A RANDOMIZED TRIAL ON EFFECTIVENESS OF HOME BASED CARE COMPARED TO CONVENTIONAL CARE FOR ANTENATAL WOMEN WITH GESTATIONAL HYPERTENSION

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ABSTRACT

BACKGROUND

Approximately 70% of hypertensive disorders in pregnancy are constituted by gestational hypertension, in which 15-25% of cases progress to pre-eclampsia. This study was undertaken to assess whether home based care for gestational hypertension would reduce pre-eclampsia and improve maternal and fetal outcomes compared to conventional care.

MATERIALS AND METHODS

A randomized controlled community based study was carried out during 2014-2015 in the service areas of a Medical College at Puducherry. One hundred and three antenatal mothers with gestational hypertension (systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg) were randomly enrolled into home care group (n=52) and conventional care group (n=51). The home care group mothers were monitored at home by three auxiliary nurse midwives. Blood pressure, weight, pedal edema, urine albumin, fetal movements, fetal heart rate and warning signs of eclampsia were assessed periodically. Both groups received usual antenatal care at hospital. Maternal and fetal outcomes at delivery were analyzed using SPSS 17.

RESULTS

The mean age of the mothers was 25.0 ± 3.9 yrs. A significant reduction ($p < 0.05$) in mean diastolic blood pressure was observed in both the groups. A reduction in mean systolic pressure was observed in home care mothers. Twenty mothers (19%) progressed to pre-eclampsia-17% in home care and 22% in conventional care group. At delivery, 46% mothers in home care and 37% of mothers in conventional care had normal blood pressure. Significant weight gain ($p < 0.05$) was observed in home care mothers. Prolongation of pregnancy to term was 89% in home care and 84% in conventional care group. No significant neonatal outcomes were observed between the two groups. However, low birth weight babies were more in conventional care group.

CONCLUSION

Home based care for gestational hypertension could be an acceptable strategy. Large scale studies are needed for more scientific evidence.

KEYWORDS

Gestational Hypertension, Home Care, Pre-eclampsia, Pregnancy-Induced Hypertension.

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INTRODUCTION

In India while maternal deaths due to haemorrhage and infections are decreasing, deaths due to hypertension are increasing.^{1,2,3} Gestational hypertension constitutes about 70% of hypertensive disorders in pregnancy.^{4,5} It occurs after 20 weeks of gestation, characterised by a systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg without proteinuria.

Although maternal risks with gestational hypertension are generally less compared to pre-eclampsia, approximately 15-25% of them progress to pre-eclampsia leading to severe obstetric complications including death. Hence, it is mandatory to monitor and treat each case of gestational hypertension as emerging pre-eclampsia.^{6,7} One of the important objective of antenatal care is to detect such high risk women and give them special care. Unfortunately, many women receive inadequate prenatal care because of problems of accessibility, financial constraints as well as personal and social reasons.^{3,8}

In the conventional management of gestational hypertension, the women are advised about warning signs of eclampsia, adequate bed rest at home, blood pressure monitoring at a locally available health facility and reporting to the hospital for timely delivery.^{9,10} However, there are no proper guidelines or uniformity in referral thresholds and assessment procedures of these women at community level.^{11,12}

Home based antenatal care primarily by a trained midwife along with institution based care by obstetrician has

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been recognized as a model globally. Hence, delivering such type of care to antenatal women with gestational hypertension could reduce the barriers and potentially improve pregnancy outcomes.¹³ Limited reports are available from observational studies on home care plan for women with mild pre-eclampsia.¹⁴ No randomized trials have been reported on the impact of home based care of gestational hypertension compared to that of conventional care. In this context, the investigators explored the effectiveness of a home care approach for women with gestational hypertension with the existing routine care service in improving the maternal and neonatal outcomes at delivery.

Research Question

Is a home based care program for antenatal women with gestational hypertension effective in reducing maternal and neonatal outcomes in terms of morbidity and mortality as compared to conventional antenatal care?

MATERIALS AND METHODS

A community based interventional study was conducted between March 2014 and February 2015 in the service areas of a Medical College in Puducherry, after obtaining permission from the Institutional Ethics Committee. Permission to screen and recruit antenatal women for the study was obtained from the Director of Medical Services, Govt. of Puducherry, Medical Superintendent of Government Maternity Hospital (RGGMH) and Director of Indira Gandhi Government Medical College respectively.

The sample size was calculated using OPEN EPI software. Taking P_1 as the proportion of antenatal women with hypertension who became normotensive by home based nursing care (56%), as reported in an earlier study,¹⁵ and with an assumption that conventional care (P_2) outcome would be 50% less than home based nursing care, the sample size was calculated to be 48 in each group with $Z\alpha$ at 0.05 and power of study as 80%. It was decided to recruit 50 mothers in each group.

