Is in-patient management of diastolic blood pressure between 90 and 100 mm Hg during pregnancy necessary?

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A randomised controlled trial was performed at the Queen Elizabeth Hospital to compare the effects and acceptance of routine in-patient versus out-patient management of diastolic blood pressure between 90 and 100 mm Hg in pregnant women. There were no significant differences in the establishment of the diagnosis of hypertension, development of severe hypertension or proteinuric hypertension, the number of women requiring obstetric interventions, or the neonatal outcome between the two groups. Antenatal hospital stay for the in-patient group, however, was more than twice as long as for the out-patient group (difference in mean stay, 3.7 days; 95% confidence interval, 1.3-6.2). The number of hospitalisations in the in-patient group was almost four times greater than that in the out-patient group (difference in mean number of hospitalisations, 1.7; 95% confidence interval, 1.2-2.2). The two groups did not differ in their levels of satisfaction of the overall management of blood pressure. Nevertheless, a greater proportion of women preferred to choose the same type of care among the out-patient group than among the in-patient group if they had hypertension in a future pregnancy (83.7% versus 51.2%; P<0.001). More women were dissatisfied about the number of admissions than on the frequency of out-patient care (40.5% versus 16.3%; P<0.001). We conclude that in-patient care, day care, or home monitoring should be individualised.

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Introduction

Hospitalisation has been a widely accepted practice in the management of mild non-proteinuric hypertension during pregnancy remote from term. It provides bedrest and close monitoring of both mother and foetus.[1-3] However, it disturbs social life.[4] Women may consider it stressful or unacceptable.[5] They may need to continue to work or take care of children at home. Moreover, bedrest is a predisposing factor of thromboembolism.

The present trend is to use out-patient care.[6-8] Day care reduces the need for or the length of hospitalisation,[7] is more efficient than in-patient care, and is very acceptable to women.[5] The initial assessment of hypertension complicating pregnancy was proven to be correct in 72% of day care patients and the condition of the remaining 27% of patients showed subsequent deterioration.[9] Day care can thus provide good initial assessment, but the subsequent progression of hypertension may remain undetected. In addition, frequent day care assessment can be inconvenient to women. Women's views on day care have been assessed in only one randomised study[7]; however, the sample size was too small for meaningful statistical analysis.

Crowther et al[8] reported that home monitoring and continued out-patient care provide a safe alternative policy to hospital admission. Nevertheless, the acceptance of home monitoring to women has not been properly assessed in a randomised controlled trial—home monitoring may not be suitable for all women.[10] Besides, there have been contradictory results in out-patient care studies of the risk of progression

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to severe hypertension.[7,8,11] Two studies have shown that in-patient care does not decrease the risk[7,11] and one study has shown that the risk is higher for out-patients.[8] Women who are non-compliant or who show unsatisfactory progress as out-patients should be admitted to hospital[10] and out-patient management must not compromise patient care.[6]

We are not aware of any published randomised controlled trials that assess the value and acceptance of the combination of day care and home monitoring. In our department, prior to the introduction of day care and home monitoring, all pregnant women who were suspected of having hypertension were hospitalised for further assessment. The purpose of this randomised controlled trial is to compare the effects and acceptance of routine in-patient and out-patient (day care followed by home monitoring) treatment in managing pregnancies in which the diastolic blood pressure is between 90 and 100 mm Hg.

Subjects and methods

Approval of the research protocol was given by the Ethics Committee of the Hospital Authority of Hong Kong. The principal outcome measure was the development of severe hypertension. According to the study conducted by Crowther et al,[8] the risk of development of severe hypertension in women with mild hypertension in the in-patient and out-patient groups were 25 in 110 (0.23) and 42 in 108 (0.39), respectively. Sample sizes were calculated according to the statistical table for the design of clinical trials.[12] To have at least an 80% chance of finding significant results at $P<0.05$ (in a one-tailed test) we needed 50 subjects in each arm of the study. A one-tailed test was chosen because the outcomes of the in-patient group were not worse than the out-patient group, as indicated by three previous trials.[7,8,11]

Subjects

Women were recruited from the antenatal clinics and antenatal wards at the Queen Elizabeth Hospital from 1 May 1995 to 30 November 1996. The inclusion criteria were as follows: singleton pregnancy, gestational age between 28 weeks and 38 weeks inclusive, and diastolic blood pressure between 90 and 100 mm Hg inclusive after 5 minutes' rest. The exclusion criteria were as follows: presence of proteinuria (≥1+ on albustix testing), and symptoms of severe pre-eclampsia (including headache, visual disturbance, epigastric pain, and vomiting).

