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A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY OF T.LABETALOL AND T. NIFEDIPINE AND ITS FETOMATERNAL OUTCOME IN PREECLAMPSIA

Obstetrics & Gynaecology

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ABSTRACT

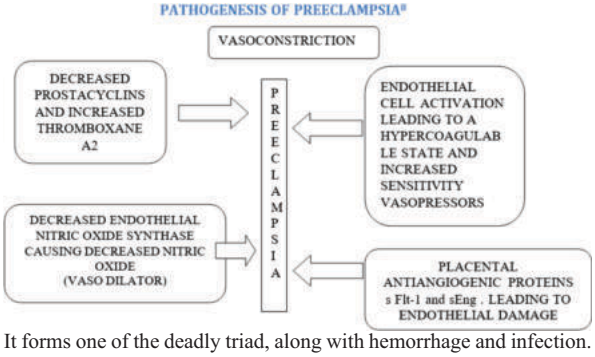
Background: Preeclampsia is hypertension with proteinuria after 20 weeks of gestation in women with previously normal blood pressure which returns to normal within 12 weeks gestation. Preeclampsia is defined as hypertension (>=140/>=90 mm Hg on two occasions 4 hours apart) associated with proteinuria, greater than 0.3 g/L in a 24-hour urine collection or 1+ by qualitative urine examination two times 4 hours apart, after 20 weeks of gestation. **Methods:** 100 antenatal women with mild preeclampsia were selected. 50 women were treated with T. Labetalol. 50 women were treated with T.Nifedipine. Thorough history and clinical examination were done. Once the diagnosis of preeclampsia was made, all patients were admitted. Investigations such as complete blood count, peripheral smear, blood sugar, liver function test, renal function test, prothrombin time, clotting time, bleeding time, ultrasound abdomen were done. Serial monitoring of blood pressure was done. **Results:** From this study it is prudent that both T.Labetalol and T.Nifedipine are equally efficacious in the control of hypertension in preeclampsia. In both the groups, there was progression to severe preeclampsia in an average of 16% of the patients even though their blood pressure was under control. There by showing that the pathology of disease was not altered significantly in both the groups. Regarding the drug side effects and tolerability, T.Labetalol was significantly better than T.Nifedipine. **Conclusion:** Thus T.Labetalol is a better alternative to T.Nifedipine, as it had lesser side effect profile. But in a limited resource setting, T.Nifedipine is an equally effective, cheap and easily available drug for mild preeclampsia.

KEYWORDS

Preeclampsia, labetalol, nifedipine

INTRODUCTION

Preeclampsia is identified in 3.9 % of all pregnancies[1] (Williams 23rd)



It forms one of the deadly triad, along with hemorrhage and infection. They contribute greatly to maternal mortality rate. In developed countries 16% of maternal deaths were due to hypertensive disorders[2]. In India around 15- 18% of maternal deaths were due to hypertensive disorders. Importantly half of these deaths were preventable[3]. Preeclampsia is a pregnancy specific syndrome related to vasospasm and endothelial damage. Where in the patient returns back to normal following delivery.

Preeclampsia is hypertension with proteinuria after 20 weeks of gestation in women with previously normal blood pressure which returns to normal within 12 weeks gestation[4].

Preeclampsia is defined as hypertension (>=140/>=90 mm Hg on two occasions 4 hours apart) can be associated with proteinuria, greater than 0.3 g/L in a 24-hour urine collection or 1+ by qualitative urine examination two times 4 hours apart, after 20 weeks of gestation[5] or with presence of features of severity in absence of preeclampsia.

Abnormal laboratory findings in tests of renal, hepatic and hematological function increase the certainty of preeclampsia. Preeclampsia often affects young and nulliparous women. The incidence is markedly influenced by race, ethnicity and has genetic predisposition. Other risk factors include obesity , multifetal gestation, thrombophilias. Taking into consideration the various devastating complications of preeclampsia such as abruption, eclampsia, HELLP syndrome, cerebrovascular accidents and various neonatal complications, the need to curtail this disease from progressing is evident. Hence we are committed to identify pregnant women with preeclampsia, manage them and thereby prevent adverse maternal and fetal outcome.

Labetalol:

Labetalol hydrochloride is an adrenergic antagonist with selective alpha blockade and non selective beta blockade in a single substance. Labetalol produces dose dependent fall in blood pressure without causing tachycardia. The peak effect of single dose of Labetalol is seen in 2 to 4 hours and duration lasts for 8 hours. With twice a day dosing the maximum steady state blood pressure response occurs in 24- 72 hours. The antihypertensive efficacy of Labetalol has a linear correlation with the logarithm of plasma concentration of Labetalol. Recommended initial dose is 100mg twice daily. Usual maintainance dose is between 200- 400 mg twice daily. Maximum dose is 2400 mg per day.

