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Impact of Tab. Labetalol and Tab. Nifedipine in the management of mild preeclampsia: A comparative study

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Abstract
Background: Hypertensive disorders are attributed to 16% maternal deaths in developed countries and 15%-18% in India. Preeclampsia is multisystem disorder of mid pregnancy associated with elevated proteinuria after 20 weeks of gestation. The most commonly used antihypertensive drugs during pregnancy are nifedipine, labetalol and methyldopa. This study was designed to assess the efficacy of 100mg Tab. Labetalol and 10mg Tab. Nifedipine in the management of hypertension in mild preeclampsia.
Materials and Methods: A total 120 antenatal women clinically diagnosed with mild preeclampsia were recruited. In group 1, 100mg Tab. Labetalol was medicated and drug dosage was increased by 100mg for every 6 hours until adequate control was achieved. In group 2, 10mg Tab. Nifedipine was medicated and 10mg of drug dosage was increased for every 6 hours until to reach adequate control. Blood pressure was monitered for every 2 hours, along with feto-maternal status.
Results: Both groups had adequate control of blood pressure after receiving required amount of drug. In Nifedipine group, headache (8.3%), palpitations (5%) and giddiness (1.66%) are the common drug related side effects, whereas in labetalol no side effects have been noticed. Full term foetal outcome was seen in 81.67% cases of group 1 and 733% cases of group 2. Majority child having birth weight more than 2.5kg (76.67% in group 1 & 70% in group 2) in both study groups
Conclusion: Labetalol group had no side effects, with sufficient dose it had adequate control on BP and had good neonatal outcome. Whereas, Nefidipine is also effective, but has minimal side effects, but it is easy available and effective drug for mild preeclampsia.

Keywords: Labetalol, nifedipine, mild preeclampsia, hypertension, fetomaternal outcome

Introduction
Hypertensive disorders are usually complicates 5-10% of all pregnancies and leads to intra uterine growth restriction (IUGR), premature delivery and intra uterine death [1]. Reports of WHO revealed that hypertensive disorders are causing 16% of maternal deaths in developed countries [2]. Preeclampsia is a multisystem disorder of second trimester of pregnancy usually diagnosed by the onset of hypertension and proteinuria after 20 weeks of gestation [3]. Pregnancy with preeclampsia is rapidly spreading and becoming leading cause of mortality and morbidity in foetus and mother [4]. Based on American College of Obstetricians and Gynecologists; hypertension in Pregnancy preeclampsia is classified in to severe, mild, early onset and late onset syndrome [5].
The most commonly used antihypertensive drugs during pregnancy are nifedipine, labetalol and methyldopa [6]. Labetalol, a competitive antagonist at α and β- adrenergic receptors, which reduces the systemic vascular resistance without affecting renal, cerebral and coronary blood flow [3, 7]. Nifedipine is a L type voltage gated calcium channel blocker acts on arterioles, lowers peripheral resistance resulting the fall in BP [7]. Both the drugs are rapid in onset and effective in the management of hypertension in mild preeclampsia with minimal side effects. With the above literature, this study was designed to assess the efficacy of 100mg Tab. Labetalol and 10mg Tab. Nifedipine in the management of hypertension in mild preeclampsia.

Materials and Methods
The present prospective randomized comparative study was conducted in Department of Obstetrics and Gynaecology, MNR Medical College and Hospital and Government Medical College, Nizamabad during June 2018 to September 2019. A total 120 antenatal women clinically diagnosed with mild preeclampsia were recruited. Cases with chronic hypertension, gestational hypertension, chronic hypertension with superimposed preeclampsia and clinically

diagnosed with mild preeclampsia were included. Cases with only eclampsia, cardiovascular disorders, renal disorders and respiratory disorders were excluded.

Informed consent was obtained from all the study participants and study protocol was approved by institutional ethics committee. Based on the type of drug administered, the study cases were randomly divided into two groups. Group 1 was administered with 100mg Tab. Labetalol and group 2 was administered with 10mg Tab. Nifedipine. All the study participants were undergone with complete haemogram and ultrasound abdomen. In group 1, Tab. Labetalol was medicated with a dose of 100mgand drug dosage was increased by 100mg for every 6 hours until adequate control was achieved. In group 2, Tab. Nifedipine was medicated with a dose of 10mg and 10mg of drug dosage was increased for every 6 hours until to reach adequate control. Blood pressure was measured and monitored for every 2 hours intervals in both drug groups along with feto-maternal status. Outcome data was noted in Microsoft Excel and was analysed by using SPSS statistical tool version 20.0.

