

## Rationale use of drugs in pregnancy induced hypertension at a tertiary care hospital

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### ABSTRACT

**Background:** Pregnancy induced hypertension known as preeclampsia is considered to be the second cause of death next to anaemia. There are significant sources of maternal and foetal mortality and morbidity. Antihypertensive medication reduces the progression of the course of hypertensive disorders. However, its effect on the outcomes of pregnancy may include development of preeclampsia, preterm delivery, foetal /neonatal demise, IUGR, low birth weight. Whether such associations are casual or confounded is unknown. Hence, we intended to study the rationale use of drugs in pregnancy induced hypertensive patients.

**Methods:** Patients diagnosed with hypertensive disorders in pregnancy were recruited. Pregnant women in the age group of 18-45 years who consented to participate were included. Non pregnant women and women with PCOD, depression and on any medications were excluded. Details on drug treatment, type of drugs, combination, dose, dosage and duration were noted.

**Results:** 105 patients were enrolled. 51% belonged to 18-25 years. 98% mothers received monotherapy and 2% received dual therapy. Labetalol was the most commonly prescribed drug. 50% of the patients received a combination of Nifedipine and Methyldopa while another 50% received Nifedipine with Labetalol. The outcome of new born babies born in mothers receiving antihypertensive drugs had complications of low birth weight and malformations. The dose of the medications prescribed was well within the range.

**Conclusions:** Proper counselling to the patients regarding life style management, regular follow ups and monitoring of blood pressure is important to understand, resolve the burden and complication.

**Keywords:** Pregnant women, Hypertension, Preeclampsia, Rationale drug use

### INTRODUCTION

Hypertensive disorders are considered to be the commonest disorders during gestation and they continue to be one of the major reasons for maternal and perinatal morbidity and mortality. In developing countries, Pregnancy induced hypertension (PIH) known as preeclampsia is considered to be the second cause of death next to anaemia with approximately of about 7-10% of

pregnancies being a complicated form.<sup>1</sup> In India, the incidence of PIH is considered to be 5-15% as per the data collected from the hospital based studies.<sup>2</sup> Hypertension is a disorder of an elevated Blood pressure  $\geq 140/90$  mmHg. It consists of various spectrums of disorders that include chronic hypertension, PIH, preeclampsia/eclampsia and chronic hypertension with superimposed preeclampsia.<sup>3,4</sup> There are significant sources of maternal and foetal mortality and morbidity. With raise in the understanding of the disease progression, the complication related to the

disease, the maternal and perinatal mortality have decreased in the last few years, which is mostly observed in the developed countries, where as in developing countries their in still higher rates of mortality and morbidity.<sup>5</sup> Antihypertensive medication reduces the progression of the course of hypertensive disorders during the gestation period. However, its effect on the outcomes of pregnancy may include development of preeclampsia, preterm delivery, foetal /neonatal demise, IUGR, low birth weight. Whether such associations are casual or confounded is unknown.<sup>6</sup> Antihypertensive medications are used in the treatment of PIH. Labetalol is considered in guidelines as the first line preferred agent for treatment of hypertension in pregnancy.<sup>7</sup> Concerns regarding the side effects, the cost of drugs and the pattern of prescribing drugs were heightened, since then the value of drug utilization studies have gained momentum.<sup>8,9</sup> Hence we intended to study the rationale use of drugs in pregnancy induced hypertensive patients.

## METHODS

A prospective observational study was conducted at a Rajarajeswari Medical college and hospital in Bangalore from Aug 2018 to Dec 2019 after obtaining permission from the ethical committee. Outpatients and inpatients diagnosed with hypertensive disorders in pregnancy were recruited for the study from Obstetrics and gynaecology department in collaboration with department of pharmacology. Patient's recruitment was done based on strict inclusion and exclusion criteria. Pregnant women with confirmed case of PIH, in the age group of 18-45 years and those who consented to participate were included in the study. Non pregnant women and women with any other disorders like PCOD, depression and on any other medications were excluded from the study. Data was collected on obtaining institutional ethical committee approval. We collected data in a specially designed case record form. Data with respect to their demographic details like, name, age, height weight, socioeconomic status was collected and categorised according to modified Kuppuswamy scale. The baseline characteristics of the disease like age at last menstrual period, co morbidities, maternal complications, investigations if any were noted. Information about the drug treatment i.e. monotherapy/polytherapy, types of drugs, their combination, dose, dosage and duration were noted. Statistical analysis was done using SPSS ver 21 for descriptive and continuous variables.

## RESULTS

A total of 105 patients were diagnosed with hypertensive disorder in pregnancy and were enrolled in the study. 51% of the patients belonged to the age group of 18-25 years, 43.8% belonged to the age group of 26-35 years and 4.8% belonged to the age group of 36-40 years. 0.9% of the pregnant women belonged to the upper class, 20% belonged to the upper middle class, 51% belonged to the lower middle class, 25% belonged to the upper lower class

and 1.9% belonged to the lower class according to the modified Kuppuswamy scale.