Nifedipine:

Nifedipine was the first of the dihydropyridine group of calcium channel blockers licensed for use L type slow calcium channel blockers, nifedipine causes negative inotropic effect on heart. It inhibits the calcium influx into smooth muscle cells and myometrial cells, there by producing vasodilation and tocolysis. As a reflex to vasodilation there is tachycardia. L type voltage sensitive calcium channels are present in cardiac and smooth muscle, SA and AV node. The channels are located on the surface of plasma membrane of these cells. Nifedipine binds to these cells and blocks the entry of calcium ions there by causing relaxation. At therapeutic doses, nifedipine does not depress cardiac function. 10 mg is given initially followed by 20 mg given every 20- 30 minutes until a maximum dose of 120 mg/day.

In India the most commonly used antihypertensives in pregnancy are labetalol and nifedipine. This study is to compare the anti hypertensive efficacy of T.Labetalol and T.Nifedipine in mild preeclampsia. The feto maternal outcome were also studied.

MATERIALS AND METHODS

The study was conducted at the C U SHAH MEDICAL COLLEGE & HOSPITAL from May 2022 to May 2023.

100 antenatal women with mild preeclampsia were selected. Informed consent obtained. 50 women were treated with T.Labetalol. 50 women were treated with T.Nifedipine. Thorough history and clinical examination were done. Once the diagnosis of preeclampsia was made, all patients were admitted. Investigations such as complete blood count, peripheral smear, blood sugar, liver function test, renal function test, prothrombin time, clotting time, bleeding time, ultrasound abdomen were done. Serial monitoring of blood pressure was done. Antihypertensive efficacy and feto maternal outcomes were monitored. Control aimed to keep systolic BP <150 mm Hg and

diastolic between 80-100 mm Hg (NICE Guidelines, UK- 2011). Keeping patient's health as a priority, patient whose BP wasn't controlled, combination of both tablets according to the dose were given.

RESULTS

The average dose required for control of blood pressure with T.Labetalol was 300 mg and 30 mg for T.Nifedipine. Inspite of adequate control the disease progressed in both groups. In group A (T.Labetalol) 14% progressed to severe preeclampsia. In group B (T.Nifedipine) 20% progressed to severe preeclampsia. Among the babies delivered, in group A 86% were term babies and 8% required SNN admission. In group B 80% were term babies and 10% required SNN admission.Comparing the two groups, group B (T.Nifedipine) had significantly higher number of side effects as compared to group A (T.Labetalol). None of the patients developed grave complications such as HELLP syndrome, pulmonary edema, coagulopathy, postpartum collapse, eclampsia. **The maternal mortality was nil.** Thus when patients with preeclampsia are identified and treated at an earlier stage the morbidity and mortality associated with preeclampsia can be significantly reduced.

Table 1

	Labetalol N%	Nifedipine N%
OBSTETRIC SCORE(PRIMI)	52	48
PROGRESSION TO SEVERE PREECLAMPSIA	14	20
WORSENING OF PROTEINURIA	2	6
ONSET OF IMMINENT ECLAMPSIA	2	2

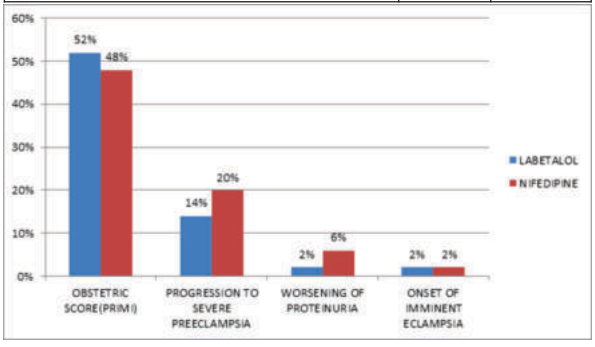


Chart 1

Table 2

	Labetalol N%	Nifedipine N%
ADVERSE EFFECTS	0	12
C SECTION DELIVERIES	24	30
VAGINAL DELIVERIES	76	70
NEONATAL OUTCOME	86	80
NEONATAL ADMISSIONS	8	10
POSTPARTUM F'UP	4	8

