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Comparison of Efficacy of Intravenous Labetalol versus Oral Nifedipinein Control of Acute Hypertension in Severe Pre-Eclampsia/ Eclampsia

Dr.B.S.V.Sivaranjani[1]MS,DGO(OBG) Asst.Professor,
Dr.V.Aruna[2]MD(OBG) Asst. Professor,
[1,2]*Department of Obstetrics And Gynaecology, GGH and Guntur Medical College, Guntur, India.*

Abstract: *This is a hospital based prospective randomized study conducted at department of Obstetrics and Gynaecology, Guntur Government Hospital , Guntur, Andhra Pradesh.*
Objective *: To compare efficacy of intravenous Labetolol versus oral Nifedipine in their rapidity to control hypertensive emergencies.*
Conclusion*: Our study showed that both intravenous Labetolol and Nifedipine are equally effective and well tolerated.*
Keywords:*Eclampsia, Labetolol, Nifedipine, Pre-eclampsia*

I. Introduction

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]
It is associated with 30% of all maternal deaths and as much as 22% of all perinatal deaths. It has been estimated by WHO (World Health Organization) that worldwide approximately 50,000 women will die each year from hypertensive disorders of pregnancy [2] .Severe pre-eclampsia requires prompt treatment because of risk of cardio-vascular accident, to prevent intra cerebral hemorrhage, hypertensive encephalopathy and other target organ damage [3,4] It also presents an increased risk of complication for the fetus including prematurity, low birth weight, NICU admission and even fetal death[4,5]

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 concomitantly with magnesium sulphate[6].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

Aim Of Study

To compare the efficacy of intravenous labetalol versus oral nifedipine in the treatment of acute hypertension in severe pre-eclampsia and ecclampsia with blood pressure ≥160/110 mmHg. To assess the time taken and the number of doses required to achieve target blood pressure of ≤150/100mmHg., safety profile and adverse effects of the drug and also to observe the fetomaternal outcomes

II. MaterialsAnd Methods

This is a comparative study conducted at Guntur Government hospital from January 2015 to July 2016. A total number of 50 patients diagnosed as severe preeclampsia / eclampsia 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.Inclusive criteria were patients with severe preeclampsia/ eclampsia and blood pressure ≥160/110mmhg,Medical decision to rapidly control blood pressure. Exclusion criteria were patients with essential hypertension,H/o cardiac disease,bronchialasthma,hematologicaldisorder,allergy to labetalol or nifedipine,Diabetes ,liver disorders, maternal heart rate <60 or >120 beats/ minute

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.

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 B.P., 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. Continuous maternal vital parameters and electronic fetal monitoring is done with 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. After deliveryAPGAR score and birth weights, signs of prematurity and IUGR of all babies were noted.

The study protocol was approved by ethical committee of the institution and the written informed consent was taken from all antenatal women.

III. Results

Table 1: 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	

Mean number of doses required in I.V labetolol group was 2.16 and in nifedipine group was 2.04

Table 2:comparison of timetaken 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	

This comparison showed no difference in the two groups with a P value of 0.29

Table 3 Mode Of Delivery In 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%

IVD- Induced vaginal delivery, SVD- spontaneous vaginal delivery

SVD was more in labetalol group i.e, 28% when compared to nifedipinei.e, 16%. A significant higher incidence of induction of labour and LSCS was found in nifedipine group.

Table 4 Comparison Of Birth Weight Between Two Groups

Variable	Group	N	Minimum	Maximum	Mean	SD	P-Alue
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	

This comparison was statistically not significant (P=0.07)

Table 5: Comparison 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%

The 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 labetolol group.

Table:6comparison 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 and IUGR was more in labetolol group, when compared to nifedipine group. Incidence of HELLP syndrome was 4% in nifedipine group and nil inlabetolol group.

Table – 7 Comparison 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%
Sob	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

IV. Discussion

Preeclampsia complicates 6 to 8% of pregnancies [7] and is the third common cause for maternal mortality and morbidity next to haemorrhage and infections [8]. The most extensively used antihypertensive drugs in pregnancy are nifedipine, methyldopa and labetalol (Ghanem and Movahed, 2008) .[9]

In the presenr 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 palpitation was the most frequent adverse effect followed by headache, fatigue, weakness, dizziness and flushing with Labetalol. In Nifedipine treated patients headache was experienced as major side effect, but was tolerable, since it did not result in need for discontinuation of therapy. The side effects of Nifedipine are due to its vasodilatation action The most common side effect i.e. severe headache can mimic impending eclampsia [10] The Cochrane review14 on drugs for the treatment of very high blood pressure in pregnancy conclude that until and unless better evidence is available the choice of antihypertensive should depend on the clinician's experience & familiarity with a particular drug and its adverse effects And our study clearly indicates that both intravenous Labetalol and oral Nifedipine are equally efficacious in controlling high blood pressures in severe Pre-eclampsia with minimal side effects

V. Conclusion

Both oral Nifedipine and intravenous Labetalol are equally effective in controlling blood pressure. Both drugs showed no or mild adverse effects in mother and baby. But Nifedipine is cheaper and convenient to administer. Therefore it is of importance in low resource settings. Intravenous Labetalol is important in patients who are unable to take medicine orally.

References

[1]. Cunningham F, Leveno K, Blomm S, Hauth J, Rouse D, Spong C. Williams Obstetrics. 23ra ed. Bethesda, Maryland: McGraw - Hill Companies. 2010.
[2]. Khan KS, Wojdyla D, Say L, Gülmezoglu AM, Van Look PF. W HO analysis of causes of maternal death: a systematic review. The lancet. 2006 Apr 7; 367(9516):1066 -74.
[3]. Payne B, Magee LA, vonDadelszen P. Assessment, surveillance and prognosis in pre-eclampsia. Best practice & research Clinical obstetrics &gynaecology. 2011 Aug 31;25(4):449 -62
[4]. Berg CJ, Callaghan W M, Syverson C, Henderson Z. Pregnancy - related mortality in the United States, 1998 to 2005. Obstetrics & Gynecology. 2010 Dec 1;116 (6):1302 - 9.
[5]. Levine RJ, Hauth JC, Curet LB, Sibai BM, Catalano PM, Morris CD, DerSimonian R, Esterlitz JR, Raymond EG, Bild DE, Clemens JD. Trial of calcium to prevent preeclampsia. New England Journal of Medicine. 1997 Jul 10;337(2):69 -77.

[6]. Mirzaie F, Rahimi-Shorbaf F, Kazeronie AH. Association of maternal serum C- reactive protein levels with severity of preeclampsia. ActaMedicaIranica. 2009;47(4):293 -6.
[7]. Podymow T, August P. Update on the use of antihypertensive drugs in pregnancy. Hypertension. 2008 Apr 1;51(4):960 -9
[8]. Duley L, Henderson-Smart DJ, Meher S. Drugs for treatment of very high blood pressure during pregnancy. ACP JOURNAL CLUB. 2003 Jul;139(1):4 -6.
[9]. Duley L, Henderson-Smart DJ, Meher S. Drugs for treatment of very high blood pressure during pregnancy. ACP JOURNAL CLUB. 2003 Jul;139(1):4 -6. [90] Prakash J, Pandey LK, Singh AK, Kar B. Hypertension in Pregnancy-Hospital Based Study. Journal-Association of Physicians of India. 2006 Apr 2;54 (R): 273.
[10]. Duley L, Henderson-Smart DJ, Meher S. Drugs for treatment of very high blood pressure during pregnancy. ACP JOURNAL CLUB. 2003 Jul;139(1):4 -6.