and the device for systolic pressure.

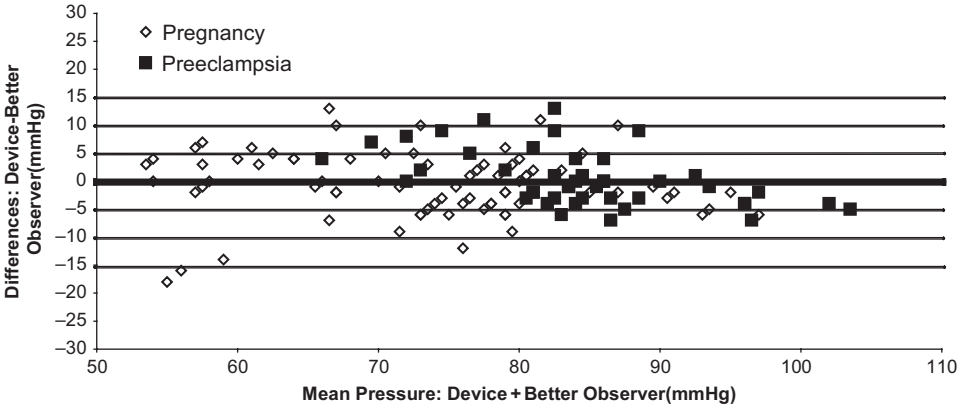

Figure 2: Bland-Altman plot presenting the differences in blood pressure between the better observer and the device for diastolic pressure.

was 31 weeks. The majority of patients were recruited under the 'Hypertension alone/High Risk for Preeclampsia' Category (76%).

The home monitoring devices were used between 1–54 days. Forty-eight percent of women used home monitoring for up to 1 week and 38% of women used it for more than 4 weeks. Eighty-one percent of patients had their BP monitored every day, with an average of 6 measurements per day. Up to 75% of the remaining patients monitored their BP at least 4 days per week with an average of 3 measurements per day.

Eleven patients acted (i.e. rang the DAU) on raised BP measurements according to the instructions given to them regarding thresholds. Two patients

were subsequently admitted before their next scheduled antenatal appointment. The first of these patients had a diagnosis of mild preeclampsia (proteinuria <0.5g/dL) and was being managed as an outpatient at 35 weeks gestation. She had a HBPM of 171/110 mmHg and a repeat measurement of 164/104 mmHg. She seeked advice as instructed and was subsequently admitted until delivery. Her 24-hr proteinuria level was 0.56 g/dL. The second patient was chronic hypertensive and was being monitored for 8 weeks (since 23 weeks gestation) showing a gradual increase in BP over time. Methyldopa was prescribed and increased to 500 mg TDS. She had a HBPM of 152/105 mmHg, with repeat readings of 151/102 mmHg and 164/93 mmHg, together with a trace of protein on that day. She seeked advice as instructed and was admitted for rapid onset preeclampsia. Her 24-hr proteinuria level was 0.53g/dL.

Ten patients did not respond appropriately to their HBPM according to the instructions given. Three patients rang the DAU for a raised BP at home (although it was below the instructed 'action' threshold) and subsequently visited the DAU on the advice of the attending midwife. In contrast there were 33 occasions where a patient's BP was raised above the instructed action threshold, but they did not ring the DAU to seek advice. On 12 occasions, patients did not call the DAU immediately as a subsequent BP was below the 'action' threshold. On 4 occasions patients did not call the DAU, as they already had a hospital appointment the following day. The remaining 17 occasions occurred in two patients who both had a severe language barrier. On consultation, it was clear that the patients had poor understanding of the instructions given and the importance of alerting midwives of their raised BP readings. None of the inappropriate actions were instigated due to home protein dipstick readings.

Only 50% of diagnosed hypertensive pregnant women could be reconfirmed to be hypertensive according to HBPM (average BP ≥135/85 mmHg). There was 1 incidence of device malfunction due to a deflation valve error on a large cuff. A few women expressed difficulty in reaching midwives when phoning the DAU and some expressed difficulty in carrying out the full BP measurement schedule due to clashes with work-related commitments.