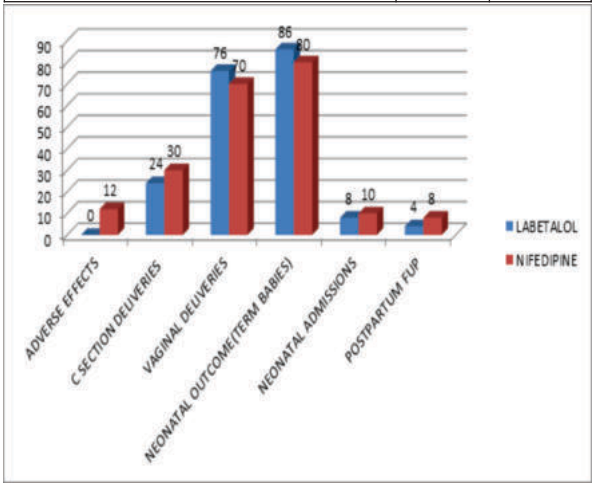


Chart 2

Drug Side Effects

Table 3 Chi-square Test

Drug side effects	Group A		Group B		Total		Statistical Inference
	(n=50)	*(%)*	*(n=50)*	*(%)*	*(n=100)*	*(%)*	
Giddiness	0	0%	1	2.0%	1	1.0%	X^2=11.383 Df=3 .049<0.05 Significant
palpitation	0	0%	2	4.0%	2	2.0%	
headache	0	0%	3	6.0%	3	3.0%	

Drug Side Effects:

In group A none of the patients developed drug side effects.

In group B 12% of the patients had side effects. Of which 6% had headache. 4% had palpitation and 2% had giddiness.

There was statistically significant difference between the two groups. Group B had significantly higher side effects than group A.

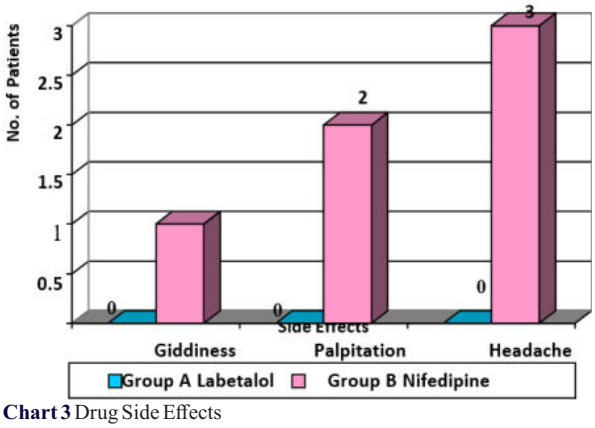


Chart 3 Drug Side Effects

DISCUSSION

This study compares the efficacy of two antihypertensives, T.Labetalol and T.Nifedipine in mild preeclampsia.The drug side effects and feto maternal outcome were also studied. 100 patients were included in the study. 50 patients were assigned to take T.Labetalol and 50 patients were assigned to take T.Nifedipine. Both groups were similar in age group, BMI and gestational age at diagnosis. Age of the patients in both groups were between 21 and 25 years. Most of the patients in both groups were over weight with BMI more than 25. In a study by Kumar S Ganesh et al,(June 2010) risk factors of preeclampsia were studied. In this study the common age group at diagnosis was between 21 and 30 years[7]. Most of the patients in this study also were over weight with BMI more than 25.

Regarding the obstetric score, most of the patients in both groups were primi gravida. In a study by Prakash et al. (2006) it was proved that preeclampsia was common among primi gravida rather than multi gravida. In both the groups, for 60% of the patients, gestational age at diagnosis was between 34 and 36 weeks.

In group A, that is patients on T.Labetalol the dose required to achieve adequate control of blood pressure ranged from 200mg upto 600mg per day. 34% of the patients required 200mg, 26% of the patients required 300mg, 22% of them required 400mg, 14% required 500mg, 4% required 600mg.

In group B, that is patients on T.Nifedipine the dose required ranged from 20mg to 40 mg per day. 28% of the patients were controlled with 20mg, 48% were controlled with 30mg, 24% were controlled with 40mg.

In both the groups adequate control of blood pressure was achieved. There by proving that both T.Labetalol and T.Nifedipine are equally efficacious.

This result is consistent with a meta analysis by Prof.Peter Von Dadelszen et al.(2007). Here the efficacy of oral labetalol and nifedipine were analysed in mild preeclampsia. They have proved that both the drugs are effective, safe and rapid in their onset of action.

