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HOME BLOOD PRESSURE MONITORING IN A HYPERTENSIVE PREGNANT POPULATION

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ABSTRACT

Objective: The majority of patients with chronic or gestational hypertension do not develop pre-eclampsia. Home blood pressure monitoring (HBPM) has the potential to offer a more accurate and acceptable means of monitoring hypertensive patients during pregnancy compared with traditional pathways of frequent outpatient monitoring. The aim of this study was to determine whether HBPM reduces visits to the antenatal services and is safe in pregnancy.

Methods: This was a case–control study of non-proteinuric hypertensive pregnant women. Patients in the HBPM group were taught how to measure and record their blood pressure using a validated machine at home and attended every 1–2 weeks for assessment depending on clinical need. The control group was managed as per local protocol.

Results: There were 108 women in the HBPM group and 58 patients in the control group. There was no difference in maternal age, parity, body mass index, ethnicity or smoking status between the groups, but there were more women with chronic hypertension in the HBPM compared with the control group (49.1% *vs* 25.9%, *P*=0.004). The HBPM group had significantly fewer outpatient attendances (6.5 *vs* 8.0 visits per patient, P=0.003) and this difference persisted when accounting for differences in duration of monitoring (0.8 vs 1.6 visits per week, p<0.001). There was no difference in the incidence of adverse maternal, fetal or neonatal outcomes between the two groups.

Conclusion: Home blood pressure monitoring in hypertensive pregnancies has the potential to reduce the number of hospital visits required by patients without compromising maternal and pregnancy outcomes.

INTRODUCTION

Hypertensive disorders of pregnancy include gestational hypertension, chronic hypertension and preeclampsia (PE). They complicate up to 10% of pregnancies and are associated with adverse maternal and fetal outcomes such as eclampsia, stroke, renal and hepatic dysfunction, fetal growth restriction and stillbirth.[3] Monitoring, early recognition, and treatment are therefore key to reducing severe complications and mortality.[4] Traditionally, women who develop hypertension in pregnancy are advised to attend an out-patient service or Day Assessment Unit (DAU) at their maternity hospital, commonly two to three times weekly for blood pressure monitoring and urine testing.[5] The purpose of these assessments is to monitor for the development of PE and/or placental insufficiency. However, the vast majority of these women (more than 80%) do not develop PE.[6] Frequent monitoring can represent a source of anxiety to these women and their families, is demanding for them in terms of time, transport costs and work absence, and has significant service implications for healthcare providers. These women may also undergo unnecessary medical interventions, such as early delivery.

An alternative to this pathway is home blood pressure monitoring (HBPM), whereby patients monitor and record their own blood pressure using a validated machine with instructions from a healthcare professional on the frequency of monitoring and when to attend the hospital. HBPM is recommended in the general population for diagnosing hypertension, but there is a paucity of data on the use of HBPM in pregnancy.[7-9] It has also been noted that 30% of pregnant women monitor their own blood pressure without informing their healthcare provider and using a wide range of devices, not all of which have been validated in pregnancy.[10,11] This highlights the need for evidence-based patient education to establish and maintain safety of this practice. We therefore developed a pathway for HBPM in pregnancy where eligible women performed the majority of the blood pressure checks at

home and recorded the results on a smartphone application. Our main aim was to assess if HBPM can be used in women at risk of PE and whether such monitoring reduces the number of hospital appointments without causing discernable adverse outcomes.

METHODS

Population and Study Design

This was a case control study involving a cohort of hypertensive pregnant patients enrolled on HBPM pathway and a control group managed according to the traditional pathway of regular day assessment unit visits for blood pressure monitoring. The inclusion criteria were women with chronic hypertension, GH or women at high risk of developing PE, no significant proteinuria (≤1+ protein of urine dipstick testing) and normal biochemical and haematological markers. The exclusion criteria were maternal age less than 16 years, systolic blood pressure above 155 mmHg or diastolic blood pressure above 100 mmHg, significant proteinuria (≥2+ proteinuria on dipstick or protein/creatinine ratio >30mg/mmol), evidence of small for gestational age (estimated fetal weight less than 10th centile), signs of severe PE (oliguria of less than 500 mL urine output in 24 hours, cerebral or visual disturbance, pulmonary oedema, epigastric or right upper quadrant pain, impaired liver function (twice the upper limit of normal levels for AST and/or ALT), thrombocytopenia (platelet count less than 100,000/mm3)), significant mental health concerns and insufficient English language understanding.