Randomisation

After giving informed consent, eligible women were allocated randomly to either in-patient or out-patient groups according to the instructions, which were put inside a series of consecutively numbered opaque sealed envelopes.

The in-patient group

Women belonging to the in-patient group were admitted to the antenatal ward on the same day as, or the day after, recruitment. They were advised to rest in bed as much as possible. Obstetricians examined them daily. Blood pressures were checked every 4 hours and urine was tested daily for proteinuria by nurses. Foetal assessment was performed by standard clinical methods. Blood tests and modes of foetal monitoring were decided by each obstetrician; blood tests included full blood count, renal function test, and determination of serum urate level. Foetal tests included antenatal cardiotocography, ultrasound examination for growth and liquor volume, and Doppler waveform analysis.

The out-patient group

Women allocated to the out-patient group were assessed in the day care centre and educated about home monitoring before discharge. The day care centre in our department is a day ward consisting of 12 beds. Women who were suspected of or already having mild hypertension could rest there. Urine was analysed for proteinuria. Foetal assessment was performed by standard clinical methods. Blood tests and foetal monitoring, including antenatal cardiotocography and ultrasonography, were decided by each obstetrician. Blood pressures were rechecked after 4 hours' rest and women were reassessed by the obstetricians for further treatment. The frequency of day care was usually weekly for women with mild hypertension.

Some women were assessed in the out-patient clinic. In contrast to the day care centre, the out-patient clinic did not offer a favourable environment for women to rest; there were also no facilities for cardiotocography and ultrasound examination. Women recruited in the antenatal ward were discharged after full explanation and assessment. We advised them to continue their normal activities at home. An instruction sheet and a container of albustix were given to each patient; patients were encouraged to test their urine for proteinuria every day. During each weekly antenatal visit to the out-patient clinic, the inclusion and exclusion criteria were reassessed. If the criteria were still met, out-patient management was continued; otherwise, patients were admitted to hospital. If there was any evidence of foetal growth restriction, out-patient management would also be discontinued and women would be admitted to hospital.

Patients were instructed to come to hospital if proteinuria developed, there were a decrease in or absence of foetal movement, or symptoms of severe pre-eclampsia (including headache, visual disturbance, epigastric pain, and vomiting) developed. They were assessed in the day care centre. The non-stress test was performed for women who had a decrease in foetal movement. Urine testing using albustix was repeated. If hypertension were still mild, out-patient management would be continued. On the other hand, if a patient had significant proteinuria, a diastolic blood pressure >100 mm Hg, or abnormal results to the non-stress test, they were admitted to hospital and treated as usual.

Characteristics

The following information was recorded on entry: date of entry; age; gestational age at entry; number of gravidae; height; weight; diastolic and systolic blood pressures before 20 weeks' gestation; diastolic and systolic blood pressures at study entry; proteinuria; and known history of chronic hypertension or renal disease.

Outcome measures

The following outcomes were recorded on separate data sheets: establishment of the diagnosis of hypertension; development of severe hypertension; development of proteinuria (≥1+ on albustix testing); gestational age at delivery, induction of labour; mode of delivery; use of antihypertensive therapy; birthweight of baby; Apgar score at 1 minute and 5 minutes; admission into the special care nursery; stillbirth or neonatal death; and length of antenatal and postnatal hospital stay.

Hypertension was defined as a diastolic blood pressure of ≥90 mm Hg on two consecutive occasions, 4 hours or more apart. Severe hypertension was defined as a diastolic blood pressure of ≥110 mm Hg on two consecutive occasions, 4 hours or more apart, or a diastolic blood pressure of ≥90 mm Hg. Blood pressure was measured by trained midwives using the auscultatory technique. Auscultatory observations of phase one and phase four were taken as systolic and diastolic blood pressure, respectively. Severe proteinuria was defined as ≥3+ on albustix testing.

Each woman was given a questionnaire after the delivery and was requested to complete it before discharge from hospital. Their views on the management of hypertension and their preferences for out-patient or in-patient care were assessed using the questionnaire.

Adjustment of bias

Adjustment of bias was made in the interpretation of results with respect to the development of severe hypertension, by taking into account the number of and the indications for obstetric interventions. Since there were more blood pressure recordings and assessments in the in-patient group than in the out-patient group, there might have been fewer cases of progression to severe hypertension in the in-patient group because of an earlier intervention before the development of severe hypertension. Another possible bias might have been in the measurement of the length of antenatal hospital stay. A reduction in antenatal hospital stay should not be accompanied by an increase in the length of postnatal hospital stay. The latter might be the consequence of severe hypertension, obstetric intervention, or poor foetal outcome. Thus, the length of postnatal hospital stay was also measured, as were the interval between recruitment and the subsequent development of severe hypertension or proteinuria; the interval between recruitment and spontaneous labour or obstetric intervention; the number of out-patient visits, day care sessions, and number of admissions. All these parameters may have affected antenatal hospital stay.