With relation to the history of PIH, there were 41.1% of patients with previous history. Among the pregnant women 52.6% had chief complaints headache, visual disturbances, pain abdomen, decreased foetal movements, convulsions, pedal edema? On examination 93% of the mothers had elevated blood pressure in their antenatal checkups. We then assessed the comorbidities of the patients and found that 73% of the patients had no comorbidities while 27% of the patients had comorbidities, out of which 4% of the patients had gestational diabetes mellitus, 10% of the patients had type 2 diabetes mellitus, 10% of the patients had type 2 diabetes mellitus with hypothyroidism, 3.5% had hypertension and diabetes mellitus, 3.5% had hypertension along with chronic kidney disease and hypothyroidism and another 3.5% had chronic hypertension with type 2 diabetes mellitus and hypothyroidism. However, a majority (53.5%) of the patients were found to have hypothyroidism.

Based on the type of antihypertensive therapy received, 98% mothers received monotherapy and 2% received dual therapy. Tablet Labetalol was the most commonly prescribed drug received by 63% of the patients, followed by tablet Nifedipine which was received by 36% of patients. Tablet Labetalol 100mg was prescribed in 4 dosages as follows once daily [OD], twice daily [BD], thrice in a day (TID) and four times in a day [QID]. Majority (33.9%) of the patients received medications BD, followed by 23.3% received medications TID and 4.8% received QID and only 0.97% received OD. With respect to Nifedipine, 0.97% received Nifedipine 5 mg BD, 20%, 0.97% and 0.97% received tab Nifedipine 10 mg BD, OD and TID respectively, while 7.7% received tab Nifedipine 20 mg BD. 1.9% of patients received tab Nifedipine 10mg sos when BP  $\geq$ 140/90 mmHg. Polytherapy was prescribed with various drugs such as Labetalol, Nifedipine and Methyldopa among 2% of the patients. 50% of the patients received a combination of tab Nifedipine 10mg TID and Methyldopa while another 50% received tab Nifedipine 10mg BID if BP >140/90 mmHg with tab Labetalol 100 mg OD. With respect to the outcome new born babies born to hypertensive mothers receiving antihypertensive drugs had complications of low birth weight and malformations. The normal range for the birth weight is 2.5 kg to 4 kgs. 41% of the neonates were less than 2.5 kgs and 0.95% neonates were above 4 kg and the remaining 58% of neonates were within the normal range of birth weight.

## DISCUSSION

Study on rationale use of drugs is being carried out worldwide. Such studies help is to evaluate the factors that are associated with prescribing the drugs, their dispensing, administration of medications and its related events. These studies help to determine the drug utilization pattern among specific group of patients or population in order to

prevent the problems that occur due to medications, its treatment, its safety and efficacy.

In our study, the data we have collected will be of help to evaluate the rationality of the drug usage and its pattern among pregnant women with hypertension, complications related to it either in the pregnant women or in new born. This study was carried out in Bangalore among 105 inpatients. The prevalence of hypertension in pregnant women has been classified as per the age group. In our study the majority were in the age group of 18-25 years which was similar to the study conducted by Senthil Selvi and his colleagues.<sup>10</sup> While a similar study conducted in Nigeria by Swathi Singh et al found that the prevalence rate among PIH was 17% and was associated with increase in the age.<sup>11</sup> With respect to history of PIH, Chug and his colleagues reported that they had maximum number of patients with history of PIH, while our study reported less percentage in comparison to their study. It was reported by Kirsten et al that risk of PIH is increased in pregnant women with previous history of preeclampsia.<sup>12,13</sup> Many of the patients in our study had co morbid conditions among which only a small portion of women had gestational diabetes which was in contrast to the study conducted by Senthil et al.<sup>14</sup>

With regards to the treatment, majority of the patients in our study received labetalol as monotherapy followed by nifedipine. Only a small percentage of patients received combination therapy. The dose of the medications prescribed was well within the range. Our study shows that the commonly drug which was prescribed was labetalol. Only in severe cases they were prescribed or changed to nifedipine. Studies conducted by Stephanie et al showed that the labetalol was the most commonly prescribed drug in their study and which was effective in reducing the blood pressure effectively which was similar to our study.<sup>15</sup> Similar results were also found by Harshini et al labetalol is known to considerably reduce the blood pressure and is the most common drug prescribed among women with PIH. It is considered that labetalol is more effective in controlling blood pressure than nifedipine among women with PIH. With regards to complications eclampsia was common in study conducted by Bangal et al which was similar to our study.<sup>16</sup> The neonatal complications showed low birth weights were most common in our study which was in contrast to the study conducted by Kumar et al while study by Archana et al was similar to our study.<sup>17,18</sup>

### **Limitations**

Limitation of study was long term follow up study is required on large number of patients. Data collected in our study can be considered as preliminary work.

### **CONCLUSION**

Hypertension during pregnancy is considered as one of the major serious complications which is a leading cause of

mortality among maternal and neonates. Screening of PIH at right time, diagnosis and treatment managements among pregnant women needs to be carefully considered and carried out by the clinicians to reduce the burden of eclampsia and preeclampsia. Proper counselling to the patients regarding life style management, with regular follow ups and monitoring of blood pressure is more important in order to understand and resolve the burden and complication of the condition.

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