The diagnosis of PE and gestational hypertension was made according to the criteria of the International Society for the Study of Hypertension in Pregnancy.[12] In gestational hypertension, the systolic blood pressure should be 140 mm Hg or more and/or the diastolic blood pressure 90 mmHg or more on at least two occasions four hours apart developing after 20 weeks of gestation in previously normotensive women in the absence of significant proteinuria. In PE, there should be GH with proteinuria of 300 mg or more in 24 hours, or two readings of at least ++ on dipstick analysis of midstream or catheter urine specimens if no 24-hour collection is available. In PE superimposed on chronic hypertension, significant proteinuria (as defined above) should develop after 20 weeks of gestation in women with known chronic hypertension (history of hypertension before conception or the presence of

hypertension at the booking visit before 20 weeks of gestation in the absence of trophoblastic disease). The diagnosis of chronic hypertension was made when there was a documented presence of chronic non-gestational hypertension prior to this pregnancy, or history of anti-hypertensive medication prior to 20+0 weeks. The diagnosis of White Coat Hypertension was made when there were confirmed high blood pressure recordings in the hospital/clinic with normal readings on HBPM or ambulatory monitoring.

Patients in the HBPM group presented either via referral to the Hypertension Clinic or to the DAU between December 2013 and November 2016. HBPM was implemented as a quality improvement initiative at St George's Hospital. The control group was derived retrospectively from maternity databases and consisted of a historic cohort of women who presented to the DAU with hypertension in pregnancy and managed as per the local hospital protocol prior the implementation of HBPM. Our search criteria included women referred to the DAU for blood pressure monitoring who did not have a plan for delivery made within one week of their first visit. Ethical approval was obtained for the study (16/NW/0206).

Home Blood Pressure Monitoring Pathway

Eligible patients were counselled and trained by a specialist midwife and provided with an automated Microlife© 'WatchBP Home' blood pressure machine which has been validated in pregnancy and in PE.[13] They were taught how to measure their blood pressure accurately and record their readings in their notes or on a specially designed smartphone app. Each patient was given a personalized schedule of frequency of monitoring and timing of hospital visits depending on his or her clinical need. Whilst the schedule varied per patient, the frequency of monitoring complied with National Institute for Health and Care Excellence (NICE) guidance on hypertension in pregnancy.[14] A typical regime for a woman with well-controlled chronic hypertension would be to measure blood pressure two or three times a week whereas a woman initiating new treatment would be asked to measure blood pressure

twice a day and reviewed one week later. The same specialist midwife reviewed patients at the interim visits and the HBPM recordings were reviewed. Blood pressure and urine were assessed and ultrasound for fetal wellbeing was performed as indicated. Patients were given written instructions of when to present to hospital based on their home blood pressure readings being out of normal range or them reporting symptoms of PE. Our protocol used a systolic blood pressure of more than 155mmHg or a diastolic blood pressure of more than 100mmHg as the trigger for patients to contact the hospital for review to avoid patients developing severe hypertension at home. This is in line with the recommendation of hospital admission for systolic blood pressure of 160mmHg or diastolic blood pressure of 110mmHg.[14] For those using the smartphone app, a warning was automatically generated if they inputted an abnormal reading. Any patients presenting with such concerns were reviewed as per normal hospital protocol. Patients in the control group presented either directly to the DAU or were referred from an Antenatal Clinic. They were managed according to the hospital protocol and had all their blood pressure checks performed in the DAU. The hospital protocol at that time was based on National Institute for Health and Care Excellence (NICE) guidance on hypertension in pregnancy and follow-up visits were once or twice a week depending on blood pressure control.[14]

Data on maternal age, body mass index (BMI) at booking, ethnicity, parity, smoking, mode of conception and pregnancy outcomes were collected. The diagnosis at the start of the blood pressure monitoring and at delivery was ascertained from the medical records. We also recorded the duration of blood pressure monitoring, number of the blood pressure-related visits to the DAU, the Hypertension Clinic, the Family Practitioner practice, number of ultrasound scans, hematological and biochemistry tests in the maternal blood, administration of steroids, magnesium sulphate, as well as the blood pressure related hospital admissions or the need for care on the High Dependency Unit (HDU) admission for severe PE.

