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Original Research Article

An Assessment of Labetalol and Nifedipine in the Management of Severe Pre-Eclampsia: A Comparative Study

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Abstract

Aim: The aim of the present study was to compare the labetalol and Nifedipine in the management of severe pre-eclampsia.

Methods: The study was conducted in the Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna, Bihar, India for Jan 2021 to December 2021 and in this study all the cases of pregnancy induced hypertension patients of acute hypertensive crisis admitted under OBGY department about 50 cases was studied. Patients of acute hypertensive crisis was divided in two groups Group A -25 patients of acute hypertensive crisis treated with Nifedipine Group B-25 patients of acute hypertensive crisis treated with Labetalol.

Results: The current study shows pertaining to Labetalol patients, the maximum number women fell in age group of 15-20 yrs,i.e 4, In age group of 21-25 yrs were 12, In age group of 26-30 yrs were 3, In age group of 31-40 were only 4. Similarly patients administered with Nifedipine, in age group of 15-20yrs were 5, in 21- 25 yrs had maximum number of patients as 15, in age group of 26-30yrs were only 5 and no patients belonging in age group of 31-40yrs. In my current study, of severe pre eclamptic women, 68% women were primigravida and whereas 32% were multigravida. Statistical status of intergroup differences of changes in Mean Fetal heart rate after the treatment started, (the P-value obtained was > 0.05), not significant in both Nifedipine and Labetalol group. In Grade of 0 had 12 patients, Grade 1 had 3 patients, Grade 2 had 4 patients, Grade 3 had 6 patients and Grade 4 and grade 5 zero patients were there. Similarly in patients given Labetalol were in grade 0 had 15 patients, Grade 1 had 3 patients, grade 2 had 6 patients, Grade 3 had 1 patient, Grade 4 and Grade 5 category were zero patients.

Conclusion: The present study concluded that Nifedipine is the preferred drug in case of severe pre-eclampsia to control blood pressure as it is more efficacious and can be used in the peripheral centers due to cost effectiveness and its ease of administration and storage.

Keywords: Severe pre-eclampsia, Nifedipine, labetalol, blood pressure

Introduction

Preeclampsia is hypertension with proteinuria that occurs after 20 weeks of gestation in women whose Blood Pressure (BP) was previously normal and returns to normal by 12 weeks of gestation. [1] High blood pressure disorders complicate about 5 to 10% of pregnancies, and the prevalence of preeclampsia is about 3.9%. [2] As it could be accompanied by bleeding and infection, it has a huge impact on maternal mortality. [3] In developed countries, mortality due to hypertensive disorders in pregnancy is about 16%3, while in India, it ranges between 15-18%. [4]

About half of this mortality can be prevented. The prevalence of chronic hypertension in pregnancy is expected to increase with maternal age and the global obesity epidemic. [5] Chronic hypertension is associated with more maternal and perinatal adverse events, so it is important to determine the optimal antihypertensive therapy. Data supporting guidelines on the prescription of antihypertensive drugs for chronic hypertension in pregnancy are scarce. In India, methyldopa, labetalol, and nifedipine are the most commonly used antihypertensive drugs during pregnancy. [5] Previously, methyldopa was the most commonly used drug, which has nowadays been largely

replaced by labetalol and nifedipine due to the slower onset of action of methyldopa. Both labetalol and nifedipine have a fast onset of action and effectively treat high blood pressure with minimal side effects for the mother and foetus. [6]

Several drugs are available to rapidly lower BP in case of hypertensive emergencies of pregnancy. The three most commonly employed are labetalol, nifedipine, and hydralazine. All three of these are recommended as first-line agents. [7] According to Cochrane's evaluation of medications for treating very high BP during pregnancy, the selection of an antihypertensive should be based on the clinician's experience and familiarity with the medication in question and what is known about potential side effects. [8]

The aim of the present study was to compare the labetalol and Nifedipine in the management of severe pre-eclampsia.

