NIFEDIPINE VS ORAL LABETALOL IN MANAGEMENT OF HYPERTENSION IN PREGNANCY

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mahi Publication

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ISBN: 978-81-948528-4-1

First Edition: Sep 2020

PRICE ₹ 149/-

PUBLISHER
MAHI PUBLICATION

Office No.1, Krishnasagar Society, Nr. Shivsagar sharda Mandir Road, Ahmedabad-380007

mahibookpublication@gmail.com

+(91) 798 422 6340

www.mahipublication.com

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INTRODUCTION

Hypertensive disorders complicating pregnancy are common, and form a deadly triad, along with hemorrhage and infection. These hypertensive disorders contribute greatly to maternal morbidity and mortality [1].

One in ten women will develop hypertension during pregnancy and preeclampsia complicates 2% to 8% of pregnancy (WHO 1988) and contributes to 9% of maternal mortality in Asia and 12% in India [2,3].

The spectrum of hypertensive disease that can complicate pregnancy is broad, ranging from "white coat" hypertension to gestational hypertension, chronic hypertension and preeclampsia to chronic hypertension with superimposed pre- eclampsia.

Particularly challenging, however, is hypertension in pregnancy that be come severe enough to qualify as a hypertensive crisis,bring ing immediate risk to both them other and fetus [4].

The risk may evolve over day so just few hours and may present as worsening blood pressure that may culminate into hypertensive emergencies.

The role of anti hypertensive therapy for pregnant women with mild to moderate hypertension is unclear. As there is no immediate need to lower BP, the rationale for treatment is that it will prevent or delay progression to more severe diseases, there by benefitting the women or her baby or both, and reducing consumption of health service resources.

As well as reducing BP, the belief has been that these drugs reduce the risk of preterm delivery and placental abruption and improve fetal growth.[5]

There is 5 fold increase in perinatal mortality [6] which is mainly due to iatrogenic prematurity .In women with gestational hypertension or pre-eclampsia, greater the severity of hypertension, greater the adverse perinatal outcome.

Recent studies have attributed the occurrence of fatal intra cranial hemorrhages to inadequate treatment of severe systolic hypertension (≥ 160mmHg) in preeclampsia and recommend urgent and effective antihypertensive treatment for such cases.

It is important to stabilize the maternal hypertension prior to delivery to avoid dangerous fluctuations or exacerbations of blood pressure during labor.

Thus adequate and safe blood pressure control will allow definitive treatment of delivery of the baby to be carried out with minimal delay in many cases of severe hypertension in pregnancy .

Delivery is the most appropriate therapy for the mother but may not be so for the fetus which is remote from term.

The obstetricians should aim not just for the diagnosis, but also for the prevention of complications of hypertensive disorders.

Maternal complications of acute hypertension in pregnancy include cerebrovascular accident, renal failure, hepatic dysfunction, **HELLP** syndrome and left ventricular failure.

The fetus is also at risk of growth restriction, prematurity, asphyxia and intra uterine death due to placental abruption.

There is consensus that due to these risks the patients should be treated with anti hypertensive agents as an inpatient to achieve rapid control of hypertension.

There have been many drugs that have been described in control of pre eclampsia,they include Hydralazine,Labetalol,Nifedipine.

A few trial shave been conducted on the above mentioned drugs, but no single drug has been identified as being superior to the other.

Labetalol, a beta blocker, has arteriolar vasodilating action that lowers peripheral resistance.

Calcium channel blockers include Nifedipine, Nicardine, Nimodipine and Verapamil. These drugs inhibit influx of calcium ions to vascular smooth muscles resulting in arterial vasodilatation.

Nifedipine has the advantage of being cost effective and can be administered orally, however it is known to cause sudden hypotension and respiratory embarrassment when used sublingually concomitant with magnesium sulphate.

An interaction between Nifedipine and magnesium sulphate may be associated with profound muscle weakness and hypotension.

Nifedipine and magnesiumsulp hate both have to colytic effect and can prolong the duration oflabour.

In India, Nifedipine is the most commonly used antihypertensive because of ease of administration.

It is however banned in countries like Australia in view of sudden unpredictable fall of blood pressure and cardiac side effects.

Very few studies comparing the efficacy of Nifedipine and Labetalol have been done so far,and the reisno set protocol for the rapy.

Hence the need for a comparison between these 2 drugs Nifedipine and Labetalol, to recognize the superior drug is essential.