Adverse pregnancy outcomes

The maternity, ultrasound and neonatal records were reviewed to collect data on adverse maternal, fetal and neonatal outcomes. Adverse maternal outcomes included acute renal failure (maternal serum creatinine level above 100 micromol/L antenatally, or above 130 postnatally) or need for dialysis, acute myocardial ischaemia, need for third intravenous agent to control blood pressure (e.g., in addition to labetalol and hydralazine, hypertensive encephalopathy (altered mental status with characteristic cerebral imaging), cortical blindness, retinal detachment, stroke (ischaemic or haemorrhagic), pulmonary oedema or adult respiratory distress syndrome (defined as characteristic pulmonary imaging in addition to oxygen requirement), need for mechanical ventilatory support (other than for Caesarean section), disseminated intravascular coagulation, thrombotic thrombocytopenic purpura or haemolytic uraemic syndrome, acute fatty liver, liver haematoma or rupture, placental abruption and maternal death. Adverse fetal outcomes included preterm delivery (prior to 37+0 weeks' gestation), small for gestational age (birthweight below the 10th centile for gestational age, fetal growth restriction (birthweight below the 5th centile for gestational age) and antepartum or intrapartum fetal death. Adverse neonatal outcomes included neonatal death, respiratory distress syndrome, intraventricular haemorrhage, necrotising enterocolitis, bronchopulmonary dysplasia, periventricular leukomalacia, retinopathy of prematurity, seizure and admission to the neonatal unit for more than 48 hours (for full-term infant).

Statistical Analysis

The outcome data were obtained from the maternity databases as well as detailed review of the patient's hospital notes. The categorical variables were described as a number and percentage and continuous variables as median and interquartile range. The Chi-Square test, or Fisher's exact test when appropriate, was used to compare the categorical variables. The Mann Whitney-U test was used for the analysis of the continuous data. A p-value less than 0.05 was deemed statistically significant. All statistical analysis was performed using the IBM SPSS Statistics version 24 (IBM Corporation, Armonk, New York, United States).

RESULTS

There were 166 women included in the analysis: 29 with HBPM recorded on the smartphone app, 79 with HBPM recorded in their medical notes and 58 control patients with conventional management. Three women (2.7%) who were approached for HBPM declined, as they were not confident in using the technology. Two women (1.8%) initiated on HBPM were discontinued at their first review as it became clear they were non-compliant. They reverted to the usual care. The demographic characteristics, diagnosis at the beginning of blood pressure monitoring and at the end of pregnancy are outlined in Table 1. There were significantly more women with chronic hypertension in HBPM compared to the controls (49.1% vs 25.9%, p=0.004). Significantly fewer patients developed PE in the HBPM group compared to the control group (20.4% vs 34.5%, p= 0.046). Across both groups, 20.6% of chronic hypertensives and 32.1% of those with gestational hypertension developed PE.

The duration of outpatient monitoring was significantly longer in the HBPM group (Table 2: 8.9 vs 4.9 weeks p=0.004). Patients in the HBPM group had significantly fewer visits to the DAU (4.0 vs 6.0 visits per patient, p<0.001). When including other blood pressure-related visits to the hypertension clinic, DAU, out-of-hours triage and additional reviews by health care staff, the HBPM group had significantly fewer attendances (6.5 vs. 8.0 visits per patient, p=0.003). When calculated as the number of visits per week, the HBPM group still had fewer visits compared to the control group (0.8 vs 1.6 visits per week, p<0.001). In subgroup analysis (Table 3), women with chronic hypertension had significantly fewer visits to the DAU and fewer visits per week in the HBPM group than in the control group. Women with gestational hypertension also had significantly fewer visits to the DAU compared to controls, but no difference in the visits per week. There was no significant difference in the number of blood pressure-related hospital admissions in either the group with chronic hypertension or gestational hypertension.

There were no significant differences in the number of blood pressure-related hospital admissions or HDU admissions between the two groups (Table 2). There were also no significant differences in adverse outcomes such as gestational age at delivery, birthweight, admissions to the neonatal unit, administration of steroids or magnesium sulphate, maternal, fetal or neonatal adverse outcomes (Table 4).