Results were expressed as mean (standard deviation) or number (%). The Student's *t* test and odds ratios with 95% confidence intervals (CIs) were used for continuous data and categorical data, respectively. The Statistical Package for Social Science/PC was used for statistical analysis of the data.

Results

Ninety women were recruited for the study; 45 women were randomly allocated to the out-patient group (day care plus home monitoring) and 45 to the in-patient group. We terminated the study prematurely because the risk of progression to severe hypertension was so similar between the two groups. Ten women who were eligible for the study refused to join the trial; six of them were reluctant to be admitted and the remainder did not like out-patient management. The non-compliance rate was 2.2%. Two women (one belonged to the out-patient group and the other belonged to the in-patient group) defaulted follow-up and did not deliver in our hospital.

Results were analysed according to allocation at randomisation despite non-compliance. Twelve women from the out-patient group subsequently required hospitalisation because of worsening hypertension or development of proteinuria; their data were analysed with that of the out-patient group. The characteristics at study entry were similar between the in-patient and

Table 1. Characteristics at study entry of the out-patient and in-patient groups

	Out-patient group*, n=44	In-patient group*, n=44	Difference between groups (95% CI) or P value
Age (SD) [years]	32.5 (5.3)	31 (5.2)	1.5 (-3.7–0.8)
Primigravidae (%)	18 (40.9)	14 (31.8)	
Multigravidae (%)	26 (59.1)	30 (68.2)	P=0.391
Height (SD) [cm]	156.8 (6.3)	157.0 (4.9)	0.2 (-2.2–2.6)
Weight at entry (SD) [kg]	58.8 (14.7)	55.8 (17.7)	3 (-9.9–3.9)
Gestation at entry (SD) [weeks]	33.1 (3.0)	33.2 (2.9)	0.1 (-1.1–1.4)
Blood pressure at booking clinic (SD) [mm Hg]			
systolic	128.9 (13.7)	126.9 (14.5)	2.0 (-8.9–4.7)
diastolic	77.5 (8.5)	75.2 (9.2)	2.3 (-6.5–2.0)
Blood pressure at entry (SD) [mm Hg]			
systolic	144.6 (7.6)	144.3 (10.0)	0.3 (-4.0–3.5)
diastolic	91.9 (4.4)	92.0 (3.9)	0.1 (-1.7–1.9)
No. with history of pre-existing hypertension or renal disease (%)	2 (4.5)	5 (11.5)	P=0.702

* Results are expressed as the mean (standard deviation) or No. (%)

out-patient groups (Table 1). Eighteen women from the entire population had other complications which included premature rupture of the amniotic and chorionic membranes (six in-patients and five out-patients), impaired glucose tolerance on dietary control (one in-patient and one out-patient), suboptimal cardiotocogram (two in-patients), antepartum haemorrhage of undetermined origin (one out-patient), postmaturity (one out-patient), and urinary tract infection (one in-patient). Two women were already in-patients before recruitment; they were admitted for abdominal pain due to irregular uterine contraction and they had no other complications.

Establishment of the diagnosis of hypertension

Hypertension was diagnosed in 36 (81.8%) women of the out-patient group and 31 (70.5%) women of the in-patient group. Three women of the out-patient group and nine women of the in-patient group had started spontaneous labour before the establishment of the diagnosis of hypertension or the development of severe hypertension.

Progression of hypertension

Similar proportions of women in each group developed severe hypertension (Table 2). No significant difference in the development of proteinuric hypertension was found between the two groups. Among those women with severe hypertension or proteinuria, there were no significant differences in the proportions of women with risk factors (eg pre-existing hypertension or renal disease) between the two groups.