This is also consistent with the study by Bharathi et al.(2009)[48]. Here antihypertensive efficacy in mild preeclampsia was studied and it was proved that both T.Labetalol and T.Nifedipine are equally effective. In contrary to this study, Patel NK et al. (2012 Dec)[49] have proved that

T.Labetalol has better efficacy than T.Nifedipine in mild preeclampsia. Even though adequate control of blood pressure was achieved in both the groups the basic pathology behind the disease could not be altered. This is evident because in both the groups few patients progressed to severe preeclampsia with adequate blood pressure control. In group A patients (T.Labetalol) 14% progressed to severe preeclampsia. Among them 2% had worsening of proteinuria, 8% had utero placental insufficieny which was evident by the onset of oligohydramnios (4%) , IUGR (2%) and intrauterine death of the fetus (2%) , 2% developed papilledema and 2% developed imminent eclampsia. In group B patients (T.Nifedipine) 20% progressed to severe preeclampsia. Among them 6% had worsening of proteinuria, 6% had oligohydramnios, 6% had IUGR and remaining 2% of them developed imminent symptoms.

Thus even though the rate of disease progression to severe preeclampsia was higher in group B, it was not statistically significant. Regarding the drug side effects , in group A patients who took T.Labetalol none of them developed any side effects. In group B patients who took T.Nifedipine 12% of them developed side effects.

This difference was statistically significant. The most common side effect being headache (6%) followed by palpitation (4%) and giddiness (2%). Thus proving that T.Labetalol was well tolerated and without any side effects.

In the same study by Bharathi et al. both drugs had side effects but the side effects were higher in T.Nifedipine group .Similar to our study the most common side effect with T.Nifedipine was headache. In group A patients taking T.Labetalol 86% of them delivered at term gestation. Rest of the 14% delivered preterm as pregnancy was terminated due to progression to severe preeclampsia, among which 8% delivered between 28 and 33 weeks gestation and the rest 6% were between 34 and 37 weeks gestation.

In group B patients taking T.Nifedipine 80% of them delivered at term gestation. Rest of the 20% delivered preterm as pregnancy was terminated due to progression to severe preeclampsia. Among which 8% delivered between 28 and 33 weeks gestation and 12% delivered between 34 and 37 weeks.

Thus in both the groups majority delivered at term. There was no significant difference in the gestational age at delivery between both the groups.

In group A patients,76% had vaginal delivery and 24% had caesarean section. In group B patients, 70% had vaginal delivery and 30% had caesarean section.

Regarding the neonatal outcome , in group A 86% were term babies and 14% were preterm babies. Among the 14%, 8% had birth weight between 2 and 2.5 kg. The remaining 6% had birth weight less than 2 kg.

In group B 80% were term babies and 20% were preterm babies. Among the 20%, 12% had birth weight between 2 and 2.5 kg. The remains 8% had birth weight less than 2 kg.

In group A 8% of the babies were admitted in SNN ward and in group B 10% of the babies were admitted in SNN ward. The most common reason being respiratory distress of new born due to pre maturity. Thus in both the groups there is no significant difference in the neonatal outcome.

This is consistent with the results of study by E.J.Waterman et al (2004)[50], which showed that there are no differential effects on utero placental or fetal hemodynamics with the use of T.Labetalol and T.Nifedipine in hypertension in pregnancy. The same study proved no differential effects on neonatal outcome including birth weight.

In contrary to this, the study by Patel NK et al.(2012) the neonatal outcome was better with T.Labetalol as there was lower incidence of respiratory distress of new born. This is because T.Labetalol maintains adequate placental perfusion and there by tissue oxygenation.

Post partum follow of patients in both the groups, 4% patients in group A (T.Labetalol) and 6% patients in group B (T.Nifedipine) required continuation of antihypertensive in the post partum period.

In this study none of the patients developed life threatening complication of preeclampsia such as coagulopathy, eclampsia, pulmonary edema, HELLP syndrome and postpartum colapse. There was **no maternal mortality in this study.**

CONCLUSION

From this study it is prudent that both T.Labetalol and T.Nifedipine are equally efficacious in the control of hypertension in mild preeclampsia. In both the groups, there was progression to severe preeclampsia an average of 16% of the patients even though their blood pressure was under control. There by showing that the pathology of disease was not altered significantly in both the groups.

Regarding the drug side effects and tolerability, T.Labetalol was significantly better than T.Nifedipine.

There was no significant difference in the neonatal outcome between the two groups.

Thus T.Labetalol is a better alternative to T.Nifedipine, as it had lesser side effect profile.

But in a limited resource setting, T.Nifedipine is an equally effective, cheap and easily available drug for preeclampsia.

DECLARATION

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