DISCUSSION

Summary of study findings

Our results demonstrate that HBPM significantly reduced the number of DAU visits for blood pressure monitoring compared to traditional outpatient antenatal monitoring. HBPM was also associated with an overall significant reduction in all other antenatal outpatient attendances for hypertension-related reasons and this reduction remained significant when accounting for differences in the duration of monitoring. The duration of monitoring was significantly longer in the HBPM group, which is likely to be due to the greater proportion of patients with chronic hypertension who are likely to have started monitoring at an earlier gestational age. There were no significant differences in the number of hospital or HDU admissions or any other markers of adverse maternal, fetal or neonatal outcomes between the HBPM and control groups.

Interpretation of study findings and comparison to the existing literature

To date, there is limited published literature of HBPM in hypertensive pregnant women. Our results demonstrate a reduction in hospital visits for hypertensive pregnant women using HBPM without increasing adverse outcomes for either the mother or the baby. Although possibly underpowered to assess the adverse maternal, fetal and neonatal outcomes, our findings are supported by previous studies of home monitoring in women with gestational hypertension.[15-17] In their pilot study, Lanssens *et al*. retrospectively compared antenatal

attendances and pregnancy outcomes in 55 hypertensive women using remote monitoring with a hypertensive group managed by traditional means. Whilst they reported less hospital attendances in the remote monitoring group, this was not significant on multivariate analysis. Importantly, their study populations differed with the remote monitoring group having fewer preeclamptic women and the study utilized blood pressure monitors that were not validated for use in pregnancy. Furthermore, the retrospective nature of the study also increases the possibility of selection bias.[15] Similarly, Barton *et al.* compared a large cohort of hypertensive pregnant women using home BP monitoring reporting similar maternal and perinatal outcomes in this group.[1617] Although they also reported fewer days of hospital admission in the home BP group, this difference was inevitable as the control group was a historical cohort managed as inpatients. The findings were also limited by a non-standardized management protocol defined by the patient's individual private physicians.

Study strengths and limitations

There were no significant differences in the maternal age, BMI, ethnicity, parity and smoking status between the two groups, thereby reducing the risk of confounding for adverse outcomes. Our study also benefits from robust data and outcome collection, whereby all hospital notes as well as maternity databases were reviewed in order to gain detailed information about the number of visits and admissions, as well as the pregnancy outcomes. Furthermore, pregnant women in the HBPM group were reviewed by one specialist midwife, reducing variation in practice and related biases.

One of the limitations of our study is that the majority of patients in the HBPM group had chronic hypertension whereas the control group had significantly more women with gestational hypertension. The latter make comparisons between the groups harder to interpret as any differences may have been due to the management of the underlying condition rather than HBPM itself. However, our subgroup analysis demonstrated that there was still a significant reduction in DAU and total outpatient visits in the patients with chronic

hypertension on HBPM and a significant reduction in DAU visits in the GH group on HBPM. Secondly, the control group was recruited retrospectively meaning selection bias cannot be excluded. Finally, our HBPM protocol was designed to comply with the organization and recommended practice of antenatal care in the United Kingdom which may not be representative of antenatal care in other countries. This should be considered when applying the results to other populations.

Clinical and research implications

Despite the paucity of evidence regarding the use of HBPM in pregnancy many professional bodies acknowledge the potential benefits and need for further research.[8,18,19] This is one of the first studies to compare HBPM with traditional monitoring in a hypertensive pregnant population. The finding of a reduction in hospital visits for hypertension-related reasons without an increase in maternal or fetal harm support the notion that a large randomized trial is justified. If women developed PE whilst on HBPM, they reverted to the traditional care pathway. Therefore, our findings cannot be applied to a PE population and the role of HBPM in PE remains unclear. Concerns over differences in the home and clinic readings of PE patients using an automated device and mercury sphygmomanometry have been reported,[20] and although validation studies for devices used in pregnancy often include PE patients, readings in this group may be less accurate.[11,21,22]