Table 2. Development of severe hypertension and proteinuric hypertension in women diagnosed with hypertension

	Out-patient group, n=36 No. (%)	In-patient group, n=31 No. (%)	Odds ratio* (95% CI)
Development of severe hypertension (DBP† ≥110 mm Hg) with or without proteinuria			
without PHRD‡	3 (8.3)	3 (9.7)	0.77 (0.14-4.16)
with PHRD	1 (2.8)	1 (3.2)	3.0 (0.08-107.45)
Total	4 (11.1)	4 (12.9)	0.84 (0.19-3.70)
Development of proteinuric hypertension and DBP <110 mm Hg			
without PHRD	3 (8.3)	2 (6.5)	1.2 (0.19-7.81)
with PHRD	0	0	
Total	3 (8.3)	2 (6.5)	1.32 (0.21-8.45)

* In-patient group as the reference group
† DBP diastolic blood pressure
‡ PHRD pre-existing hypertension or renal disease

Table 3. Foetal outcome in women diagnosed with hypertension

	Out-patient group*, n=36	In-patient group*, n=31	Difference between groups or odds ratio† (95% CI)
Mean birthweight (SD) [g]	3101 (508)	3196 (467)	95 (-147.9–339.1)
Low-birthweight baby (%)	4 (11.1)	2 (6.5)	OR=1.8 (0.3-9.9)
Preterm delivery (%)	4 (11.1)	3 (9.7)	OR=1.2 (0.2-5.7)
Small for gestational age infants (%)	2 (5.6)	0	OR=3.1 (0.2-98.9)
Requiring admission into NICU‡ (%)	1 (2.0)	1 (3.2)	OR=0.9 (0.1-4.3)

* Results are expressed as the mean (standard deviation) or No. (%)
† In-patient group as the reference group
‡ NICU neonatal intensive care unit

Three women in the out-patient group developed proteinuric hypertension; however, none reported the detection of proteinuria during home monitoring.

Foetal outcome

There were no statistically significant differences between the two groups in mean birthweight, number of low-birthweight infants, number of small for gestational age infants, or number of infants requiring admission into the neonatal intensive care unit (Table 3). Two babies were admitted into the neonatal intensive care unit. The mother of one of them belonged to the out-patient group; the reason for admission was low birthweight resulting from spontaneous premature labour. The mother of the other baby belonged to the in-patient group. Caesarean section was done at 35 weeks' gestation because of severe hypertension.

Obstetric intervention

There were no statistically significant differences in the number of women requiring induction of labour, caesarean section or antihypertensive therapy between the two groups (Table 4). The numbers of women undergoing induction of labour or caesarean section because of hypertension were similar in both groups.

Length of hospital stay and number of admissions to hospital

Women in the in-patient group experienced on average more than twice the length of antenatal hospital stay than women in the out-patient group (difference in mean stay, 3.7 days; 95% CI, 1.3-6.2; Table 5). The number of hospitalisations in the in-patient group was almost four times that of the out-patient group (difference in mean number of hospitalisations, 1.7; 95% CI, 1.2-2.2). Confounding factors between the two groups were compared. No difference was found in the length of postnatal hospital stay between the two groups. There were also no differences in the interval between recruitment and the subsequent development of severe hypertension or proteinuric hypertension, and the interval between the recruitment and spontaneous labour or intervention. The numbers of out-patient visits in the two groups were similar.

Table 4. Obstetric intervention in women diagnosed with established hypertension

	Out-patient group, n=36 No. (%)	In-patient group, n=31 No. (%)	Odds ratio* (95% CI)
Induction of labour			
for hypertension	7	7	
for other reasons	5	6	
Total	12 (33.3)	13 (41.9)	0.7 (0.3-1.9)
Caesarean section			
for hypertension	4	2	
for other reasons	3	5	
Total	7 (19.4)	7 (22.6)	0.9 (0.3-2.6)
Antihypertensive therapy	4 (11.1)	3 (9.7)	1.2 (0.2-5.7)

* In-patient group as the reference group

Table 5. Length and frequency of care received by women diagnosed with established hypertension*

	Out-patient group, n=36	In-patient group, n=31	Difference between groups (95% CI)
Antenatal hospital stay (SD) [days]	3.1 (2.5)	6.8 (6.3)	3.7 (1.3-6.2)†
Postnatal hospital stay (SD [days]	4.8 (3.0)	4.7 (2.9)	0.1 (-1.45–1.44)
Interval 1‡ (SD) [days]	45.3 (25.6)	46.3 (18.3)	1.0 (-28.7–26.6)
Interval 2§ [days]	45.3 (25.6)	48.3 (18.6)	3.0 (-30.9–24.8)
No. of out-patient visits per woman	1.9 (1.9)	1.7 (1.6)	0.2 (-0.6–0.9)
No. of day care visits per woman	1.8 (1.5)	0	
No. of hospitalisations per woman	0.6 (0.8)	2.3 (1.4)	1.7 (1.2-2.2)‖

* Results are expressed as the mean (standard deviation)
† Significant (P=0.004)
‡ Interval 1 Interval between recruitment and the subsequent development of severe hypertension or proteinuria
§ Interval 2 Interval between recruitment and spontaneous labour or obstetric intervention among women who had developed severe hypertension or proteinuria
‖ Significant (P<0.001)

Women's views

Forty-three of the 44 women in both the in-patient and out-patient groups returned the questionnaire after delivery. There was no statistical difference in the overall satisfaction between the two groups. All the women in the out-patient group and 98% of those in the in-patient group were satisfied with their treatment. However, when asked about preferred future management of hypertension during future pregnancy, 36 (83.7%) women in the out-patient group chose out-patient management while 22 (51.2%) women in the in-patient group chose in-patient management; the difference was statistically significant (P<0.001).