Materials and Methods

The study was conducted in the Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna, Bihar, India for Jan 2021 to December 2021 and in this study all the cases of pregnancy induced hypertension patients of acute hypertensive crisis admitted under OBGY department about 50 cases was studied. Patients of acute hypertensive crisis was divided in two groups Group A -25 patients of acute hypertensive crisis treated with Nifedipine Group B-25 patients of acute hypertensive crisis treated with Labetalol.

Case selection was done in the criteria of history, clinical examination. Soon after the admission clinical data was recorded according to the Performa. The diagnosis was mainly based on clinical examination.

Inclusion Criteria

1. Pregnant women completed 20 weeks of gestation (primigravida and multigravida) of blood pressure more than or equal to 160/110mmHg in acute uncontrolled hypertension.

2. Period of gestation accurately known by last menstrual period.

3. Singleton pregnancy.

4. Twins plus PIH.

Exclusion Criteria

1. Heart disease.

2. Diabetes Mellitus.

Results

Table 1: Baseline characteristics

Age groups in years	Group A	Group B	Total
15-20 years	4	5	9
21-25 years	14	15	31
26-30 years	3	5	8
31-40	4	0	4
Parity			
Primigravida	15	19	34
Multigravida	10	6	16

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Table 2: Mean heart rate

Mean HR(beats/min)			P – value
	Group A	Group B	
0 MIN	92.21±8.46	94.60±7.60	0.196
5 MIN	88.60±7.12	86.21±5.64	0.106
10 MIN	85.63±9.89	86.30±7.58	0.740
15 MIN	88.80±5.89	87.11±6.23	0.225
20 MIN	82.32±11.27	89.76±7.3	0.264
25 MIN	84.70±10.9	82.33±10.11	0.326
30 MIN	80.1±9.23	85.30±7.67	0.680
40 MIN	76.23±9.0	83.90±12.03	0.174

Statistical status of intergroup differences of changes in Mean Fetal heart rate after the treatment started, (the P-value obtained was > 0.05), not significant in both Nifedipine and Labetalol group.

Table 3: Intergroup comparison of diastolic blood pressure

	Mean DBP(mm Hg)		P – value
	Group A	Group B	
0 MIN	112.6±10.26	112.2±8.64	0.584
5 MIN	108.7±8.76	105.9±10.23	0.789
10 MIN	106±6.99	99.7±7.15	0.272
15 MIN	99.9±7.28	94.2±6.78	0.309
20 MIN	96±7.28	90.2±5.27	0.337
25 MIN	91.8±6.31	87±6.58	0.489
30 MIN	87.4±5.86	86.2±7.66	0.847
40 MIN	82.3±4.12	81.8±5.82	0.229

There was a significant difference in the time taken, to reduce the blood pressure to the target level. At the end of 30 minutes onwards was seen, that both the drugs statistical status of intergroup differences of changes in Mean Diastolic blood pressure after treatment started, was not significant.

Table 4: Fundoscopic findings

Fundoscopic findings	Group A	Group B	Total
Grade 0	12	15	27
Grade 1	3	3	6
Grade 2	4	6	10
Grade 3	6	1	7
Grade 4	0	0	0
Grade 5	0	0	0

In Grade of 0 had 12 patients, Grade 1 had 3 patients, Grade 2 had 4 patients, Grade 3 had 6 patients and Grade 4 and grade 5 zero patients were there. Similarly in patients given Labetalol were in grade 0 had 15 patients, Grade 1 had 3 patients, grade 2 had 6 patients, Grade 3 had 1 patient, Grade 4 and Grade 5 category were zero patients.

Table 5: Complications

Complications	Nifedipine group	Labetalol group	Total
Abruptio	4	1	5
HELLP	1	3	4
Eclampsia	5	1	6
Total	10	5	15

In Nifedipine group, there were 10 complications as compared to labetalol group.