Our study was not designed to compare the ability of HBPM with traditional monitoring in detecting PE and this is an important question to be addressed in any future trials. Ambulatory blood pressure monitoring (ABPM) in pregnancy has been shown to be effective in diagnosing white coat hypertension and therefore reducing unnecessary intervention and HBPM is likely to offer a similar benefit.[23,24] Conversely, it would be hoped that HBPM would allow for earlier detection of severe hypertension and PE by virtue of the patients measuring their blood pressure more frequently than if they were attending traditional outpatient monitoring. The fact that significantly fewer patients in the HBPM group progressed to PE

may be explained by the fact that HBPM, as compared to conventional care, offers a closer follow up in women at risk for PE, allowing for better fine tuning of antihypertensive therapy with subsequent lower risk for progression to a more advanced and severe stage of the disease, but the difference was small and should be interpreted with caution in view of the differences in the underlying diagnoses. ABPM studies have shown higher 24-hour readings in patients who subsequently develop PE or fetal growth restriction when compared to routine BP measurements, however refinement is required in enabling these measures to be used as a prognostic tool.[23-27]

HBPM is acceptable to patients and does not appear to increase anxiety.[28,29] It requires less visits to hospital which can save both time and money for patients. Many patients self-monitor their BP in pregnancy without the advice of a healthcare professional and using a large variety of devices.[10,11] It is therefore important to develop evidence-based protocols to ensure this practice is performed safely. Finally, HBPM has the potential to offer cost savings and service improvements by reducing the number of lengthy visits required. This is important in both low and high-income settings which are all under strain to streamline services.

CONCLUSION

Our results suggest that using HBPM in hypertensive pregnancies has the potential to reduce the number of hospital visits required by patients without compromising safety. A larger prospective study is now warranted to further explore whether HBPM can make a difference in terms of requirement of antihypertensive treatment, requirement of early delivery for blood pressure-related reasons, maternal and fetal adverse outcomes.

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DISCLOSURES OF INTERESTS

AK holds ownership rights of the smartphone application used by some participants in the study.

CONTRIBUTION TO AUTHORSHIP

AK conceived the study idea. AK and ES designed the HBPM pathway and recruited participants. HP obtained outcomes, performed data analysis and wrote the body of the manuscript. All authors contributed to the manuscript and approved the final version.

ETHICAL APPROVAL

Ethical approval was obtained for this study (16/NW/0206).

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Table 1. Description of the two study groups.

	Home Blood Pressure group (n=108)	Control group (n=58)	P
Maternal age (years)	32.5 (21-54)	32 (16-44)	0.185
Body mass index (Kg/m2)	27.7 (17.9-55.2)	27.9 (20.1-44.2)	0.986
Ethnicity			
Caucasian	69 (63.9)	38 (65.5)	0.834
Afro-Caribbean	20 (18.5)	13 (22.4)	0.549
Asian	16 (14.8)	7 (12.1)	0.625
Mixed/Other	3 (2.8)	0 (0)	0.200
Nulliparous	61 (56.5)	32 (55.2)	0.871
Smokers	3 (2.8)	1 (1.7)	0.673
Assisted Conception	6 (5.6)	1 (1.7)	0.242
Starting Diagnosis			
Chronic Hypertension	53 (49.1)	15 (25.9)	**0.004**
Gestational Hypertension	47 (43.5)	37 (63.8)	**0.013**
Previous history of preeclampsia	6 (5.6)	4 (6.9)	0.729
White Coat Hypertension	2 (1.9)	2 (3.4)	0.522
End Diagnosis			
Chronic Hypertension	43 (39.8)	11 (19)	**0.006**
Gestational Hypertension	33 (30.6)	25 (43.1)	0.106
Preeclampsia	22 (20.4)	20 (34.5)	**0.046**
Normotensive	8 (7.4)	2 (3.4)	0.307
White Coat Hypertension	2 (1.9)	0 (0)	0.543

Values are given as median (interquartile range) or n (%).Comparisons between the two study groups by X^2 test and Fisher's exact test for categorical variables and Mann–Whitney test for continuous variables

Table 2. Antenatal outpatient visits and hospital admissions per patient in the group undertaking Home Blood Pressure Monitoring and the control pregnancies.