There was also a significant difference in women's views on the frequency of care between the two groups (P<0.001)—the frequency of day care visits was rated as 'excellent'/'good' by 83.7% of women, and that of hospital admissions by 59.5% of women. On the other hand, women's views on the setting of out-patient and in-patient care were very similar between the two groups—90.7% and 88.3% of women rated 'excellent'/'good' as the setting of out-patient and in-patient care, respectively.

Discussion

This study has shown that in-patient management does not prevent the development of proteinuric hypertension or severe hypertension and confirms the findings of previous studies.[7,11] However, the finding of Crowther et al[8] that hospital admission for bedrest decreases the risk of developing severe hypertension was not confirmed. The combination of day care and home monitoring was shown to be safe in managing mild non-proteinuric hypertension. There were no differences in foetal or maternal outcomes between the in-patient and out-patient groups.

In general, both in-patient and out-patient care were acceptable to women—98% and 100%, respectively. Nevertheless, significantly more women preferred out-patient care if the choice were given. The frequency of either out-patient care or hospital admission but not their setting was a significant factor. More women were dissatisfied about the number of admissions than about the frequency of out-patient care. To improve the level of satisfaction, efforts should be made to reduce the number of admissions rather than to improve the setting.

This study has also shown that out-patient management significantly decreases the length of antenatal hospital stay by more than half and the number of hospital admissions by almost one quarter. If the mean number of day care visits (1.8) and hospital admissions (0.6) in the out-patient group are added, the sum (2.4) is similar to the mean number of hospital admissions (2.3) in the in-patient group. The reduction in the number of hospital admissions was thus related to the use of day care. Although there is an increasing pressure towards cost-effective care, women's welfare should not be compromised.

We are concerned about the three women in the out-patient group who did not report the detection of proteinuria during home monitoring but who were subsequently found to have proteinuria. Proteinuria might have developed on the dates of antenatal visit or the patients might not have used albustix testing. It was unlikely that they were not taught well enough. Crowther et al[8] reported that women who could not read were able to perform the urinalysis satisfactorily and recognise a clinically significant result; we hold a different view. Some women may not comply with the urinalysis or report the true result. We agree with Barton et al[6] that women who are non-compliant should not be considered for out-patient care. It is necessary

to select well-motivated and compliant women, and to educate them on how to use and read albustix.

Among the women who had severe hypertension, one woman in the out-patient group and another in the in-patient group had pre-existing hypertension or renal disease. None of the women with pre-existing hypertension or renal disease developed proteinuric hypertension. Further studies are needed to confirm the efficacy of out-patient management of hypertension in these groups of women.

At present, we do not advocate home blood pressure monitoring as part of the home monitoring as suggested by Barton et al.[6] We have been using conventional methods—sphygmomanometry and the Korotkoff 4 (K4) method—to measure diastolic blood pressure. Automated blood pressure machines use the Korotkoff 5 (K5) method, however.[13] The K4 and K5 readings overestimate diastolic blood pressure by 9 to 11 and 4 to 7 mm Hg, respectively.[14,15] Although the use of the K5 method was recommended recently,[13,16] the correlation to traditional measurements of the K4 method and the use of established guidelines and prognosis are not clear.[13] Greater patient compliance is also needed.

In conclusion, our study did not show that routine admission of all women with diastolic blood pressure between 90 and 100 mm Hg from 28 to 38 weeks' gestation is beneficial. Routine out-patient management is not always appropriate because some women may find it unacceptable or may not comply. We recommend the careful selection of women for appropriate treatment. The use of in-patient care, day care, or home monitoring should be individualised, after proper counselling. Patient characteristics and preferences about different types of care are important. In-patient care should be offered to women who choose that option. On the other hand, in-patient care will be inappropriate to women who do not want to be admitted to hospital. If patients are well motivated to perform home monitoring, then continued out-patient care with home monitoring after day care assessment will be preferred. Otherwise, frequent day care visits are needed to decrease the risk of the undetected development of hypertension.

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