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# A study on efficacy of intravenous labetalol versus oral Nifedipine in control of acute hypertension in severe pre-eclampsia/eclampsia

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**Abstract**
A Hypertensive disorder of pregnancy is one of the life threatening complication encountered in obstetrics. Management of hypertension in pregnancy is a challenging task, because drastic reduction of BP leads to uteroplacental insufficiency & that may lead to intrauterine fetal death and continuation of pregnancy with severe hypertension leads to adverse feto-maternal outcome. Therefore, there is a need for an ideal antihypertensive agents for effective control of severe hypertension in pregnancy. Our present study compares the efficacy of oral Nifedipine and IV Labetalol in reaching the therapeutic goal. From the results of our study we can well conclude that both the Labetalol & Nifedipine regimen are equally effective & well tolerated when used for the rapid control of blood pressure in severe hypertension in pregnancy.

**Keywords:** intravenous labetalol versus, Nifedipine, pre-eclampsia/eclampsia

## Introduction
Pre-eclampsia is the development of hypertension, proteinuria, or both after 20 weeks of pregnancy in women with previously normal blood pressure. The incidence of pre-eclampsia is 5-10%. Pre-eclampsia accounts for 12-18% of maternal mortality. Besides it is associated with a fivefold increase in perinatal mortality [1].

Severe pre-eclampsia is a disorder in pregnancy which is characterized by a systolic blood pressure of ≥160mm of Hg and a diastolic blood pressure of ≥110mm of Hg. Severe pre-eclampsia is characterised by pre-eclampsia superimposed with proteinuria > 300 mg per 24 hrs urine [1]

Hypertensive disorders represents the most common medical complications of pregnancy with a reported incidence between 5-10% [1] and this hypertension which develops denovo in pregnancy appears to be unique to human [2]. These disorders are a major cause of maternal and perinatal mortality and morbidity worldwide [1]. It is associated with 30% of all maternal deaths and as much as 22% of all perinatal deaths [3]. It has been estimated by WHO (World Health Organization) that worldwide approximately 50,000 women will die each year from hypertensive disorders of pregnancy [4]. Severe pre-eclampsia requires prompt treatment because of risk of cardio-vascular accident, to prevent intra cerebral haemorrhage, hypertensive encephalopathy and other target organ damage [5, 6]. It also presents an increased risk of complication for the foetus including prematurity, low birth weight, NICU admission and even fetal death [6-8].

In addition to the risk they present to the pregnancy, hypertensive disorders of pregnancy have been linked to future high blood pressure and cardio-vascular diseases in woman [9]. The most commonly used hypertensive agents for hypertensive emergencies in pregnancy are Nifedipine, Labetalol and hydralazine. Nifedipine has the advantage of being cost effective, rapid onset of action, long duration of action and can be administered orally, however it is known to cause sudden maternal hypotension and fetal distress caused by placental hypoperfusion, palpitation and transient neuromuscular weakness when used concomitant with magnesium sulphate [10]. Intravenous Labetalol is considered to control severe hypertension in pregnancy. Its advantages include little placental transfer, less palpitation and less maternal tachycardia, however neonatal hypotension and neonatal bradycardia has been observed in some trials and is not as cost effective as Nifedipine [10].

A meta analysis of randomized clinical trials using Hydralazine for the treatment of severe hypertension in pregnancy concluded that the evidence does not support the use of these agents as first line drug when compared with Labetalol and Nifedipine [11].

Hence, the aim of the present study is to compare the two most commonly used drug in India, i.e. oral Nifedipine and IV Labetalol in terms of efficacy, time required and doses required to achieve desired level of blood pressure, safety profile and adverse effect of the drug and also to observe the fetomaternal outcomes.

## Patients and Methods

### Patients

This is a comparative study conducted in Kamineneni Institute of Medical Sciences from 2017 April to 2019 October. A total number of 50 patients diagnosed as severe preeclampsia / ecclampsia with blood pressure ≥160/110 mmHg were included in the study. 25 patients are treated by intravenous labetalol and 25 patients are treated by oral nifedipine. In both the groups the patients are selected according to the following criteria.

### Inclusion Criteria

1. Patients with severe preeclampsia/ eclampsia and blood pressure ≥160/110mmhg
2. Medical decision to rapidly control blood pressure.

