A Comparative Study on Labetalol Versus Labetalol With Magnesium Sulphate In Severe Preeclampsia Patients

Suhera sahi¹, T.Kanthi priya², Dr.B.Swathi³, Mrs.R.Sandhya⁴, A.Vishnu priya⁵, Dr.Mini Mohan DGO⁶

¹Department of pharm D, Bharat school of pharmacy, Mangalpally, Ibrahimpatnaam, Hyderabad- 501510.
²Department of pharm D, Bharat school of pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510.
³Assistant professor, Bharat school of pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510.
⁴Assistant professor, Bharat school of pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510.
⁵Department of pharm D, Bharat school of pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510.
⁵Department of pharm D, Bharat school of pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510.
⁶DNB, Department of obstectrics and gynaecology, Durgabhai deshmukh hospital and research centre, vidyanagar, Hyderabad.

Abstract:

AIM: The aim of the study was comparison of labetalol versus labetalol with magnesium sulphate in severe preeclampsia patients. **METHODOLOGY:** A randomized prospective study will be carried out in pre-eclampsia patients to evaluate the efficacy of labetalol versus labetalol with magnesium sulphate in department of gynecology, Durgabai Deshmukh Hospital, a 250 bedded multispecialty hospital from July 2018 – march 2019. **RESULTS:** Among the total number of patients (60), labetalol is given to 80% of patients and labetalol with magnesium sulphate was given to 20% of patients. Based on blood pressure monitoring the age group between 25-30years were more treated with labetalol only. Most of the patients affected with preeclampsia at 3rd trimester and in primi conditions. **CONCLUSION:** The total number of patients required magnesium sulphate in combination. Hence labetalol can be considered more effective in preeclampsia patients.

Key Words: Pre-eclampsia, Labetalol, Magnesium sulphate, Gestational hypertension, IUGR, Proteinuria.

Date of Submission: 13-07-2020

Date of Acceptance: 28-07-2020

I. Introduction:

• Hypertension in pregnancy is defined as systolic blood pressure >140mmHg or diastolic blood pressure >90mmHg. Pregnancy induced hypertension can be serious and life threatening complication. Patients with elevated blood pressure are at increased risk of pre-eclampsia and intrauterine growth retardation ^[1].Types included are : 1) Chronic hypertension-hypertension before pregnancy or before 20thweek is called chronic hypertension. 2) Pre-eclampsia-eclampsia-preeclampsia is characterized by increase in blood pressure along with proteinurea, edema may or may not be present, proteinurea should be 300mg or more urinary protein. 3)Pre-eclampsia superimposed on chronic hypertension-when a pregnant women with previous hypertension develops proteinurea after weeks of gestation. 4)Gestational hypertension- blood pressure increased for first time after 20weeks is known as gestational hypertension, it does not accompanies by proteinurea and returns to normal 12 weeks after postpartum whereas final diagnosis can only be made 12 weeks postpartum.^[2]

• Pre-eclampsia is a pregnancy specific condition occurring after 20weeks of gestation and consists of hypertension with proteinurea. Preeclampsia include progressive placental and maternal endothelial cell dysfunction, increased platelet aggregation, loss of arterial vasoregulation.^[3].

• They need frequent checks of their blood pressure,urinanalysis and fetal growth. Pre-eclampsia. Preeclampsia is diagnosed when the blood pressure by 30/15mmHg from measurements obtained in early pregnancy or if the diastolic blood pressure exceeds 110mmHg and proteinurea is present. Following clinical presentations considered signs are persistent headache, vomiting, visual disturbance, decreased fetal growth, impaired LFTs, thrombocytopenia, epigastric pain, hemolysis, oligohydramnios, cyanosis.When a woman with pre-eclampsia develop seizures, the term eclampsia is used.^[4]

• Gestational hypertension which includes preeclampsia abs eclampsia is responsible for 70% of cases whereas chronic hypertension represents 30% of hypertensive disorders in pregnancies.^[5]

• The HELLP SYNDROME (hemolysis, elevated liver enzymes, low platelets) is a subtype of severe preeclampsia and a major cause of morbidity and mortality in this disease. Coagulation disorder and platelet dysfunction further increase the risk of stroke. ^[6]

• In preeclampsia, a reduced plasma volume, reduced glomerular filtration rate, reduced renal flow. Hence extra fluid is present with extra sodium in it. Retention of sodium and its movement into arterial walls leads to sensitivity of pre-agents that finally leads to preeclampsia.^[7]

II. Material And Methods:

For this study, consent of Institutional ethics committee, Durgabai Deshmukh hospital was taken. This prospective observational study was conducted for 6 months in Department of gynecology, Durgabai deshmukh hospital a 250 bedded multispeciality hospital.

