COMPARATIVE STUDY OF LABETALOL AND NIFEDIPINE IN MANAGEMENT OF PREECLAMPSIA, TERTIARY CARE HOSPITAL, INDIA

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Abstract

Background: Preeclampsia is one of the most challenging diseases of pregnancy. Both nifedipine and labetalol have been used for treatment of pregnancy-induced severe preeclampsia.

Objectives: to evaluate safety of labetalol and nifedipine in management of preeclampsia. And to compare efficacy of labetalol and nifedipine for management of preeclampsia. Tertiary Care Hospital, India.

Method: A hospital based prospective cross sectional descriptive study was conducted on inpatients from OBG department who have been diagnosed with preeclampsia and admitted to tertiary care Hospital India. Demographic details (Name, age) of patient were collected. Admission, discharge date, diagnosis of the patient and drug data (Brand and generic name) of antihypertensive drugs (labetalol, nifedipine) prescribed, dose frequency, route of administration, dose were recorded. Blood pressure at day of admission was recorded and compare with mean blood pressure after receiving labetalol and nifedipine. Data were analyzed using statistical software. Probability values (p value) less than 0.05 were considered significant. Quantitative variables have been indicated in mean ± SD. Results of continuous measurements are presented on mean and results of categorical measurements are presented in Number, percentage (%).

Results: In this study fall in systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) in labetalol group was statistically significant when compared to nifedipine. Outcome of fetus was also better with use of oral labetalol.

Conclusion: The present study indicates labetalol to be better antihypertensive in terms of control of hypertension and fetal outcome and also Labetalol was safer and more effective than nifedipine in lowering blood pressure in patients with pregnancy-induced hypertension/preeclampsia.

Keywords: labetalol; nifedipine; preeclampsia; pregnancy

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Introduction

Pregnancy is associated with profound anatomical, physiological, biochemical and endocrine changes that influence multiple organs and systems [1]. These progressions are crucial for help the woman to adjust to the pregnant state and to aid fetal growth and endurance. Such anatomical and physiological changes might create turmoil during clinical assessment of a pregnant woman. [2]

Hypertensive problems of pregnancy are a significant reason for serious grimness and mortality among both mother and embryo [3]. Pregnant ladies with hypertension have more opportunity to develop placental abruption, spread intravascular coagulation (DIC), cerebral discharge, hepatic disappointment and intense renal disappointment [4]. Hypertensive problems of pregnancy incorporate Preeclampsia, Eclampsia, Chronic hypertension, gestational hypertension and preeclampsia superimposed on chronic hypertension [5, 6]. Among the pregnancy muddling hypertensive problems, Toxemia and Eclampsia are the major reasons for maternal and perinatal mortality and dreariness [3].

Preeclampsia is characterized as a systolic pulse ≥ 140 mmHg or diastolic circulatory strain ≥ 90 mmHg on 2 events no less than 4 h separated after 20 w gestation in ladies with a formerly typical pulse or ≥160 mmHg systolic or ≥110 mmHg diastolic, affirmed inside a short stretch (minutes) to work with opportune antihypertensive treatment and Proteinuria ≥ 300 mg/24 h or a protein/creatinine proportion ≥ 0.3 mg/dl or a dipstick reading of ≥ 1+reading [7].

Worldwide around 76,000 pregnant ladies bite the dust every year from preeclampsia and related hypertensive issues. Fetal death rate is believed to be on the request for 5,00,000 for every annum [8]. The prevalence of Preeclampsia in developing nations goes from 1.8% to 16.7% [9]. The New Joined Realm (UK) guidelines from the National Institute of Health and Clinical Excellence (Decent) suggest oral Labetalol as the primary line decision in the treatment of hypertension in pregnancy [10]. Determination of antihypertensive specialist is the major issue worried about toxemia. National Institute of Health and Clinical Excellence Guidelines proposes that Labetalol, Nifedipine and Methyldopa are favored selection of medications. The utilization of hostile to hypertensive medications in pregnancy is controversial as most antihypertensive specialists utilized in pregnancy are assigned as Class 'C' expressing that human examinations are deficient. Clinicians differ in their decision of treatment for hypertension in pregnancy and there is vulnerability with respect to likely advantages and damages of involving antihypertensive medications in pregnancy. A meta-examination investigation of Randomized controlled preliminaries led for the evaluation of viability, side effects and perinatal result of nifedipine contrasted and different antihypertensives for treating extreme preeclampsia in pregnant ladies concluded that nifedipine is associated with more noteworthy successful control of pulse and prolongation of gestation, contrasted and other antihypertensive for ladies with serious preeclampsia [11].

A prospective report directed in 2012 evaluated the viability and safety of oral Labetalol and oral Nifedipine in pregnant ladies with Pregnancy induced hypertension (PIH) and concluded that labetalol is more compelling than Nifedipine in controlling blood pressure though tachycardia (11 %) and occipital headache are more normal with nifedipine [12]. Regardless of various clinical trials directed, there is only from time-to-time power in the treatment guidelines of preeclampsia. In this manner, our review centers around to assess safety of labetalol and nifedipine in management of preeclampsia. And to analyze adequacy of labetalol and nifedipine for management of preeclampsia.