### Exclusion Criteria

1. Patients with essential hypertension
2. H/o cardiac disease
3. H/o bronchial asthma
4. H/o hematological disorder
5. H/o allergy to labetalol or nifedipine
6. Diabetes
7. Liver disorders
8. Maternal heart rate <60 or >120 beats/ minute

### Methods

This study is conducted in Kamineni Institute of Medical Sciences from April 2017 to October 2019. A total of 50 patients of severe preeclampsia /eclampsia with BP ≥160/110 mmHg are included in the study. Severe hypertension is taken as a sustained systolic blood pressure of ≥160 mmHg or diastolic blood pressure ≥110mmHg on repeat measurements 15 minutes apart while the patient is in a lateral recumbent position. Enrolled patients will be randomized to receive either oral nifedipine or intravenous labetalol.

Demographic and standard laboratory data will be collected on admission.

Magnesium sulphate is started if required if any symptoms of impending eclampsia/eclampsia.

- Patients are randomly assigned to be started either with intravenous labetalol (study group) or oral nifedipine (control group) until satisfactory b.p control is achieved.
- Study group A: injection labetalol 20 mg iv bolus over 10 minutes repeated every 20 minutes increasing to 40, 80, 80, to maximum of 220 mg.
- Control group B: nifedipine 10 mg stat and then repeated at 45 minutes interval till satisfactory bp is achieved. Maximum dose willl be 5 doses.
- During the study period maternal blood pressures are recorded at every 15 minutes interval till first 30 minutes after achieving target blood pressure less than or equal to 150/100 mmHg, then every 30 minutes for next 2 hours then every hourly.
- Continous maternal vital parameters and electronic fetal monitoring is done CTG trace is taken at the beginning and then one at the end of the study.
- Treatment is considered as failure if blood pressure doesn't decrease even after increasing the dose to maximum. Additional antihypertensive agent is added and is managed accordingly.
- If patient develops hypotension BP <90/60mmHg then the trial is terminated and patient treated with iv fluids and ionotropes as needed.

Maternal complications like imminent signs, abruption, pulmonary oedema, oliguria, renal failure, HELLP syndrome are looked for. Most of the patients delivered at term spontaneously while some needed induction. AGAR score and birth weights, signs of prematurity and IUGR of all babies were noted.

## Observations and Results

**Table 1:** Comparision of Age Distribution of the two groups

| Age | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| 18-24 | 17 | 68.0% | 16 | 64.0% | 33 | 66.0% |
| 25-29 | 6 | 24.0% | 7 | 28.0% | 13 | 26.0% |
| 30-35 | 2 | 8.0% | 2 | 8.0% | 4 | 8.0% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

Shows age distribution of patients of both groups. All the patients were aged between 18-35 yrs. In the Labetalol grou 68% of the patients were between 18-24 years & in the Nifedipine group 64% of all the patients were between 18-24 years. Mean age in labetalol group was 23.44 and in nifedipine group was 23.60. Majority of women in both the groups belong to age group of 18-24 years

**Table 2:** Gravida Distribution of the two groups

| Gravida | Intravenous Labetalol | | NIFEDIPINE | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| Multi | 6 | 24.0% | 9 | 36.0% | 15 | 30.0% |
| Primi | 19 | 76.0% | 16 | 64.0% | 35 | 70.0% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

Shows the gravida distribution of patients studied in each group with a range of primigravida and multigravida. Maximum patients of severe pre-eclampsia were primigravida in both the groups, 76% in the Labetalol group & 64% in the Nifedipine group.

**Table 3:** Comparison of Gestational Age of the two groups

| GA in Weeks | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| <36 | 4 | 16% | 4 | 16% | 8 | 16% |
| 36-37 | 11 | 44% | 9 | 36% | 20 | 40% |
| 38-40 | 10 | 40% | 12 | 48% | 22 | 44% |
| Total | 25 | 100% | 25 | 100% | 50 | 100% |

Shows the gestational age at presentation in each group. Most patients with pre-eclampsia belonged to 38-40 weeks of gestational age, 40% in the Labetalol group & 44% in the Nifedipine group.

**Table 4:** Comparision of systolic blood pressure at the time of admission

| Variable | Group | N | Minimum | Maximum | Mean | SD | P-value |
|---|---|---|---|---|---|---|---|
| SBPa in mmHg | Intravenous Labetalol | 25 | 160 | 190 | 170.40 | 8.888 | 0.06 |
| | Nifedipine | 25 | 160 | 180 | 165.96 | 6.432 | |

Shows comparision of systolic & diastolic BP of the two groups. Mean SBP was 170.4 ± 12 mm of Hg in the Labetalol group & 165.96± 12 mm of Hg in the Nifedipine group, which was statically not significant as 'P' value was 0.06.