	Home Blood Pressure group (n=108)	**Control group (n=58)**	**P**
Duration of monitoring (weeks)	8.9 (0.40-30.6)	4.9 (1.10-18.40)	**0.004**
Ultrasound scans for fetal assessment	2 (0-8)	2 (0-5)	0.920
Blood tests for pre-eclampsia	2 (0-22)	4 (1-32)	**<0.001**
Number of Day Assessment Unit visits	4 (0-14)	6 (3-18)	**<0.001**
Number of out-of-hours reviews	0 (0-5)	0 (0-1)	0.384
Total antenatal outpatient attendances for hypertension	6.5 (0-26)	8.0 (3-31)	**0.003**
Total antenatal outpatient attendances for hypertension per week of monitoring	0.8 (0-14)	1.6 (0.3-7.9)	**<0.001**
Total hospital bed stay (days)	4 (1-31)	5 (1-36)	0.200
High Dependency Unit days	0 (0-7)	0 (0-4)	0.349

Values are given as median (interquartile range).

Table 3. Subgroup analysis of the antenatal outpatient visits and hospital admissions per patient according to whether the diagnosis at the start of the Home Blood Pressure Monitoring (HBPM) was chronic hypertension or gestational hypertension.

	Chronic hypertension			**Gestational Hypertension**		
	HBPM (n=53)	**Control (n=15)**	**P**	**HBPM (n=47)**	**Control (n=37)**	**P**
Number of Day Assessment Unit visits	4 (0-11)	7 (3-18)	**<0.001**	4(0-14)	6 (3-16)	**0.002**
Total antenatal outpatient attendances for hypertension	7 (0-26)	11 (4-31)	**0.001**	5 (1-16)	7 (3-18)	0.33
Total antenatal outpatient attendances for hypertension per week	0.59 (0-5.73)	1.23 (0.3-2.6)	**0.006**	1.23 (0.2-14)	1.75 (0.5-4.1)	0.191
Total hospital bed stay (days)	3.5 (1-31)	5 (1-36)	0.189	4 (1-26)	5 (1-14)	0.984

Values are given as median (interquartile range).

Table 4. Pregnancy outcomes and adverse maternal, fetal and neonatal events in the two study groups.

	Home Blood Pressure group (n=108)	**Control group (n= 58)**	**P**
Gestational age at birth (weeks)	39 (28.9-41.6)	39.25 (28.3-42.1)	0.395
Birthweight (gr)	3211 (970-4440)	3100 (450-4700)	0.730
Neonatal unit admission	12 (11.1)	11 (19)	0.163
Steroids administration	11 (10.2)	4 (6.9)	0.481
Magnesium sulphate administration	3 (2.8)	5 (8.6)	0.094
Adverse maternal outcome*	1 (0.9)	2 (3.4)	0.245
Adverse fetal outcome†	27 (25)	14 (24.1)	0.902
Adverse neonatal outcome‡	6 (5.6)	3 (5.2)	0.979

Values are given as median (interquartile range) or n (%).

*Adverse maternal outcomes included acute renal failure (maternal serum creatinine level above 100 micromol/L antenatally, or above 130 postnatally) or need for dialysis, acute myocardial ischaemia, need for third intravenous agent to control blood pressure (e.g., in addition to labetalol and hydralazine, hypertensive encephalopathy (altered mental status with characteristic cerebral imaging), cortical blindness, retinal detachment, stroke (ischaemic or haemorrhagic), pulmonary oedema or adult respiratory distress syndrome (defined as characteristic pulmonary imaging in addition to oxygen requirement), need for mechanical ventilatory support (other than for Caesarean section), disseminated intravascular coagulation, thrombotic thrombocytopenic purpura or haemolytic uraemic syndrome, acute fatty liver, liver haematoma or rupture, placental abruption and maternal death.

†Adverse fetal outcomes included preterm delivery (prior to 37+0 weeks' gestation), small for gestational age (birthweight below the 10th centile for gestational age, fetal growth restriction (birthweight below the 5th centile for gestational age) and antepartum or intrapartum fetal death.

‡Adverse neonatal outcomes included neonatal death, respiratory distress syndrome, intraventricular haemorrhage, necrotising enterocolitis, bronchopulmonary dysplasia, periventricular leukomalacia, retinopathy of prematurity, seizure and admission to the neonatal unit for more than 48 hours (for full-term infant).