Methodology

A Prospective Observational Study has been completed on Correlation of Safety and Viability of oral Labetalol and oral Nifedipine in Pre-eclampsia patients in Obstetrics and Gynecology Division at Government General Clinic, Guntur for a considerable length of time from 1st March 2022 to 31st August 2022. The study is totally ongoing based; essential information was created by studying patients conceded for the management of preeclampsia. Incorporation Measures is pregnant ladies of age between 15-40 y with preeclampsia with raised systolic blood pressure of ≥ 140 mmHg and diastolic blood pressure of ≥ 90 mmHg. Pregnant ladies with co-morbidities like Asthma/Obstructive Aviation route Illness and Cardiovascular breakdown are barred.

A complete number of 120 patients who were prescribed with one or the other Labetalol or

Nifedipine were chosen and remembered for the study. On affirmation point by point patient case history was gathered which incorporates the subtleties like age, obstetric and gynecological history, past clinical history, medicine history, blood pressure, financial status [13]. Blood Pressure is recorded utilizing mercury sphygmomanometer [14]. Subsequent to diagnosing preeclampsia, composed informed assent is taken and the preliminary gathering was treated with one or the other Labetalol or Nifedipine. Pregnant ladies getting labetalol 100 mg two times day to day are considered as gathering An and who are getting Nifedipine 10 mg threefold every day (TID) are considered as gathering B. Portion was expanded each 1-2 days whenever expected, up to Labetalol 2400 mg/d and Nifedipine 120 mg/d until palatable Blood Pressure (BP) (≤120/80 mmHg) control was accomplished. Average of three consecutive measurements is considered as Blood pressure (BP) reading and is monitored fourth hourly by sphygmomanometer. On the off chance that blood pressure doesn't decrease even in the wake of expanding the portion to most extreme, extra antihypertensive agent is added and the treatment is considered as failure. Descriptive statistical analysis has been carried out in the present study. Data were analyzed using SPSS software. Probability values (p value) less than 0.05 were considered significant. Quantitative variables have been indicated in mean ± SD. Results of continuous measurements are presented on mean ± SD and results of categorical measurements are presented in Number,
percentage (%), Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

A study consisting of 120pregnant women, 60 pregnant women with preeclampsia treated with Labetalol (Group A) and 60 pregnant women with preeclampsia treated with Nifedipine (Group B) is undertaken to study the safety & efficacy of the drugs. Both the two groups had homogeneous comparable demographics and their characteristics are represented in table 1.

Table 1: Characteristics of pregnant women in oral nifedipine or oral labetalol

Characteristic (range)	**Labetalol**	**Nifedipine**
Age Group (15-40 y)	**25.21±3.64**	**24.6±3.28**
Prime's	**15**	**20**
Gravidity (1-3)	**2**	**2**
Parity (0-3)	**1**	**1**
Systolic Blood Pressure (130-210)	**161.36±21.73**	**145.05±9.16**
Diastolic Blood Pressure (80-140)	**105±12.46**	**95.26±6.87**
Pulse rate (80-105)	**88.94±4.39**	**86.29±2.74**

Table 2: Maternal Systolic and Diastolic Blood Pressure after Administration of Labetalol

Systolic Blood Pressure (mm Hg)	**Number of Patient (n = 60)**	**Percentage (%)**
120 - 129	**27**	**45.00**
130 - 139	**26**	**43.33**
140 - 149	**7**	**11.67**
150 - 159	**0**	**-**
≥ 160	**0**	**-**
Diastolic Blood Pressure (mm Hg)	**Number of Patient (n = 60)**	**Percentage (%)**
80 - 89	**43**	**71.67**

90 - 99	**16**	**26.67**
100 - 109	**1**	**1.67**
110 - 119	**0**	**-**
≥ 120	**0**	**-**

Table No. 3: Maternal Systolic and Diastolic Blood Pressure after Administration of Nifedipine

Systolic Blood Pressure (mm Hg)	**Number of Patient (n = 60)**	**Percentage (%)**
120 - 129	**15**	**25.00**
130 - 139	**31**	**51.67**
140 - 149	**14**	**23.33**
150 - 159	**0**	**-**
≥ 160	**0**	**-**
Diastolic Blood Pressure (mm Hg)	**Number of Patient (n = 60)**	**Percentage (%)**
80 - 89	**24**	**40.00**
90 - 99	**29**	**48.33**
100 - 109	**7**	**11.67**
110 - 119	**0**	**-**
≥ 120	**0**	**-**

Systolic and diastolic blood pressure of included patients was recorded after receiving antihypertensive medications (Labetalol and Nifedipine). All these data are demonstrated in Table No. 2-3

Table 4: adverse effects of oral labetalol and nifedipine

Adverse effect	**Labetalol (n=60)**		**Nifedipine (n=60)**	
	No of Patients	**Percentage**	**No of patients**	**Percentage**
Pedal Edema	30	50	28	47.36
Headache	17	28.94	16	26.31
Sweating	14	23.68	9	15.78
Orthostatic Hypotension	13	21.05	6	10.52
Blurred Vision	13	21.05	2	2.63
Chills & Rigors	9	15.78	5	7.89
Facial Edema	9	15.78	5	7.89
Dizziness	6	10.52	6	10.52
Nausea & Vomiting	6	10.52	0	0
Bronchospasm	5	7.89	2	2.63
Fever	5	7.89	2	5.26

Cough	0	0	6	10.52
Anasarca	0	0	2	2.63
Periorbital Edema	0	0	2	2.63

*n-sample size

Out of total, 120 patients complained adverse drugs reactions. In present study we found, labetalol and nifedipine only contributed in all reported adverse effects including Pedal Edema and headache. (Table No. 4).