**Table 5:** Comparision of diastolic blood pressure at the time of admission

| Variable | Group | N | Minimum | Maximum | Mean | SD | P-value |
|---|---|---|---|---|---|---|---|
| DBPa in mmHg | Intravenous Labetalol | 25 | 110 | 130 | 118.40 | 5.01 | 0.67 |
| | Nifedipine | 25 | 110 | 130 | 117.60 | 4.98 | |

The mean diastolic blood pressure was 118.40mmHg in the labetalol group and 117.20 mmHg in the nifedipine group, which was statistically not significant as 'P' Value was 0.67.

**Table 6:** Comparison of No. of doses of drugs required to control BP between two groups

| Variable | Group | N | Minimum | Maximum | Mean | SD | P-value |
|---|---|---|---|---|---|---|---|
| No. of Doses to Achieve Target Bp | Intravenous Labetalol | 25 | 1 | 3 | 2.16 | .473 | 0.3 |
| | Nifedipine | 25 | 1 | 3 | 2.04 | .351 | |

Shows comparison of No. of doses of drugs required to control BP between two groups and no. of patients requiring crossover treatment to control BP between two groups. Most of the patients were controlled by two doses of each drug, 88% in the Labetalol group and 76% in the Nifedipine group. Mean number of doses required in IV labetalol group 2.16 and in nifedipine group was 2.04.

**Table 7:** Comparision of time taken in minutes to control BP between two groups i.e. to achieve BP 150/100 mm of Hg.

| Variable | Group | N | Minimum | Maximum | Mean | SD | P-value |
|---|---|---|---|---|---|---|---|
| Time In Minutes To Achieve Target Bp | Intravenous Labetalol | 25 | 30 | 80 | 50.40 | 10.985 | 0.29 |
| | Nifedipine | 25 | 40 | 60 | 47.00 | 5.774 | |

Shows comparison of time taken to control BP between two groups, i.e. to achieve BP 150/100mm of Hg. The mean time required were 50.40 ± 10.98 mins in the Labetalol groups and 47.0 ± 5.7 minutes in the Nifedipine group. This comparision showed no difference in the two groups with a 'P' value of 0.29.

**Table 8:** Mode of Delivery of two groups

| Delivery | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| IVD | 5 | 20.0% | 7 | 28.0% | 12 | 24.0% |
| LSCS | 13 | 52.0% | 14 | 56.0% | 27 | 54.0% |
| SVD | 7 | 28.0% | 4 | 16.0% | 11 | 22.0% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

SVD- Spontaneous Vaginal Delivery; IVD- Induced Vaginal Delivery LSCS-Lower Segment Caesarean Section.

Shows mode of delivery of the two groups. Spontaneous vaginal delivery was more in the Labetalol group i.e 28% when compared to the Nifedipine i.e 16%. A significant higher incidence of induction of labour was found in the Nifedipine group i.e. 28%. Caesareans section rate was 52% and 56% in the Labetalol and Nifedipine group respectively.

**Table 9:** Comparision of birth weight between two groups

| Variable | Group | N | Minimum | Maximum | Mean | SD | P-value |
|---|---|---|---|---|---|---|---|
| Wt. of baby in Kgs | Intravenous Labetalol | 25 | 1.5 | 4.0 | 2.836 | .6441 | 0.07 |
| | Nifedipine | 25 | 1.0 | 3.5 | 2.460 | .6837 | |

Shows the comparision of the birth weight between the two groups. Mean birth weight was 2.83 ± 0.64 kg in the Labetalol group and 2.46 ± 0.68 kg in the Nifedipine group, which was statistically not significant (P=0.07).

**Table 10:** Comparision of Perinatal Outcome between two groups

| Outcome | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| Bad | 2 | 8% | 4 | 16% | 6 | 12% |
| Good | 23 | 92% | 21 | 84% | 44 | 88% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

Incidence of perinatal mortality was 12% in our study. Perinatal outcome was poor in 16% of babies in nifedipine group and 8% of babies in labetalol group.

**Table 11:** Comparision of complications of preeclampsia in both the groups

| Outcome | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| No complications | 19 | 76.0% | 17 | 68.0% | 36 | 72.0% |
| Abruption | 2 | 8.0% | 1 | 4.0% | 3 | 6.0% |
| Eclampsia | 3 | 12.0% | 3 | 12.0% | 5 | 12.0% |
| HELLP | 0 | 0.0% | 1 | 4.0% | 1 | 2.0% |
| IUGR | 1 | 4.0% | 3 | 12.0% | 4 | 8.0% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

Incidence of abruption in labetalol group was 8% and in nifedipine group was 4%.
Incidence of ecclampsia in both the groups was 12%.
Incidence of HELLP SYNDROME was 4% in nifedipine group and nill in labetalol group.
Overall incidence of IUGR was 8% with 1 case in labetalol group and 3 in nifedipine group.

