



ORIGINAL RESEARCH PAPER

Obstetrics & Gynecology

COMPARISON OF EFFICACY OF LABETOLOL VERSUS ALPHA METHYL DOPA IN THE MANAGEMENT OF PREECLAMPSIA

KEY WORDS: meliodosis, burkholderia, pseudomallie, septic arthritis

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ABSTRACT

Preeclampsia complicates 2-8% of pregnancies. Preeclampsia can affect virtually every organ system in the body and is a major cause of maternal and perinatal mortality and morbidity. Though the definitive treatment of Preeclampsia is termination of pregnancy, aggressive treatment is necessary to ameliorate the disease progression. Oral anti-hypertensive drugs have a major role in the management of Preeclampsia. A comparison is made here between Labetalol and the commonly used drug Alpha methyl dopa in the management of Preeclampsia.

Materials and Methods

This randomized prospective comparative study was conducted at Government Thoothukudi Medical College Hospital on hundred patients, diagnosed as preeclampsia and admitted in the Eclampsia ward from January 2017 to August 2017.

Results

Statistically significant fall occurred only in the diastolic blood pressure in the Labetalol group after 48 hours ($p=0.007$). There was no statistically significant difference between the need for PGE2 induction between Alpha methyl dopa and Labetalol groups. 86% of cases in the Alpha methyl dopa group and 82% of cases in Labetalol group went in for spontaneous labour. Only 5% of babies born in Alpha methyl dopa group and 2% of babies born in Labetalol group required neonatal admission. This difference was also not statistically significant ($p=0.240$).

INTRODUCTION

Preeclampsia is a multi-system disorder of unknown etiology, unique to pregnancy characterized by occurrence of Gestational Hypertension along with proteinuria after the 20th week of pregnancy in a previously normotensive and non-proteinuric patient.

Gestational Hypertension is defined as Systolic blood pressure of 140mm Hg or more and diastolic blood pressure of 90mm Hg or more on two occasions, measured at least 6 hours apart but within 7 days.

Proteinuria is defined as excretion of 0.3g or more of protein in a 24 hour urine sample or >1+ on dipstick in a random sample after excluding urinary tract infection.

Preeclampsia complicates 2-8% of pregnancies. Preeclampsia can affect virtually every organ system in the body and is a major cause of maternal and perinatal mortality and morbidity. Preeclampsia, when not controlled or left untreated can lead to catastrophes like Eclampsia, Abruptio-placenta, HELLP syndrome, fetal growth restriction, and intrauterine fetal death. Though the definitive treatment of Preeclampsia is termination of pregnancy, aggressive treatment is necessary to ameliorate the disease progression in order to carry on the pregnancy till adequate fetal maturity is obtained.

Oral anti-hypertensive drugs have a major role in the management of Preeclampsia. A comparison is made here between Labetalol and the commonly used drug Alpha methyl dopa in the management of Preeclampsia.

AIM OF THE STUDY

This study compares the efficacy of oral Labetalol versus oral Alpha methyl dopa in the management of Preeclampsia in terms of reducing the blood pressure, need for labour induction, mean birth weight, APGAR score, and rate of neonatal admissions.

MATERIALS AND METHODS**STUDY DESIGN:**

Prospective case control study

SETTINGS:

This randomized prospective comparative study was conducted at Government Thoothukudi Medical College Hospital on hundred

patients, diagnosed as preeclampsia and admitted in the Eclampsia ward.

DURATION OF STUDY:

From January 2017 to August 2017.

METHODOLOGY:

The patients included in this study were assigned to two groups at random of 50 patients in each group.

GROUP 1:

Tablet Alpha methyl dopa (Aldomet) 250 mg was given thrice daily.

GROUP 2:
Tablet Labetalol 100 mg was given twice daily.