A study was conducted to evaluate patients (females) with pre-eclampsia. Baseline demographic data was collected from the patient case reports. Patients presenting with elevated blood pressure and proteinurea of age group 18-45 years were included. Patients less than 18 years and more than 45 were excluded.

III. Results And Discussion :

In the current clinical research study, we have performed a prospective observational study regarding blood pressure monitoring in patients receiving labetalol and labetalol with magnesium sulphate who are admitted in gynaecology ward. This study was conducted at Durgabai Deshmukh hospital under expertise doctor guidance. Extensive study of 6 months has been done on 60 subjects and results have been interpreted. Regular observations of each patient was done in which medication charts dosing schedules, lab details, and vitals were analysed based on their length of stay in hospital. The recorded data of each patient was entered into our data collection form which is designed to meet our study requirements. Results have been displayed below based on our objective of study using histograms, pie diagrams.

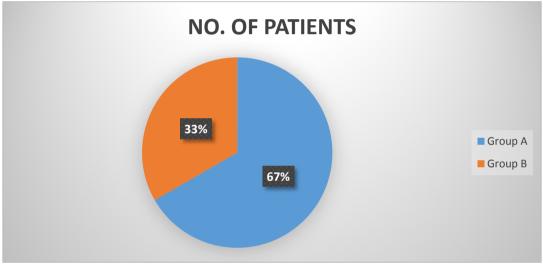


Figure 1 :- Comparision of two groups

Result : Group-A therapy was much efficient in which patients are undergoing with labetalol therapy when compared with group-B in which patients are undergoing with labetalol with magnesium sulphate therapy.



A Comparative Study on Labetalol Versus Labetalol With Magnesium Sulphate In ..

Figure 2 :- Comparision based on Age.

Result: The above chart describes that the age group between 25-30 where more treated with labetalol when compared to labetalol with magnesium sulphate.

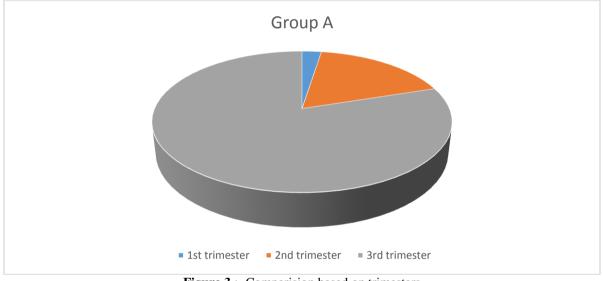


Figure 3 :- Comparision based on trimesters

Result :- The above pie diagram shows that many patients are affected with pre-eclampsia at 3^{rd} trimester when compared with group A and group B.

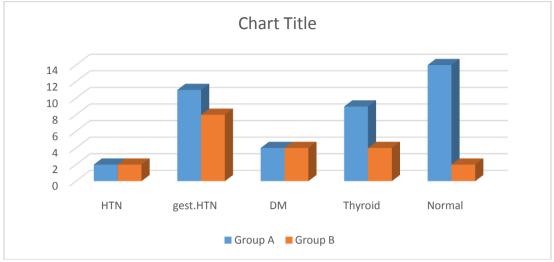


Figure 4:- Comparision based on comorbidities

Result :- The above chart describes that patient with Gestation Hypertension are more compared to other comorbidities.

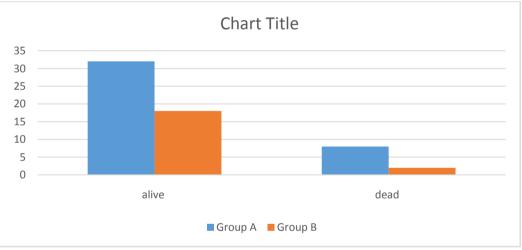
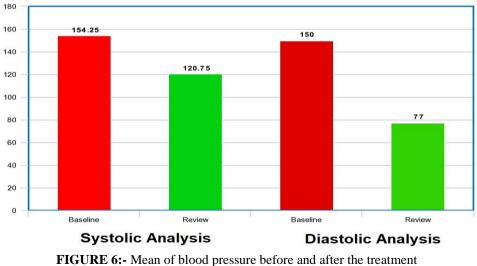
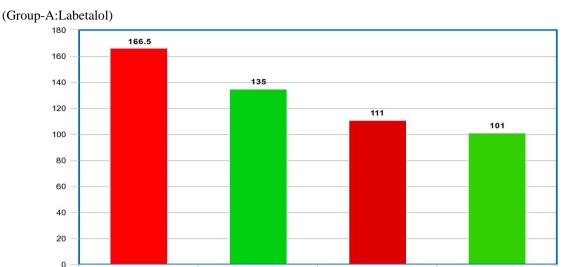


Figure 5:- Comparison based on baby status

Result:- The above chart shows the baby status where found to be alive more in group-A when compared to dead status more in group -B.