**Table 12:** Comparision of adverse effects of drugs in 2 groups

| Adverse Effects | Intravenous Labetalol | | Nifedipine | | Total | |
|---|---|---|---|---|---|---|
| | Count | % | Count | % | Count | % |
| Head Ache | 1 | 4.0% | 3 | 12.0% | 4 | 8.0% |
| Palpitations | 3 | 12.0% | 1 | 4.0% | 4 | 8.0% |
| Postural Hypotension | 0 | 0.0% | 1 | 4.0% | 1 | 2.0% |
| Shortness of Breath | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% |
| Nausea | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% |
| No Adverse Effect | 21 | 84.0% | 20 | 80.0% | 41 | 82.0% |
| Total | 25 | 100.0% | 25 | 100.0% | 50 | 100.0% |

Shows the comparison of adverse effects of the drugs. 4% patients had headache in the Labetalol group. In the Nifedipine group 4% of the patients had postural hypotension. palpitations were present in 12% in labetalol group and 4% in nifedipine group. 82% of patients did not have any side effects.

## Discussion

Pre-eclampsia is one of the common medical disorders of pregnancy. It complicates 6 to 8% of pregnancies (Pod mow and August, 2010 [12]) and is the third common cause for maternal mortality and morbidity next to haemorrhage and infections (Duley, 2009) [13]. 18% of maternal deaths are due to pregnancy related hypertension complications. It affects both mother and foetus (Soares *et al*., 2009 [14]).
Controlling hypertension in pregnancy using antihypertensive drugs brings down these complications. The most extensively used antihypertensive drugs in pregnancy are nifedipine, methyldopa and labetalol (Ghanem and Movahed, 2008) [15]. These drugs are used alone or in combinations in routine obstetric practice in our country. Each of these drugs have different mode of action. Nifedipine is vasodilator and calcium channel blocker. Methyl dopa is centrally acting antihypertensive. Labetolol is both β and α blocker. The present study was undertaken to evaluate and compare nifedipine and labetalol in severe Pre-eclampsia. For this study pregnant women fulfilling the definition of severe pre-eclampsia, inclusion and exclusion criteria were enrolled. They were divided into two groups based on antihypertensive drugs used. Base line characters were analysed together in severe Pre-eclampsia patients in two treatment groups. Whereas efficacy, maternal and neonatal out comes were analysed separately in two treatment groups.

### Baseline characters and pre-treatment risk factors

When base line characters of Pre-eclampsia patients were analysed between the groups it was found that 66% of patients were in the age group of 18 to 25 years. There was no significant difference in age distribution between the groups.
Primigravida were more often affected than multigravida as there were 70% primigravida in the study group. This is similar to the hospital based studies of Prakash *et al*., 2006 [16], in which majority of patients were primigravida (57%). Incidence of Pre-eclampsia in the present study was high in nulliparous women (74%). A study conducted to throw light on incidence of preeclampsia in women attending for care and delivery at a hospital, revealed that high proportion of pre-eclamptic cases were occurring among nulliparous women and those at extreme ends of reproductive age (Al-Mulhim *et al*., 2003) [17]. The incidence of complications in hypertensive pregnantwomen varied by parity but not by gravidity (Williams and Wilson, 2002) [18].

### Efficacy of antihypertensive agents

In our present study the results indicate that both intravenous Labetalol and oral Nifedipine are equally efficacious having minimal side effects. There was a similar study conducted by Raheem IA *et al*. in January 2012 [19] with the similar objective of comparing oral Nifedipine with intravenous Labetalol in their rapidity to control hypertensive emergencies of pregnancy.
In our study the mean systolic BP at the time of admission was 170.40 ± 8.8 mm of Hg in the Labetalol group and 165.96 ± 6.4 mm of Hg in the Nifedipine group with a 'P value of 0.06 which was not clinically significant. While in the study of Raheem *et al*. [19] the mean systolic BP was 175 (170-180) mm of Hg in Nifedipine group and 170 (165-180) mm of Hg in Labetalol group with 'P value 0.25.
In our present study the mean diastolic BP was 110.40 ± 6.7 mm of Hg in the Labetalol group and 111.20 ± 5.2 mm of Hg in the Nifedipine group with the 'P value was 0.67 which was not clinically significant. Raheem et.al showed that the mean

diastolic BP was 110 (110-116) mm of Hg in Nifedipine group and 108 (100-112) mm of Hg in Labetalol group with a P value of 0.012.