Discussion

Hypertension in pregnancy is one of the components of the dangerous triad—along with bleeding and infection. Hypertensive disorders of pregnancy affect 5% to 10% of all pregnancies globally.[9] In a study population in India, the prevalence of hypertensive disorders of pregnancy was found to be 7.8% and pre-eclampsia to be 5.4%. [10] There is consensus that sustained severe hypertension should be treated as it is considered to be a risk factor for maternal end-organ complications such as stroke, intracranial hemorrhage, cardiopulmonary decompensation, and fetal decompensation due to decreased uterine perfusion, abruption, and stillbirth. [11] The aim of treatment is to bring down blood pressure (BP) quickly and smoothly, which is safe for the mother and baby. [12]

The current study shows pertaining to Labetalol patients, the maximum number women fell in age group of 15-20 yrs,i.e 4, In age group of 21-25 yrs were 12, In age group of 26-30 yrs were 3, In age group of 31-40 were only 4. Similarly patients administered with Nifedipine, in age group of 15-20yrs were 5, in 21- 25 yrs had maximum number of patients as 15, in age group of 26-30yrs were only 5 and no patients belonging in age group of 31-40yrs. In my current study, of severe pre eclamptic women, 68% women were primigravida and whereas 32% were multigravida. The risk may evolve over days or just few hours and may present as worsening blood pressure that may culminate into hypertensive emergencies. Placental abruption and fetal distress are common with severe preeclampsia along with maternal complications like hypertensive encephalopathy and cerebrovascular accidents. [13] Overall, 10% to 15% of direct maternal deaths are associated with preeclampsia and eclampsia. [14] Where maternal mortality is high, most of deaths are attributable to eclampsia, rather than preeclampsia. [14] It has been estimated by the WHO that worldwide approximately 45,000 women will die each year from hypertensive disorders of pregnancy.

[15] Cerebral hemorrhage is the commonest cause of maternal death in pre-eclampsia and eclampsia, hence treatment is mandatory.

Statistical status of intergroup differences of changes in Mean Fetal heart rate after the treatment started, (the P-value obtained was > 0.05), not significant in both Nifedipine and Labetalol group. There was a significant difference in the time taken, to reduce the blood pressure to the target level. At the end of 30 minutes onwards was seen, that both the drugs statistical status of intergroup differences of changes in Mean Diastolic blood pressure after treatment started, was not significant. Until better evidence is available, the best choice of drug for an individual woman probably depends on the experience and familiarity of her clinician with a particular drug and on what is known about adverse maternal and fetal side effects. [16] The mode of administration and rapidity of the action forms the basis for selection of anti- hypertensive therapy in hypertensive emergencies. The Society of Obstetricians and Gynecologists of Canada recommend that, blood pressure should be lowered to <160 mmHg systolic and <110 mmHg diastolic. Initial antihypertensive therapy should be with Labetalol, Nifedipine capsules or Hydralazine. Nifedipine and MgSO4 can be used at the same time. [17] In opposition to present study results, Raheem IA et al., (2012) and Shi DD et al., in their studies found that Nifedipine reduces BP with fewer doses when compared with the Labetalol group. [18,19] Ultimately, the choice of drugs that will be used to control hypertension to some extent depends mainly on the clinician's experience and familiarity with the drug. [20] In Grade of 0 had 12 patients, Grade 1 had 3 patients, Grade 2 had 4 patients, Grade 3 had 6 patients and Grade 4 and grade 5 zero patients were there. Similarly in patients given Labetalol were in grade 0 had 15 patients, Grade 1 had 3 patients, grade 2 had 6 patients, Grade 3 had 1 patient, Grade 4 and Grade 5 category were zero patients. In Nifedipine group, there were 10 complications as compared to labetalol group.

Conclusion

In the present study, both oral Nifedipine and IV Labetalol were ultimately effective in reaching the therapeutic goal, but Nifedipine achieved the target blood pressure more rapidly and with fewer doses than Labetalol. Both drugs demonstrated a similar adverse effects profile. Nifedipine is also cheaper, easier to store, easier to administer as it is given orally, whereas IV Labetalol is more expensive, needs to be stored at a lower temperature and needs slow IV administration. Thus the present study concludes that Nifedipine is the preferred drug in case of severe pre-eclampsia to control blood pressure as it is more efficacious and can be used in the peripheral centers due to cost effectiveness and its ease of administration and storage.