Baseline

Review

Diastolic Analysis

FIGURE 7:-Mean of blood pressure before and after treatment (Group B:- labetalol with magnesium sulphate)

STATISCAL METHOD:

The paired t-test provides a hypothesis test of the difference between population means for a pair of random samples whose differences are approximately normally distributed.^[8-9]

SYSTOLIC BLOOD PRESSURE :(GROUP-A)

Baseline

 H_0 : There is no significant difference between systolic blood pressure before and after the treatment H_1 : There is significant difference between systolic blood pressure before and after treatment.

Review

Systolic Analysis

Paired --t-test:

TEST	DF	P value	T statistic	One sided or two sided	Statistical Significance
Paired t-test	39	< 0.0001	20.53	Two tailed	Yes

Result: The above table shows that there is a statistical difference between systolic blood pressure before and after the treatment i.e., there is recovery of symptoms and blood pressure after treating with labetalol.

DIASTOLIC BLOOD PRESSURE (GROUP-A)

 $H_{0:}$ There in no significant difference between diastolic blood pressure of labetalol before and after the treatment H_1 : There is a significant difference between diastolic blood pressure of labetalol before and after the treatment. Paired –t-test:

TEST	DF	P value	T statistic	One sided or two sided	Statistical Significance
Paired t-test	39	< 0.0001	12.55	Two tailed	Yes

Result: The above table shows that there is a statistical difference between diastolic blood pressure before and after the treatment as the labetalol therapy is effective.

SYSTOLIC BLOOD PRESSURE (GROUP-B)

 $H_{0:}$ There is no significant difference between the systolic blood pressure before and after treatment. H₁: There is significant difference between the systolic blood pressure before and after the treatment. Paired –t-test:

TEST	DF	P value	T statistic	One sided or two sided	Statistical Significance
Paired t-test	19	< 0.0001	12.41	Two tailed	Yes

Result: The above table shows there is a statistical difference between systolic blood pressure before and after treatment where treated with Labetalol with Magnesium sulphate.

DIASTOLIC BLOOD PRESSURE (GROUP-B)

 H_0 : There is no significant difference between the diastolic blood pressure of before and after treatment.

 H_1 : There is significant difference between the diastolic blood pressure of before and after treatment.

Paired –t-test:

TEST	DF	P valu	T statistic	One sided or two sided	Statistical Significance
Paired t-test	19	< 0.0001	5.210	Two tailed	Yes

Result: The above table shows there is a statistical difference between diastolic blood pressure before and after treatment where treated with labetalol with magnesium sulphate

IV. Conclusion

In this study we evaluated blood pressure changes in patients receiving labetalol and labetalol with magnesium sulphate and we concluded that the changes in blood pressure are in the range of 40/20mmHg. Hence most of patients with preeclampsia are treated with labetalol. Only 33% patients required labetalol with magnesium sulphate.

ETHICS AND CONSENT

The entire study was conducted according to the AHA/ASA guidelines. All the relevant and necessary data was collected from in patient records, laboratory reports, prescriptions and by interviewing the patients.

CONFLICTS OF INTEREST:

None.

References

- [1]. Mary annekode-kinble, Lloyd Yee Young et al , Applied therapeutics the clinical use of drugs 9th edition 46-16.
- [2]. **Roger walker, Catewhittlesea**, Clinical pharmacy and therapeutics, 4th edition 274.
- [3]. Richard A. Helms, david J. quan et al, textbook of therapeutics drugs and disease management, 8th edition
- [4]. Evangelia Kintiraki et al, Pregnancy induced hypertension-classification, HORMONES 2015, 14(2):211-223
- [5]. Mary annekode-kinble, Lloyd Yee Young et al , Applied therapeutics the clinical use of drugs 9th edition 46-16.

[6]. Harrisons ,kasper, fauci ,hauder et al, *principles of internal medicine* 19th edition 48

- [7]. Mary annekode-kinble, Lloyd Yee Young et al , Applied therapeutics the clinical use of drugs 9th edition 46-16.
- [8]. **K. VisweswaraRao**, Biostatics in brief made easy,2010: 153,110.
- [9]. Sanford Boltan, CharlesBon, Pharmaceutical statistics, Practical and clinical applications, 5th edition 106-107.

Suhera sahi. "A Comparative Study on Labetalol Versus Labetalol With Magnesium Sulphate In Severe Preeclampsia Patients." *IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)*, 15(4), (2020): pp. 06-10.