In our study the mean time required to achieve target BP ≤ 150/100 mmHg was 50.40 ± 10.98 mins in the Labetalol group & 47.0 ± 5.70 mins in the Nifedipine group with the 'P' value of 0.29 which is clinically not significant. In the study conducted by Raheem *et al*. [92] results showed that the median time taken to achieve target BP was 30 mins (interquartile range 22.5 to 67.5 mins) versus 45 mins (IQR 30-60 min) for Nifedipine & Labetalol respectively (P=0.59).

The results of the study conducted by Shekhar et.at showed that the median time taken to achieve target blood pressure was 40 mins (interquartile range 20-60 mins) for Nifedipine and 60 mins (interquartile range 40-85 min) for Labetalol with a P value of 0.008. while in our study the mean time required 50.4 ± 10.98 mins in the Labetalol group and 47.0 ± 5.7mins in the Nifedipine group. Shekhar *et al*. concluded by their trial that oral Nifedipine had lowered blood pressure more quickly than that of intravenous Labetalol during hypertensive emergency in pregnancy which was different from our present study.

In our present study most of the patients were controlled by two doses of each drug, 88% in the Labetalol group and 76% in the Nifedipine group with a P-value of 0.3 which was not clinically significant. As per study done by Raheem et.al, average number of total antihypertensive doses to achieve BP ≤ 150/100 mm of Hg were two (1.5-4.5) in the Nifedipine group, whereas three (2-4) in Labetalol group as compared to two doses for both groups in our study. Our study showed that 4% and 8% of patients in the Labetalol and Nifedipine group respectively required crossover therapy, whereas in the study of Raheem *et al*. [92] 20% of patients in each group required crossover therapy.

The principal findings of Vermillion et.al was that to achieve target blood pressure the oral Nefidipine is more rapidly effective and requires fewer drug doses compared with an intravenous Labetalol regimen. Patient receiving oral Nefidipine more rapidly achieved the therapeutic blood pressure goal. in 25.0 ± 13.6 mins as compared with 43.6 ± 25.4 mins in those receiving Labetalol (P=0.002). The Nefidipine group also required significantly fewer doses (1.5 ± 0.5 vs 2.5 ± 1.5, P< 0.001) to reach the blood pressure goal. Vermillion's J drug regimen used higher oral Nefidipine dose (10mg initially, then 20mg for a further four doses, as required), while we used a flat 10mg oral Nifedipine dose throughout and an intravenous Labetalol regimen of 20, 40, 80, 80 and 80 mg as required which is identical to our regimen.

In a randomized double-blind trial of oral nifedipine (10 mg) and intravenous labetalol (20 mg) in 50 patients, it was found that both oral nifedipine and intravenous labetalol were effective in the management of acute hypertensive emergencies of pregnancy, however, nifedipine controls hypertension more rapidly and was associated with a significant increase in urine output (Vermillion *et al*., 1999) [20].

Finally it is concluded that both the drugs were equally Efficacious in the treatment of severe Pre-eclampsia.

**Obstetric outcome**

The present study showed that there was no significant difference in the mode of delivery between two groups with a 'P' value of 0.365 which isclinically nill significant. But spontaneous vaginal delivery was more in the Labetalol group i.e. 28%. When compared to the Nifedipine group i.e. 16%. %. A higher incidence of induction of labour was found in the Nifedipine group i.e. 28%. In the present study, the rate of spontaneous labour was least and induction was highest in nifedipine group. This may be due to the inhibition of labour by nifedipine as studies indicate that nifedipine acts as a tocolytic and inhibits labour (Martindale, 2006) [21]. Caesarean section rate was 52% and 56% in the Labetalol and Nifedipine group respectively. These results were more or less similar to the results of the study conducted by Raheem *et al*. [92] on January, 2012.

In a study conducted to determine the risk factors, prevalence, epidemiology and maternal-perinatal outcome in pregnant women with hypertensive disorders, found 41.2% vaginal deliveries and 58.8% caesarean sections with the most frequent indication to be fetal distress (46%). Caesarean rate was highest (63.8%) in severe preeclampsia patients (Yucesoy *et al*., 2005) [22]. In our study, overall caesarean section rates was 52%.