References

1. ACOG practice bulletin. Diagnosis and management of preeclampsia and eclampsia. Number 33, January 2002. ACOG Committee on Practice Bulletins- Obstetrics. Obstet Gyne - col. 2002;99(1):159-67.
2. Cunningham et al: Williams obstetrics. 23rd edition, 34: 706.
3. Khan KS, Wojdyla D, Say L, Gülmezoglu AM, Look PFV. WHO analysis of causes of maternal death: A systematic review. Lancet. 2006;367(9516):1066-74.
4. Park: Text book of community medicine 22nd edition,10:515.
5. Duley L, Henderson-Smart DJ, Meher S. Drugs for treatment of very high blood pressure during pregnancy. ACP Journal Club. 2003;139(1):04-06.
6. Odigboegwu O, Pan LJ, Chatterjee P. Use of antihypertensive drugs during Preeclampsia. Front Cardio Med. 2018;5:50.
7. Baggio MR, Martins WP, Calderon AC, Berezowski AT, Marcolin AC, Duarte G, Cavalli RC. Changes in fetal and maternal Doppler parameters observed during acute severe hypertension treatment with hydralazine or labetalol: a randomized controlled trial. Ultrasound Med Biol. 2011 Jan;37(1):53-8.
8. Duley L, Meher S, Jones L. Drugs for treatment of very high blood pressure during pregnancy. Cochrane Database Syst Rev. 2013 Jul 31;2013(7):CD001449.
9. Williams J. Williams Obstetrics. 24th. Mc Graw-Hill Education / Medical; 2014. Hypert ensive Disorders; p. 728.
10. Sajith M, Nimbargi V, Modi A, Sumariya R, Pawar A. Incidence of pregnancy induced hypertension and prescription pattern of anti-hypertensive drugs in pregnancy. Int J Pharma Sci Res. 2014;5:1–8.
11. Pankiewicz K, Szczerba E, Maciejewski T, Fijałkowska A. Non-obstetric complications in preeclampsia. Prz Menopauzalny. 2019 Jun; 18 (2):99-109.
12. Lewis G. The seventh report on confidential enquiries into maternal deaths in the United Kingdom. London: CEMACH; 2007. The confidential enquiry into maternal and child health (CEMACH). Saving mother's lives: Reviewing maternal deaths to make motherhood safer – 2003-2005.
13. Repke J. Management of obstetric hypertensive emergencies; OBG management 20 05, 17(7).
14. Duely L. The global impact of pre-eclampsia and eclampsia. Semin Perinatol 2009;33:130-37.
15. Khan KS et al. WHO analysis of causes of maternal death: a systematic review. Lancet 20 06;367:1066-74.

16. Duely L. Henderson-Smart DJ, Meher S. drugs for treatment of very high blood pressure during pregnancy. Cochrane Database Syst Rev 2006;47:279-85.
17. SOGC clinical practice guidelines No 206 for diagnosis, evaluation, and management of the hypertensive disorders of pregnancy 2008.
18. Raheem IA, Saaid R, Omar SZ. Oral nifedipine versus intravenous labetalol for acute blood pressure control inhypertensive emergencies of pregnancy: A randomised trial. BJOG. 2012;119:78-85.
19. Shi DD, Yang F, Zhou L. Oral nifedipine vs. intravenous labetalol for treatment of pregnancy-induced severe preeclampsia. Int J Clin Pharm. 2016;41:657-61.
20. Shekhar S, Gupta N, Kirubakaran R. Oral nifedipine versus intravenous labetalol for severe hypertension during pregnancy: A systematic review and meta- analysis. BJOG. 2016;123:40-47.