DISCUSSION

The Cochrane review on drugs for the treatment of exceptionally high blood pressure in pregnancy concluded that until better evidence is available, the decision of antihypertensive ought to depend on the clinician's experience and familiarity with a particular drug [15].

The appropriate selection of antihypertensive in pre-eclampsia is controversial in the literature. Generally, commonly preferred decision of antihypertensive is Labetalol, Methyldopa, and Nifedipine in pre-eclampsia [16]. According to the National Institute for Health and Clinical Excellence (Decent) guidelines for hypertension in pregnancy, the preferred decision of drug is oral Labetalol to oral nifedipine and Methyldopa [10].

Main findings

In our study, we included 120 pregnant ladies with Gathering A(n=60), Gathering B(n=60). Bunch An is treated Labetalol and Gathering B with Nifedipine. Treatment Strategies are Labetalol 100 mg two times daily, Maximum Dosage 2400 mg/d; Nifedipine 10 mg Thrice a day (TID), Maximum Dosage 120 mg/d. Assuming there is only from time-to-time improvement to normal dosage, the dosage was increased in increments to both treatment groups. Pregnant ladies were monitored for Blood Pressure each 4 h and adverse effects regularly. Based on the statistics, we saw that Labetalol is more successful than Nifedipine in controlling blood pressure whereas the safety concern, nifedipine has less frequency of side effects than labetalol.

Strengths and Limitations

The qualities of our study are the generalizability of results is because of the variety of the study population from various regions and unbiased since there is no deficiency of data as it is a prospective study and there exists a chronological relationship between drug openness and result.

The limitations of our study are Study population is heterogenous which incorporates both proteinuric and non-proteinuric pregnant ladies with high blood pressure and Blood pressure considered is the highest single reading recorded among all four hourly measurements all day long.

Interpretation

The consequences of our study are similar to that of a prospective, randomized, open labeled study, the utilization of oral labetalol with oral nifedipine in hypertensive urgencies in the crisis department of obstetrics conducted by McDonald AJ et al. The pretreatment Blood pressure for labetalol was 195/127 mmHg which decreased to 154/100 mmHg and of nifedipine was 198/128 mm Hg, alleviated to 163/100 mm Hg (P>.2). No significant side effects happened with either drug. Labetalol is powerful when compared to nifedipine in pregnancy induced hypertensive emergencies [17].

In any case, they separate from a Meta-analysis Study conducted by Liu QQ et al., the study incorporates the assessment of the efficacy, side effects and perinatal result of nifedipine compared with different antihypertensives. Compared with different antihypertensives, nifedipine contributed greater efficacy in controlling blood pressure (OR = 2.65, 95%CI: 1.65-4.25, P<0.01) [11].

A recent prospective study conducted by Nita K. Patela et al. in 2012 to evaluate the comparative adequacy and safety of nifedipine, methyldopa and labetalol monotherapy in patients with Pregnancy induced hypertension (PIH) concluded that Labetalol was more compelling than methyldopa and nifedipine in controlling blood pressure in patients with Pregnancy induced hypertension (PIH) giving sustenance to our study [18].

There was no major adverse event attributed to either drug regimens. Our data upholds recent

guidelines and well-qualified opinion that oral labetalol is the suitable first-line antihypertensive for hypertensive emergencies of pregnancy.

Conclusion

Preeclampsia is the most often experienced medical problem in obstetrics practice and remain a major cause of maternal, fetal and neonatal morbidity and mortality. Total 60 patients who satisfied the inclusion and exclusion criteria were signed up for the study. The mean systolic blood pressure bringing down impact for labetalol was 129.88 ± 2.08 mmHg and for nifedipine was 147.91 ±5.5 mmHg. In current observation, we found labetalol was more compelling than nifedipine with P value: < 0.001 (Probability values less than 0.05 were considered significant) which showed significant impact in bringing down maternal high blood pressure. We concluded labetalol was safer and more compelling than nifedipine in bringing down blood pressure in patients with pregnancy induced hypertension (preeclampsia).

From our study, we saw that Oral Labetalol is more efficacious than Oral Nifedipine, with an exception of additional adverse effects and high expense. Thus, the greater part of the health care professionals preferring Nifedipine to Labetalol. In any case, because of entomb individual variation, prevalence of side effects may vary and because of their less severity, it's better to opt labetalol for viable control of blood pressure in preeclampsia.

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