2

REVIEW OF LITERATURE

In the year 2000, a RCT was conducted by Magee L and study on oral beta blockers for mild to moderate hypertension during pregnancy was done on 2500 women with hypertension in pregnancy and it was concluded that oral beta blockers decreases the risk of severe hypertension with placebo/ no beta blocker .[7]

In the year 2002, RCT was done on 126 women comparing Hydralazine and Nifedipine by AaliBS and it was concluded that Nifedipine is safe and more effective than Hydralazine in controlling BP in severe preeclampsia .It has the added advantage of being cheaper and more widely available than the latter and is easily available.[8]

In a systematic review of 46 trials (4282 women) conducted by Abalos E, Duley L et al [9] the primary aim was, to ascertain the maternal and fetal hazards of indicating antihypertensive agents for mild to moderate hypertension in pregnancy and secondary aim was to compare the effects of alternative agents.

The results summarised were as follows:

A) Anti hypertensive agents have the risk of developing severe hypertension irrespective of the class of drug, type of hypertension or gestational age at the trial entry. (19trials,2409women;RR0.50 ; (95%CI0.41to0.61);riskdifference(RD)– 0.10;number needed to treat(NNT)10 (8 to13).

B) There was no overall difference in risk of pre-eclampsia development, abruptio placenta or small for gestationalage.No statistically sign if i cant difference in the risk of fetal or neonatal deaths. 22 trials (2702 women) RR 0.97; 95% CI 0.83 to 1.13.

The study conducted by BartonJR, O'brienJM, BergauerNketal[10] described the prognostic signs in the natural course of mild

gestational hypertension & pregnancy outcomes in women who were remote from term with mild gestational hypertension that was expectantly managed.

A total of 748 women with mild gestational hypertension with singleton pregnancy between 24 & 35 weeks without proteinuria were studied. 46% ultimately had pre -eclampsia, with progression to severe disease in 9.6%.

The development of proteinuria is associated with an earlier gestational age at delivery, lower birth weight & an increased incidence of small for gestational age new born.

Gestational age of infants at delivery (36.5+/-2.4vs37.4+/- 2.0 weeks), birth weight (2752+/-767vs3038+/- 715g), incidence of small for gestational age newborns (24.8%vs13.8%), and duration of neonatal hospital stay (7.1+/-10vs5.0+/-9.3days) differed significantly in the patients with versus those without proteinuria ($p<0.001$ for all).

In an article on Nifedipine on maternal fetal binomial, more safety, efficacy and effectiveness were found with Nifedipine. Therefore Nifedipine can be used in antihypertensive treatment during pregnancy without serious complications.11

A prospective trial by C. A. Michael et al performed to evaluate the use of Diazoxide and Labetalol given intravenously in the management of severe hypertensive disease in pregnancy concluded that both drugs had an efficient hypotensive action.

The reduction in blood pressure in the Labetalol group was better controlled and concluded that this may be a factor influencing perinatal outcome. Because of the freedom of maternal and fetal side-effects, Labetalol given by intravenous infusion is a more appropriate drug for use in the management of hyper tensive crisisoccurring in pregnancy and labor.[12]

Duley et al compared different antihypertensive drugs for very high blood pressure during pregnancy and concluded that, the choice of antihypertensive should depend on the clinician' sexperience and

and familiar ity with a particular drug and on what is known about adverse effects. Exceptions are Diazoxide, Ketanserin, Nimodipine and Magnesium sulphate,which are probably best avoided.[13]

Tooke-Miller C, Allen JC [14], carried out a prospective observational study to research the cerebral hemodynamic effects of Labetalol in pregnant women with hypertension .

It was concluded that Labetalol effectively reduces CPP (cerebral perfusion pressure), without affecting cerebral perfusion, primarily by a decrease in systemic blood pressure. This makes it an ideal agent for blood pressure control in hypertensive pregnant women.

IA Raheem, R Saaid, SZ Omar, PC Tan [15] conducted a double blinded randomized trial comparing oral Nifedipine with intra venous Labetalol in their rapidity of controlling hypertensive emergencies in pregnancy.

Main outcome measured was the time taken to achieve a blood pressure of ≤150/100 mmHg. The median time taken to achieve target blood pressure was 30 minutes versus 45 minutes for Nifedipine and Labetalol, respectively.

It was concluded that oral Nifedipine and intravenous Labetalol regimens are similarly effective in the acute control of severe hypertension in pregnancy.

Vigil-De Gracia P, Lasso M, Ruiz E conducted a randomized control trial on 200 women with severe hyper tension in pregnancy to compare the safety and efficacy of in travenous Labetalol and intravenous Hydralazine for acutely lowering blood pressure in pregnancy.