DISCUSSION

The Microlife WatchBP Home monitor is a novel oscillometric device, designed to comply with the HBPM schedule recommended by the ESH Working Group on Blood Pressure monitoring (10,16). The device has previously been shown accurate in adults (17) and this study shows the device to also be accurate in pregnancy and preeclampsia according to the BHS protocol. This achievement has only been reached by two other devices: the Microlife 3BTO-A (22) and the Omron MIT (23) (this device has been discontinued). Although the device was not assessed in severe preeclampsia, its purpose is to diagnose around a

threshold, and in this regard our definitions and study population are suited to validating its use for home monitoring. We followed a recognised protocol, and recruited more patients than recommended.

In addition this study shows the feasibility of implementing a novel technology in HBPM in addition to antenatal care in pregnancies at risk of preeclampsia. In the adult population it has certainly been suggested that self-monitoring may improve BP control by improving compliance through increased patient involvement (24,25). The Microlife WatchBP Home device has the facility to monitor compliance by downloading measurements onto a PC, which we have shown to be necessary by the high levels of non-compliance to instructions in this study. This is in contrast to the only other study assessing home BP measurement in hypertensive pregnancy, which showed good compliance using self-reporting diaries (26). In this study only 3 out of 72 women did not have accurate results comparing device readings with their diaries, with one patient fabricating measurements. The advantage of our device is that self-reporting is not required, due to the PC interface.

It is important to note that with an overall increase in BP surveillance, women who were compliant with monitoring instructions had a far greater surveillance of their BP than they would've had in the routine hospital environment. Our results also support the findings of previous reports that questions the reliability of clinic measurements (CBPM) in diagnosing hypertension in pregnancy, as in this study half the 'hypertensive' patients were found to be normotensive according to their HBPM. The use of HBPM in pregnancies at risk of hypertensive disorders would theoretically allow for earlier disease detection and/or disease progression and therefore has the potential to facilitate optimal antenatal care and to reduce the risk of poor obstetric outcome.

Despite the small numbers of this study, appropriate self referral and earlier admission was shown in at least two patients (10%). If the results from Ross-McGill's randomised controlled trial[27] in low risk pregnancies were to be extrapolated to high risk pregnancies such as the population in this study, it would be reasonable to assume that replacement of additional antenatal visits (purely for BP monitoring) with HBPM would reduce the total number of antenatal visits required, without being compensated for by an increase in visits for other reasons. However given the high number of failures to respond to instructions, we do recommend compliance assessment before instigating reduced antenatal schedules, which is achievable with this new technology.

Admission for bed rest in hypertensive pregnancy may aid optimal monitoring of BP, but has been shown to be of no value in preventing the disease process of pregnancy induced hypertension (i.e. no improvement in fetal growth or neonatal mortality) (28). Therefore in pregnant women with/at risk of hypertensive disorders, HBPM offers an alternative management option that provides greater surveillance of BP and has far less social and emotional encumbrance, as long as other risks such as severe hypertension do not occur.

The biggest challenge with HBPM implementation in this study was patient education, with the language barrier proving to be the greatest hurdle, and perhaps the only aetiological factor for women's non-compliance. If patients are trusted and relied upon with their own surveillance of BP, it is vital that they understand the importance of BP measurements and the rationale behind the instructions. More than a third of patients recruited to this study presented with some degree of a language-related communicative barrier, which may reflect the diverse population in which this study was performed. In addition, the suggested BP measurement schedule clashed with either personal or work-related commitments. Home monitoring is only of benefit if the patient is able to take their own BP correctly, measure it as frequently as necessary and act on readings as instructed. If a woman is unable to carry out any of the above for any reason, whether it is due to inadequate understanding or work-related difficulty, addition of HBPM would be of no little value. In light of the fact that we live in a society where multi-ethnicity is becoming increasingly common, a holistic approach by the midwife and/or clinician is vital.

Despite the small sample size, important clinical principals are demonstrated from this study. Almost two thirds of all suspected preeclampsia referrals to a DAU are BP related and may benefit from the use of home monitoring.

In conclusion, implementation of HBPM in addition to current antenatal care is feasible and compliance can be monitored through improved device memory function and PC interface capabilities. Use of validated devices such as the Microlife WatchBP Home could be considered in replacing additional antenatal visits and hospital admissions prompted purely for the surveillance of BP and proteinuria in patients that are compliant in HBPM.

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