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A comparative study of antihypertensive efficacy and perinatal safety of intravenous hydralazine and labetalol in pregnancy induced hypertensive crisis

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Abstract
The study was conducted at Jay Kay Lon mother and child hospital, Government Medical College, Kota (Rajasthan) over a period of one year (2015-16) to compare efficacy of intravenous hydralazine and labetalol in lowering blood pressure in pregnancy induced hypertensive crisis. 200 women included in the study divided into two groups (100 each).Group A receive intravenous hydralazine and Group B intravenous labetalol. The pre-treatment mean arterial pressure was 132.33 mmHg in hydralazine group and 130. 39mm Hg in labetalol group. After treatment the mean arterial pressure was 110. 9mmHg for hydralazine group and 111.22mmHg for labetalol group. Mean time to achieve BP control in hydralazine group was 23.6 minutes and in labetalol group 30.8 minutes. Significantly lesser no of drug doses required in hydralazine group. None of the patients had persistent severe hypertension after receiving maximum drug dosage. None had postural hypotension. No significant difference was found in maternal and perinatal outcome. Thus both hydralazine and labetalol are effective, rapid and safe antihypertensive agents but hydralazine is superior in its impact as it lowered mean arterial pressure more rapidly and requiring lesser number of drug doses to achieve target blood pressure**.**

Keywords: Pregnancy, hypertensive, perinatal, hypertensive

Introduction
Hypertensive disorders of pregnancy are one of the most common obstetrical medical problems and affects 7-15% of all pregnancies, being a major cause of maternal, fetal and neonatal morbidity and mortality [1]. Severe pre-eclampsia with BP≥ 160/110mmHg is associated with increased risk of complications like hypertensive encephalopathy, intracranial hemorrhage, congestive heart failure, eclamptic seizures and placental abruption. The reduction of BP to levels ≤ 150/100mmHg is necessary to reduce complications. Intravenous hydralazine and lab *et al*. ol considered as first line antihypertensives for the management of severe preeclampsia [2, 3, 4]. Hydralazine is a directly acting smooth muscle relaxant, acting as vasodilator primarily in arteries and arterioles. Labetalol acts as competitive antagonist *et αl* and β receptor causes decrease in systemic arterial BP and systemic vascular resistance without substantial decrease in resting heart rate, cardiac output and stroke volume.

Aims and Objectives
To assess the efficacy of intravenous labetalol versus intravenous hydralazine in the treatment of pregnancy induced hypertensive crisis.

Material and Method
The study was carried out at GMC, Kota in 200 consented pregnant women with hypertensive crisis (BP ≥160/110mmHg) excluding those who had contraindications to the use of hydralazine and labetalol and who were hemodynamically unstable. Patients were randomly divided into two groups of 100 each. Group A- hydralazine group and group B-labetalol group. Reconstitution of intravenous hydralazine was done by dissolving 20 mg hydralazine powder with 2 ml 0.9% sodium chloride in the vial. Further dilution done with 18 ml normal saline which equates to 1 mg/ml hydralazine.Maximum 3 doses (30 mg) were given. BP was recorded 15 minutes after each dose. Injection labetalol 20 mg solution (4 ml ampule) diluted with 16 ml normal saline to make 20 ml solution of 1 mg/ml labetalol. Maximum 220 mg of labetalol to be given in doses of 20mg, 40mg 80mg 80mg.BP was recorded 15 min after each dose. All the patients in follow up were assessed for any adverse drug reaction, worsening Pre-existing symptoms.

Laboratory investigations as complete blood count with peripheral blood film, renal function test, and liver function test, LDH, Serum electrolytes, coagulation profile, urine examination, fun dos copy and ultrasound was done. Continous fetal monitoring was done. Mode of delivery and fetal outcome was recorded. Statistical analysis of the data was done using chi square test and student' st test. Probability value of <0.05 was taken as statistically significant.

Results and Discussion

Table 1: Demographic characteristics of the patients

	Group A (Hydralazine)	Group B (Labetalol)	Combined n=200	P value
Total number of patients	100	100	200	
Profile at booking				
Mean age(years)	24.87	25.31	25.09	0.433
Mean weight(Kg)	57.67	57.69	57.68	0.97
Mean systolic BP(mmHg)	170.2	167.0	168.6	0.06
Mean diastolic BP(mmHg)	113.3	112.5	112.9	1
Mean arterial BP(mmHg)	132.33	130.39	262.72	
Mean gestational age(weeks)	36.46	36.50	36.48	0.99

Table 1. shows that both the groups were well matched, no significant difference was observed in mean age, mean weight, mean gestational age and mean arterial blood pressure of patients at the time of enrollment in group A (hydralazine) and B(labetalol).This alleviate any significant contribution in discrimination