Results

Table 1: Demographic data of study participants.

	Group 1		Group 2		p-value
	Number	Percentage	Number	Percentage	
Age (In years)					
< 20	07	11.7%	08	13.3%	0.212
21-25	28	16.7%	26	43.3%	
26-30	15	25%	14	23.3%	
>31	10	16.6%	12	20%	
BMI					
<20	10	16.7%	09	15%	0.374
21-25	21	35%	23	38.3%	
>25	29	48.3%	27	45%	
Gravidity					
Gravida 1	32	53.3%	35	58.3%	0.256
Gravida 2	16	26.7%	16	26.7%	
Gravida 3	07	11.7%	06	10%	
Gravida 4	05	8.3%	03	5%	
Gestational age (In weeks)					
28-33	09	15%	11	18.3%	0.228
34-36	45	75%	42	70%	
Term	06	10%	07	11.7%	

In group 1, majority cases were administered with 200mg (43.3%) of Tab Labetalol. Followed by 300mg (23.3%), 400mg (15%), 500mg (10%) and 600mg (8.3%). In group 2, majority cases were administered with 30mg (48.3%) of Tab. Nifedipine, followed by 20mg (35%) and 40mg (16.7%).

Table 2: Details of progression of severe clinical conditions.

Parameter	Group 1 (n=60)		Group 2(n=60)	
	Number	Percentage	Number	Percentage
Severe preeclampsia	09	15%	13	12.7%
Utero placental insufficiency	01	1.67%	04	6.67%
IUGR	02	3.33%	04	6.67%
Intra uterine death	02	3.33%	02	3.33%
Papilledema	02	3.33%	NIL	-
Imminent eclampsia	01	1.67%	01	1.67%

In group 1, none of the cases showed the drug related side effects, whereas in group 2, headache (8.3%), palpitations (5%) and giddiness (1.66%) are the common drug related side effects.

Table 3: Mode of delivery in the cases of two drug groups.

Parameter	Group 1 (N=60)		Group 2 (N=60)	
	Number	Percentage	Number	Percentage
Emergency delivery	10	16.67%	12	20%
Elective delivery	08	13.3%	09	15%
Vaginal delivery	42	70%	39	65%
a. Natural	07	16.67%	08	20.5%
b. Forceps	10	23.8%	08	20.5%
c. Vaccum	03	7.14%	03	7.69%
d. Natural with episiotomy	22	52.3%	20	51.28%

Table 4: Details of foetal outcome and child birth weight among two study groups.

Parameter	Group 1 (n=60)		Group 2 (n=60)	
	Number	Percentage	Number	Percentage
Foetal outcome				
Preterm foetus	11	18.33%	16	26.67%
Term foetus	49	81.67%	44	73.33%
Child birth weight (In kgs)				
Up to 2	05	8.33%	07	11.67%
2 - 2.5	09	15%	11	18.33%
> 2.5	46	76.67%	42	70%