INCLUSION CRITERIA:

All the patients with Gestational Hypertension (more than 20 weeks of gestation till term) with

- Systolic Blood Pressure 140 mm of Hg or more
- Diastolic Blood Pressure of 90 mm of Hg or more
- Proteinuria (0.3g in 24 hours or more /1+ dipstick or more)

EXCLUSION CRITERIA:

- Chronic Hypertension
- Renal Disease
- Liver Disease
- Bronchial Asthma
- Gestational Diabetes Mellitus
- Cardiac Disease

Imminent Symptoms:

- Headache
- Blurring of vision
- Epigastric pain
- Oliguria (<500ml/24hrs)

Complications

- Acute Left Ventricular Failure
- Coagulation failure
- Intracerebral Hemorrhage

- HELLP syndrome

Eclampsia

PROCEDURE:

Informed consent was obtained from these patients before administration of the drugs. Blood pressure was recorded every 12th hourly. The treatment was continued till delivery if the Blood pressure is controlled. If the Blood pressure was not controlled within 48 hours, the dose of drugs were doubled. Blood pressure was measured in the right upper arm in sitting position with a mercury sphygmo-manometer after a period of rest for 15 minutes. Korotkoff phase 5 was used to define diastolic blood pressure. Proteinuria was detected using the sulphosalicylic acid test. The period of study was 1 year. The change in BP after 48 hours, need for induction, and mode of termination of pregnancy, birth weight, APGAR score and neonatal admissions were recorded.

RESULTS AND ANALYSIS:

This study was commenced with 100 women and outcome was analysed using various parameters. the results were subjected to statistical analysis using t test and chi square test.

Age group:

| | GROUP | N | MEAN | STD. DEVIATION | STD. ERROR MEAN |
|-------------|-------|----|-------|----------------|-----------------|
| AGE(YEARS) | 1 | 50 | 25.50 | 3.808 | 0.539 |
| | 2 | 50 | 25.82 | 4.443 | 0.628 |

The above table shows the mean ages of the patients in both the groups. The difference between the mean ages between the two groups is not statistically significant. (p value=0.700)

Parity:

| PARITY | LEGEND | | GROUP1 ALPHA METHYL DOPA | GROUP 2 LABETALOL | TOTAL |
|--------|--------|----------------|--------------------------|-------------------|--------|
| PRIMI | 1 | Count | 30 | 21 | 51 |
| | | % within group | 60.0% | 42.0% | 51.0% |
| MULTI | 2 | Count | 20 | 29 | 49 |
| | | % within group | 40.0% | 58.0% | 49.0% |
| TOTAL | | Count | 50 | 50 | 100 |
| | | % within group | 100% | 100.0% | 100.0% |

p value= 0.072

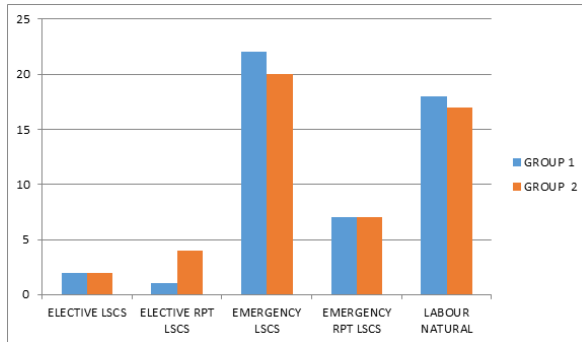
60% of women in group1 and 40% women in group 2 were primi. 40% of women in group 1 and 58% of women in group 2 were multi.

Gestational age:

| | GROUP | N | MEAN | STD. DEVIATION | STD. ERROR MEAN |
|--------------------------|-------|----|-------|----------------|-----------------|
| GESTATIONAL AGE IN WEEKS | 1 | 50 | 37.90 | 1.930 | 0.273 |
| | 2 | 50 | 37.94 | 1.596 | 0.226 |

The above table shows the mean gestational age in both the groups. the difference between the mean gestational ages between the two groups is not statistically significant. (p value=0.910)

Mode of delivery:



The above chart shows the mode of delivery in both the groups. 44% of cases in group 1 and 40% of cases in group 2 underwent emergency LSCS. 36% of cases in group 1 and 34 % of cases in group 2 were delivered by labour natural.