Table 2: Number of Doses of drugs required to achieve target blood pressure

Number of dose	Group A	Group B	Chi square	P value
1	84	62	15.09	0.002
2	14	24		
≥3	2	14		
Persistent severe hypertension	0	0		

Table 2 shows that in present study 84% of the patients in the hydralazine group and 62% in the labetalol group were required a single dose of the drug to control blood pressure. Patients in labetalol group require significantly more number of doses to achieve desired blood pressure than those of hydralazine group. While in the study of Nombur *et al.* [5] similar doses required for BP control in both group none of the patients had persistent severe hypertension after giving maximum drug dosage. Inou study theme antime to achieve blood pressure control was 23.6minutes and30.8minutes in hydralazine and labetalol group respectively showing that hydralazine is rapidly acting than labetalol. In the study conducted by Nombur *et al.* [5] an average of 40 minutes were required in both groups to achieve blood pressure control. In study conducted by Magee LA *et al.* [8] Also hydralazine was observed as a more effective antihypertensive than labetalol. Mabie and associates [6]. In their study observed that Labetalol lowered blood pressure more rapidly, but hydralazine lowered mean arterial pressure to safe levels more effectively. Vigil de gracia [7] in their study observed successful lowering of blood pressure in both the groups, however in the labetalol group one case had persistent severe hypertension. There was no maternal hypotension in any of the study groups. In study conducted by Paulino Vigil De Gracia *et al*. and Samuel Delgado De Pasquale also no statistically significant difference was there in frequency of hypotension and persistent severe hypertension among labetalol and hydralazine group. The absence of maternal hypotension and the relative success and safety profile observed in this study has earlier been reported by other workers using the same agent [9, 10].

Table 3: Mean arterial blood pressure change

Mean arterial BP(mmHg)	Hydralazine	Labetalol	P value
Before treatment	132.33	130.39	0.052
After treatment	110.79	111.22	0.47
Mean change in MAP	21	19.63	0.14

Table 3 shows that in the present study the pretreatment mean arterial pressure was 132.33 mmHg in hydralazine group and 130.39mmHg in labetalol group which was comparable with the study of Trivedi Swati *et.al* [11]. Where MAP of hydralazine group was 126.61 mmHg and of lab *et al.* ol group 127.4 0mmHg. After treatment the mean arterial pressure was 110. 79mmHg for hydralazine group and 111.22mmHg for labetalol group which was 112.25mmHg in lab *et al*. ol group and 109.27mmHginhydralazinegroupinstudyofTrivedi swati *et al*.

Table 4: Distribution of cases according to mode of delivery

Mode of delivery	Group A	Group B	Chi square	P value
Cesarean section	31	28	2.36	0.125
Vaginal delivery	69	72		
Total	100	100		

The present study showed that there was no significant difference in the mode of delivery between two groups40% of the patients in hydralazine group and 38% in labetalol group were delivered preterm (i.e. at less than 37 weeks of gestation) this is in collaboration with study conducted by Nombur IA *et al.* where 42.9% in hydralazine group and 38.1% in labetalol group were delivered preterm while in study conducted by Trivedi swati *et al.* 64.6% in hydralazine group and 55% in labetalol group were preterm.

No significant difference was found in birth weight of babies between the two groups. In our study the mean birth weight was 2.23kg in hydralazine group and 2.30kg in labetalol group.

Table 5: Perinatal outcome

Perinatal outcome	Group A	Group B	Chi square	P value
Stillbirth/IUD	9	9	0.82	0.661
Died after birth	13	9		
Alive at discharge	78	82		

Neonatal mortality was 13% and 9% respectively in hydralazine and labetalol. These neonatal deaths may be mainly because of complications of preeclampsia like prematurity, very low birth

Weight, intrauterine growth restriction etc. rather than from the effect of drug. No statistically significant difference was found in fetal and neonatal outcome in two groups. Side effect observed in hydralazine treated group include headache (38%), nausea and vomiting (10%), dizziness(8%) and epigastric pain (4%) while headache (22%), nausea and vomiting (20%), flushing (8%), epigastric pain (6%) were those observed in labetalol group. Headach was more frequent in patients given hydralazine compared to labetalol. Similar finding reported in study of IA Nombur *et al*. Vigil-De Gracia et al reported a higher frequency of maternal tachycardia and palpitations with use of hydralazine compared to the use of labetalol.

Conclusion

In general, patients well tolerated the planned maximum doses of hydralazine and labetalol. No final dose reduction or drug discontinuation was required due to major side effects. Thus both the drugs intravenous hydralazine and labetalol are effective, rapid and safe antihypertensive agents but hydralazine is superior in its impact as it lowered mean arterial pressure more rapidly and requiring lesser number of drug doses to achieve target blood pressure.

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