Three Auxiliary Nurse Midwives (ANM) were recruited for the study. They were trained on antenatal care aspects

pertaining to gestational hypertension. Training content was adopted from "Skilled Birth Attendant Module for Antenatal Care¹ (SBA)" of Department of Family Welfare, Ministry of Health and Family Welfare, Govt. of India. Training was imparted by Community Medicine Physicians, an obstetrician and two nurses specialized in Maternal and Child Health Nursing. Pretest and Post-test were conducted to assess the change in knowledge and practice of the ANMs, before and after the training. Periodic sensitization was conducted for these ANMs during the study period.

Antenatal mothers attending the Obstetric Outpatient Department were screened for gestational hypertension by the ANMs. Eligible women (Gestational age between 20 wks. and 34 wks.; no other high risk factors) were randomly enrolled either into home care group (Intervention) or conventional care (Control) group after written consent. The home care mothers were monitored at home on alternate days by the ANMs. Blood pressure, weight, pedal edema, urine albumin, fetal movements, fetal heart rate and warning signs of eclampsia were assessed and documented. Advice on diet, adequate rest and medication compliance were given periodically.

The mothers were informed to call the ANM over the phone in case of any emergencies. Any woman with clinical deterioration such as proteinuria, Systolic BP ≥ 160 mmHg and/or diastolic ≥ 110 mmHg, was referred to the hospital immediately. Regular antenatal check up in the hospitals was continued for both groups. All clinical decisions regarding management and delivery were at the discretion of the obstetricians.

Delivery details of the mother and baby were documented from the hospital records. Maternal outcomes in terms of blood pressure changes, weight gain, morbidity and mortality were assessed. Fetal outcomes in terms of birth weight, gestational age at delivery, morbidity and mortality were assessed. Data entry and analysis were done with SPSS software version 17.

Flow Chart: Recruitment of Antenatal women with Gestational Hypertension.

MATERNAL OUTCOMES

Women on home care had an average weight gain of five kilograms ($p<0.05$), decrease in mean systolic blood pressure and a significant decrease in mean diastolic blood pressure ($p<0.01$). In the conventional care group, decrease in weight, an increase in mean systolic blood pressure and a significant decrease in mean diastolic blood pressure ($p<0.01$) was noted (Table 3).

Overall, 58% women continued to have hypertension till delivery. Blood pressure became normotensive (SBP<140mmHg and DBP<90mmHg) among 46% of mothers in home care group and 37% in conventional care group at delivery. There were no eclampsia cases or mortality in both the groups. Eleven women (22%) in conventional care group and nine women (17%) in home care had signs of pre-eclampsia. However, it was not statistically significant ($p=0.617$). More women (31%) in conventional care group were on antihypertensive medications compared to home care group (25%) (Table 4).

NEONATAL MORBIDITY AND MORTALITY

All the deliveries were institutional. Overall, 10% of deliveries were preterm. Preterm delivery was more in conventional care group (12%) than home care group (8%). There was no significant difference ($p>0.05$) in the mean gestational age at delivery between the groups. Low birth weight babies (<2.5kg) were more in conventional care group than in home care group. There was no significant difference ($p>0.05$) in the mean birth weight between the groups.

There was no significant difference ($p>0.05$) in the APGAR status between the groups. There was one stillbirth in both the groups. Neonatal morbidity was documented in 14 babies (27%) in home care group and 18 babies (35%) in the conventional care group. Birth asphyxia was more in conventional care group than home care group. There was no significant difference (χ^2 0.728, $p>0.05$) in overall morbidity status of neonates between the groups (Table 5).

DISCUSSION

In our study, about 2.3% of mothers screened had gestational hypertension. Pregnancy Induced Hypertension (PIH) reported in other Indian studies ranged between 3%-6%.^{16,17} Advanced maternal age is known to be a risk for PIH. The mean age of mothers in our study was 25 years. Forty percent of mothers were in second trimester at recruitment and 58% were nulliparous. Similar findings have been reported in studies from India.^{16,17,18} and abroad.^{19,20} Majority of the participants were housewives. This was consistent to the observation by Borade et al.² Traditionally, these women take little bed rest at home and do not refrain from physical work irrespective of their pregnancy status.

An average increase of 5 kg (From recruitment period) was observed in the home care group. An average weight gain of 6.5 kg during the entire pregnancy period is usually seen in Indian mothers.³ As per literature evidence, nearly one fifth of women with gestational hypertension progress to pre-eclampsia.⁷ In this study, 19% mothers had developed signs of pre-eclampsia. Preeclampsia was more (65%) among those who had hypertension at gestation <30 weeks. Arias F et al.¹⁰ had documented a similar observation.