BP AT THE TIME OF DELIVERY:

| BP AT THE TIME OF DELIVERY | GROUP | N | MEAN | STD. DEVIATION | STD. ERROR MEAN |
|----------------------------|-------|----|--------|----------------|-----------------|
| SYSTOLIC BP | 1 | 50 | 143.00 | 9.530 | 1.348 |
| | 2 | 50 | 139.40 | 9.982 | 1.142 |
| DIASTOLIC BP | 1 | 50 | 91.60 | 7.918 | 1.120 |
| | 2 | 50 | 89.40 | 6.197 | 0.876 |

The above table shows the mean systolic and diastolic blood pressure at the time of delivery in both the groups. There is no statistically significant difference between the mean systolic blood pressures between the two groups.(pvalue= 0.068). Also there is no statistically significant difference between mean diastolic blood pressure between the two groups.(p value = 0.125)

DISCUSSION:

This randomized prospective study compares the efficacy of oral Labetalol versus oral Alpha methyl dopa in the management of preeclampsia.

Preeclampsia is an important cause of maternal mortality and perinatal mortality and morbidity. Oral antihypertensive drugs have played a major role in controlling the disease progression, preventing Eclampsia and other dreaded complications, prolonging pregnancy, and reducing fetal prematurity.

Though methyl dopa has been used routinely because of its safety profile, several controlled trials have suggested Labetalol to be a better drug in controlling hypertension with the least side effects.

In our study, the initial daily dose of Labetalol was 200 mg and that of Alpha methyl dopa was 750 mg. the dose was increased after 48 hours if satisfactory fall in BP control has not occurred. Statistically significant fall occurred only in the diastolic blood pressure in the Labetalol group after 48 hours(p=0.007). There was no statistically significant difference between the need for PGE2 induction between Alpha methyl dopa and Labetalol groups.86% of cases in the Alpha methyl dopa group and 82% of cases in Labetalol group went in for spontaneous labour. Only 5% of babies born in Alpha methyl dopa group and 2%of babies born in Labetalol group required neonatal admission. This difference was also not statistically significant (p=0.240).

In our study,44% of cases in the Alpha methyl dopa group and 40% in the Labetalol group delivered by Emergency LSCS;36%of cases in the Alpha methyl dopa group and 34% of cases in the Labetalol group delivered by Labour Natural.

In our study, there were no reports of intrauterine deaths. There was a statistically significant increase in the mean birth weight in the Labetalol group when compared to Alpha methyl dopa group (3.11 kg and 2.67kg respectively, p value=0.00)

SUMMARY:

- These 100 patients were assigned to two groups at random of 50 patients in each group. Group 1 was started on tablet Alpha methyl dopa 250 mg thrice daily and Group 2 was started on tablet Labetalol 100 mg twice daily. Blood pressure and proteinuria was recorded every 12th hourly.
- The treatment was continued till delivery if the blood pressure was controlled. If the blood pressure was not controlled within 48 hours, the dose of the drugs was doubled.
- The relationship of age, parity, gestational age and body mass index to the prevalence of preeclampsia were analysed in both the groups. Also the fall in BP after 48 hours, need to increase the dose of the drugs, need for labour induction, method of delivery, blood pressure at the time of delivery, birth weight, APGAR score and neonatal admissions in each group has been analysed.

CONCLUSION:

- This is a study comparing the efficacy of Labetalol and Alpha methyl dopa in the management of preeclampsia, in which 50 patients were started on oral Labetalol and 50 patients were started on oral Alpha methyl dopa.
- Significant fall in the diastolic blood pressure after 48 hours occurred only in the Labetalol group($p=0.007$)
- In the Alpha methyl dopa group, there was a significant need to increase the dose of the drug after 48 hours.
- There appears to be no significant difference in the rate of induction between the two groups. ($p=0.585$)
- The mean birth weight was significantly higher($p=0.00$) in the Labetalol group(3.11kg) compared to the Alpha methyl dopa group(2.67kg)
- There was no significant difference in the APGAR scores ($p=0.090$) and rate of neonatal admissions ($p=0.240$) in both the groups.

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