Discussion

Preeclampsia is a disorder of second trimester of pregnancy usually diagnosed by onset of hypertension and proteinuria after 20 weeks of gestation [8, 9]. Labetalol decreases peripheral vascular resistance with a minimal decrease in cardiac output [3, 7]. Nifedipine is a calcium channel blocker, acts on arterioles, lowers peripheral resistance resulting the fall in BP [7]. This study was designed to assess the efficacy of Tab. Nifedipine and Tab. Labetalol in on the foetal and maternal outcome in women with mild preeclampsia. In this study, majority cases were in between 21-25 years. The age difference among two study groups was statistically no significant (p=0.212). Rose DT *et al*., in their study found more cases between age group 21-30 years [10]. Ganesh SK *et al*, in their Study found, preeclampsia was commonly diagnosed in between age group 21-30 years [11]. Study by Amulya C *et al*., found majority preeclampsia cases were in between 19-28 years [7]. Study by Yadav *et al*., found that preeclampsia was commonly seen in women under 25 years [12]. In both study groups, majority cases had BMI more than 25 (48.3% in group 1, 45% in group 2) followed by 21-25 (35% in group 1, 38.3% in group 2). Related to gravidity, in group1, 53.3% cases are primi, 26.7% cases are gravida 2, 11.7% cases are gravida 3 and 8.3% cases are gravida 4. Whereas in group 2, 58.3% cases are primi followed by 26.7% (gravida 2), 10% (gravida 3) and 5% (gravida 4). The difference of gravidity in between two groups was not statistically significant (p=0.256). Rose DT *et al*., in their study observed that more preeclampsia cases were gravida 1 (52% in group A & 50% in group B) followed by gravida 2 (28% in group A & 30% in group B) [10]. Sibai and Cunningham found that incidence of preeclampsia was more in primigravida cases than multigravida cases [13]. Study by Prakash *et al*., found that preeclampsia was more common in primigravida than multi gravida [14]. In both study groups, majority cases were diagnosed at 34-36 weeks of gestation (75% in group 1 & 70% in group 2) (Table 1). Rose *et al*., in their study found that more cases belonged to 34-36 weeks of gestation [10]. Study by Amulya C *et al*., found that at the time of admission more cases were belongs to more than 34 weeks of gestation (46%) [7].

In group 1, majority cases were administered with 200mg (43.3%) and 300mg (23.3%) of Tab Labetalol. In group 2, majority cases were administered with 30mg (48.3%) and 20mg (35%) of Tab. Nifedipine. Study by Rose *et al*., noticed in Labetalol group majority cases received drug dosage 200mg to 400mg. whereas in Nifedipine group most of the cases received drug dosage 20mg-30mg [10]. In the present study, after administering sufficient doses of drugs, cases in both groups had adequate control of BP. Stud results were comparable with the results of Rose *et al*., [10]. In this study, development of various condition have been observed in both study groups such as severe preeclmpsia (15% in group 1 & 12.7% in group 2), utero placental insufficiency (1.67% in group 1 & 6.67% in group 2), intra uterine growth restriction (3.33% in group 1 & 6.67% in group 2), intra uterine death (3.33% in both study groups), papilledema (3.33%in group 1 & no cases in group 2) and imminent eclampsia (1.67% in both study groups) (Table 2). In group 2, headache (8.3%), palpitations (5%) and giddiness (1.66%) are the common drug related side effects, whereas in group 2 no side effects have been noticed.

In this study, most common mode of delivery in both group was vaginal delivery (70% in group 1, 65% in group 2) followed by emergency delivery (16.67% in group 1, 205 in group 2) and elective delivery (13.3% in group 1, 155 in group 2). Natural with episiotomy type of delivery was most common vaginal delivery in both study groups (52.3% in group 1, 51.28% in group 2) (Table 3). Full term foetal outcome was seen in 81.67% cases of group 1 and 733% cases of group 2. Majority child having birth weight more than 2.5kg (76.67% in group 1 & 70% in group 2) in both study groups (Table 4).

In this study cases medicated with Tab. Labetalol and Tab. Nifedipine and equal efficacy in the control of hypertension in mild preeclampsia. Study by Patel NK *et al*., stated that Tab. Labetalol is more effective than Tab. Nifedipine in mild preeclampsia [15]. Study by Peter Von Dadelszen *et al*. proved that Tab. Labetalol and Tab. Nifedipine are effective and safe in the management of preeclampsia [16]. Study by bharathi *et al*., found that Tab. Labetalol and Tab. Nifedipine are equal effective and have control effect on hypertension in mild preeclampsia [17].

Conclusion

Cases medicated with Tab. Labetalol and Tab. Nifedipine and equal efficacy in the control of hypertension in mild preeclampsia. In Nifedipine group, headache (8.3%), palpitations (5%) and giddiness (1.66%) are the common drug related side effects, whereas in labetalol no side effects have been noticed. After administering sufficient doses of drugs, cases in both groups had adequate control of BP. The results concluded that Labetalol group had no side effects, with sufficient dose it had adequate control on BP and had good neonatal outcome. Whereas, Nefidipine is also effective, but has minimal side effects, but it is easy available and effective drug for mild preeclampsia.

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