Even though a statistical significance was not achieved, incidence of pre-eclampsia was less in home care group compared to conventional care mothers. Nineteen (37%) mothers in conventional care group became normotensive during the study period. Hence, we expected 38 mothers (Ref: sample size calculation).¹⁵ in the intervention group to become normotensive as a consequence of home based nursing care. Even though this was not accomplished, nearly

two-third mothers (24/38) became normotensive in the home care group.

In our study, we observed that prolongation of gestation to term was slightly more in home care group (89%) than conventional care group (84%). Normal deliveries were more in home care group. About 13% of total deliveries were of low birth weight, more among the conventional group (15%) than home care group (10%). Neonatal morbidity was less in home care mothers compared to conventional care mothers. However, statistical significance could not be established in these observations. Pre-eclampsia is associated with early GA at delivery and low birth weight.²¹ about 30% of deliveries among pre-eclampsia mothers were of low birth weight and preterm in the present study. Also both the mothers who had stillbirth had pre-eclampsia.

Worldwide, midwifery model of care and delivery has brought forth acceptance and recognition in reducing maternal morbidity and mortality. Studies from Western Countries have reported the beneficial effects of prenatal home care for high risk pregnancies.^{22,23} A PIH related maternal death audit on 622 deaths during 2005-2007 in South Africa²⁴ had reported nonattendance for antenatal care (19%) and delay in seeking help (19%) as patient related causes. Such factors could be avoided in prenatal home care. The safety and acceptability of a community based nursing program for pre-eclampsia was studied among 321 mothers in Winnipeg.¹⁵ While 56% of study subjects showed better maternal outcomes in terms of blood pressure, rest (44%) got admitted due to worsening of pre-eclampsia. The program had received good support from the mothers. Regular monitoring and compliance of mothers was quoted as the success of the program.

In the Reproductive and Child Health Program (RCH) of India, the auxiliary nurse midwives provide most of vital antenatal services in Subcentres and Primary Health Centres.²⁵ Increasing their skills to monitor pregnancy-induced hypertension would decrease potential maternal and fetal complications. A protocol based nursing care at home could supplement the routine hospital care of women with gestational hypertension. It has advantages such as reducing transportation problems, long waits in the Outpatient Departments and interruption of bed rest.²²

In our health system, for an ANM covering 5000 population in a Subcentre Area, assuming birth rate of 21/1000 population, 115 pregnant mothers are expected at any time in a year.³ There would be 10 PIH mothers (Assuming 10% of all pregnancies). Even if a woman without risk is attending antenatal clinic regularly, she must be paid at least one home visit.³ Hence women with gestational hypertension could be paid additional home visits. Such home visits will win the confidence of the antenatal mother and will favour better maternal and fetal outcomes.

The median number of visits by the ANMs in the present study was 24. Other studies on home visits of high risk mothers have reported an average of 7-25.1 visits.^{23,26} Twenty eight mothers were referred to obstetrician during the study period. In a trial in Huddersfield, 38 women with gestational hypertension were visited two to three times weekly by community midwives.

It was observed that compared to routine care, admissions were less in intervention group and inpatient days were less during the study period of six months. Supervision of PIH women at home had added 5% in the workload of midwives. In addition, good rapport was reported between the mother and community midwife, which was a great benefit after delivery.²⁷

Documentation of data in our study was found to be extensive. This could be an additional workload for an ANM considering her other responsibilities in the community.

However, providing additional care to these women would not be a concern if other grass root level workers like ASHA could monitor the urine albumin and fetal movement status of the mothers and provide the information to the ANM during home visits.

The limitations in this study were that the small sample size restricts the generalizability of the findings of our study and cost comparison analysis of home based care with conventional care was not done. To conclude, home based care program for gestational hypertension would be a feasible and acceptable strategy to the community and obstetricians. Similar studies could be evaluated on a large scale for more scientific evidence.