**Maternal outcome**

Incidence of maternal mortality was absent in the present study, complications such as DIC and intracerebral haemorrhage were absent. Incidence of eclampsia was 12% in the present study with 3 cases in each of nifedipine and labetalol group.

Eclampsia is presence of new onset grand mal seizures in a woman with pre-eclampsia (ACOG, 2002) [23] not a progression from severe preeclampsia but appears to be more of a subset of preeclampsia.

Incidence of HELLP Syndrome in our study was only 2% ie., one case in nifedipine group.

Overall Incidence of abruptio placentae was 6% in our study, with 2% in nifedipine and 4% in labetalol group.

About 72% of patients did not have any incidence of maternal complications, since, incidence of eclampsia and HELLP syndrome were controlled by antihypertensive therapy. Both drugs were effective in preventing maternal complications.

In a study to determine maternal and perinatal outcome in pregnancies complicated with hypertensive disorders, observed maternal mortality of 1.2% and all the cases were complicated with HELLP syndrome. Intracranial bleeding was the cause of maternal death in one case while the other two cases were due to ARF and disseminated intravascular coagulation respectively (Yucesoy *et al*., 2005) [22]. In our study in severe PIH, though the incidence of HELLP syndrome was 2%, no maternal mortality occurred. Therefore, the antihypertensive agents used were effective in preventing maternal morbidity and mortality compared to neonatal outcome. Neonatal morbidity and mortality in PIH is often related to IUGR occurring as a result of placental insufficiency. Hypertension during pregnancy is responsible for high fetal mortality rate and LBW. Even though fetal growth retardation (FGR) is an independent entity, FGR in pregnancies complicated by hypertension had poorer perinatal outcome than FGR in normotensive women (Piper *et al*., 1996) [24].

In the present study, most cases of PIH were admitted by the end of third trimester by which much damage has already occurred to the foetus, antihypertensive treatment at that point could not reverse the underlying syndrome immediately to improve the perinatal outcome.

**Side effects**

In the present study, adverse effects occurred during treatment with antihypertensive agents, were transient and tolerable. There were no maternal adverse events, which resulted in need for discontinuation of medication. Side effects were milder and infrequent in labetalol treated patients as majority of the patients did not have (84%) any side effects. The side effects of

nifedipine are due to its vasodilation action. The most common side effects i.e. severe headache can mimic impending eclampsia (Bolte *et al*., 2001) [25].

The ability of nifedipine to enhance urine output has been attributed to a selective renal vasodilation. Urinary output in context of preeclampsia would appear to be beneficial (Vermillion *et al*., 1999) [71].

In our study results, incidences of adverse effects were less in labetalol group, head ache was more frequent in nifedipine group, but were tolerable.

As per the literature, labetalol administered intravenously or orally appears to be as effective and as safe and causes fewer side effects (Naden and Redman, 1985) [26]. In the present study intravenous labetalol was effective and safe. Nifedipine is also stated to be safe since there were any serious adverse effects in mother or foetus (Aali and Nejad, 2002) [27]. Our study results substantiate this statement.

**Perinatal Outcome**

In our study the mean birth weight was 2.83 ± 0.64 kg in the Labetalol group and 2.46 ± 0.68 kg in the Nifedipine group. In the study of Raheem *et al*. [92] the average birth weight in both the group were 2.9 kg with an interquartile range of 2.2 – 3.1 kg in the Nifedipine group and 2.7 – 3.2 kg in the Labetalol group.

Incidence of perinatal mortality was 12% in our study. Of these 6% were due to abruption, 4% were due to early preterm delivery. Rest 2% were early neonatal deaths due to IUGR. IUGR was one of the pre-treatment risk factors of present study. 8% were IUGR in our study. And our study clearly indicates that both intravenous Labetalol and oral Nifedipine are equally efficacious in controlling high blood pressure in severe Pre-eclampsia with minimal side effects.

**Conclusion**

1. Both oral nifedipine and intravenous labetalol are equally effective in controlling blood pressure.
2. Both drugs showed mo or mild adverse effects in mother and baby.
3. But nifedipine is cheaper and convenient to administer. Therefore it is of importance in low resource settings.
4. Intravenous labetalol is important in patients who are unable to tae medicine oraly.

So, to conclude both oral nifedipine and intravenous labetalol are equally efficacious in controlling acute hypertension in severe pre-eclampsia / eclampsia.

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**Conflict of Interest**

The authors declare that they have no conflict of Interest

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