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Demographic Characters	Home Care (52) No %	Conventional Care (51) No %	Total (103) No %	
Age Group (yrs)				
19-22	15 28.8	12 23.5	27 26.2	4.325 (0.228)*
23-26	18 34.6	23 45.1	41 39.8	
27-30	10 19.2	13 25.5	23 22.4	
31-34	9 17.4	3 5.9	12 11.6	
Mean Age	25.3±4.3 yrs	24.7±3.5 yrs		0.829 (0.409)\$
Education				
Primary		1 2.0	1 1.0	0.6973 (0.705)*
Secondary	4 7.7	4 7.8	8 7.8	
High School	22 42.3	22 43.1	44 42.7	
Higher Secondary	9 17.3	11 21.6	20 19.4	
College	17 32.7	13 25.5	30 29.1	
Occupation				
Housewife	48 92.3	43 84.3		1.599 (0.206)*
Others	4 7.7	8 15.7		
Table 1: Demographic Characters of Study Participants (n=103)				

Table 1: Demographic Characters of Study Participants (n=103)

* χ^2 (p value) \$ t (p value)

	Home Care (52) No %	Conventional Care (51) No %	Total (103) No %	
Parity				
Primi	31 59.6	29 56.9	60 58.2	0.080 (0.777)*
Multi	21 40.4	22 43.1	43 41.8	
Gestational Age (weeks)				
20 - 24	7 13.5	6 11.7	13 12.6	1.29 (0.522)*
25 - 29	18 34.6	13 25.5	31 30.1	
30 - 34	27 51.9	32 62.8	59 57.3	
Mean Weight (kg)	67.9±11.9	69.1±13.9		0.471 (0.638)§
Mean SBP (mmHg)	125.0±8.0	129.6±9.8		2.612 (0.010)§
Mean DBP(mmHg)	90.6±2.4	90.9±3.6		0.498 (0.619)§
Table 2: Obstetric Particulars of Study Participants at Recruitment				

Table 2: Obstetric Particulars of Study Participants at Recruitment

* χ^2 (p value) \$ t (p value) SBP – Systolic blood pressure DBP – Diastolic blood pressure

Outcomes	Baseline	At Delivery	t test p value
	Mean $\pm$ SD	Mean $\pm$ SD	
Home Care (n=52)			
Weight (Kg)	67.9 $\pm$ 11.9	72.9 $\pm$ 12.5	2.089 0.039
SBP (mm Hg)	125.0 $\pm$ 8.0	124.4 $\pm$ 11.6	0.363 0.718
DBP (mm Hg)	90.6 $\pm$ 2.4	86.4 $\pm$ 9.4	3.110 0.003
Conventional Care (n=51)			
Weight (Kg)	69.1 $\pm$ 13.9	68.9 $\pm$ 13.7	0.077 0.939
SBP (mm Hg)	129.6 $\pm$ 9.8	131.9 $\pm$ 13.9	1.193 0.238
DBP (mm Hg)	90.9 $\pm$ 3.6	87.3 $\pm$ 9.8	2. 611 0.012
Table 3: Maternal Outcomes among the Study Participants			

Table 3: Maternal Outcomes among the Study Participants

SBP – Systolic blood pressure DBP – Diastolic blood pressure

	Home Care (n=52) No %	Conventional Care (n=51) No %	χ^2 p value
Blood Pressure at Delivery			
Antenatal women who become normotensive	24 46.2	19 37.3	0.838 0.3598
Antenatal women who continued to have hypertension	28 53.8	32 62.7	
Maternal Morbidity			
Pre-eclampsia	9 17.3	11 21.6	
Oligohydromnios	3 5.7	1 1.9	
PROM	1 1.9	3 5.8	
Sepsis	2 3.8	4 7.8	
BP Medications	13 25.0	16 31.3	
Anemia	2 3.8	6 11.7	
Table 4: Blood Pressure at Delivery and Morbidity Status of Mothers			

	Home Care (n= 52) No %	Conventional Care (n=51) No %	
GA (weeks)			
Preterm ≤36	4 7.7	6 11.6	0.491 (0.782)*
Term 37- 40	46 88.5	43 84.3	
Post term >40	2 3.8	2 3.9	
Mean GA±SD	38.5±1.6	38.3±1.8	0.504 (0.616)\$
Mode of Delivery			
Normal	29 55.7	26 50.9	0.237 (0.626) *
Caesarian	23 44.3	25 49.1	
Birth Weight			
< 2.5 Kg	5 9.6	8 15.4	0.791 (0.373) *
≥ 2.5 Kg	47 90.4	44 84.6	
Mean ±SD (kg)	2.97±0.45	2.96±0.59	0.072 (0.942)\$
Range (kg)	1.47- 4.20	1.3- 4.09	
APGAR			
0-3	1 1.9	1 2.1	0.751 (0.427)\$
4-6	1 1.9	3 5.8	
7-10	49 96.2	47 92.1	
Neonatal Morbidity			
Birth Asphyxia	8 15.6	10 19.6	0.728 (0.196) *
Infection / Sepsis	4 7.8	4 7.8	
Jaundice	2 3.9	2 3.9	
GI Bleed	-	2 3.9	
Table 5: Neonatal Outcomes in the Study Participants			

* χ^2 (p value) \$ t (p value)