The primary endpoint was successfull ower in gofblood pressure and maternal hypotension.

The trial concluded that Labetalol and Hydralazine fulfil the criteria required for an antihypertensive drug to treat severe hypertension in pregnancy. [16]

Calcium antagonists generally constitute second line agents, usually administered late in pregnancy.

A prospective cohort study suggests that calcium channel blockers (especially Nifedipine) do not represent a major teratogenic risk.

Nifedipine has shown to result in a lower incidence of overshoot hypotension and to have a more rapid onset of action.[17]

Acute arterial hypertension in pregnancy causes cerebral haemorrhage and infarction, hence the control of blood pressure, and more specifically cerebral perfusion pressure, assumes greater importance in the management of pre eclamptic women at risk for eclampsia.

Most of the drugs currently used to control severe hypertension in preeclampsia are:

1) Calcium channel blockers (Nifedipine,Nicardipine),

2) Sympathetic nervous system inhibition; α 2 agonist (α methyldopa),

3) Peripherally acting adrenergic receptor agonist; α and β adrenergic receptor blocker (Labetalol)and'

4) Arterial vasodilators (Hydralazine).[14,18]

Magee LA et al in their systematic review of meta analysis of randomised controlled trials on assessing effectiveness of antihypertensive treatment for mild hypertension during pregnancy concluded that for mild chronic or mild to moderate late hypertension in pregnancy , anti hypertensive treatment benefit the mother , but the overall benefit to the infant is unclear.

Early delivery of women with severe hypertension increase adverse neonatal outcomes related to prematurity, without providing benefit to the mother.[19]

A randomized controlled trial was conducted by Chorine Mkoop manset al[20] to find out whether induction of labour in women with a singleton pregnancy complicated by gestational hypertension or mild pre-eclampsia reduces severe maternal morbidity.

The primary outcome was a composite measure of poor maternal outcome – maternal mortality, maternal morbidity (eclampsia, **HELLP** syndrome, pulmonary oedema, thromboembolic disease and placental abruption), progression to severe hypertension or proteinuria and major post partumhaemorrhage (> 1000ml blood loss). 756 patients were allocated to receive induction of labour (n= 377patients) or expect ant monitoring (n=379).

Of women who were randomised,117(31%)allocated to induction of labour developed poor maternal outcome compared with 166(44%) allocated to expectant monitoring (relative risk 0.71%, 95%. CI 0.59-0.86, p<0.0001).No cases of maternal or neonatal death or eclampsia were recorded.

Study concluded that, induction of labour is associated with improved maternal outcome and should be advised for women with mild hypertensive disease beyond 37 weeks gestation.

Sauden et al [21] in retrospective review of 416 patients with gestational hypertension, demonstrated that 15 % (62 patients) subsequently developed pre eclampsia .

An altogether separate, but prospective, aim of the study involving a cohort of 112 patients showed that 26% (29 patients) developed pre eclampsia.

Patients in whom the initial diagnosis of gestational hypertension was made beyond 36 weeks gestation demonstrated a 10 % risk (much lower lower than the overall risk) of developingpre-eclampsia.

Multiple logistic regression analysis of the data identified previous miscarriage and early gestation of presentation as markers associated with an increased likelihood of develop in gpre-eclampsia.

A prospective study assessing the effect of maternal age on outcome in mild hypertension in a cohort of 379 mature women (>34 years old) by Barton et al [22] reported similar maternal outcomes but a higher still birth rate in women over 35 years of age compared with a cohort of women with less than 35 years .

Although his was statistically in significant(p-0.63),thes ample size was too small to detect a significant difference.

A further study from Barton et al [23] evaluated the influence of ethnicity on outcome in a prospective analysis of 1182 patients of Hispanic , African ,American & Caucasian ethnicity. They reported that Hispanics demonstrated a higher rate of progression to severe pre Eclampsia compared to Caucasians(<0.005).

The incidence of small for gestational age (**SGA**) was highest among the Hispanic newborns. The rates of progression to **HELLP** & eclampsia were similar among all the groups.

An African Americans when compared to white patients demonstrated a lower gestational age at delivery as well as lower birth weights (< 0.005 for both parameters). In addition, Africans had a higher still birth & neonatal death incidence compared to other 2 ethnic groups.

A case control study by HumaTasleem et al 24 studied the correlation of pregnancy induced hypertension with placental abruption & effect of anti-hypertensive therapy.

In this study patients who were on anti-hypertensive therapy had no abruption & where as the women with **PIH** who were not onanti-hypertensive therapy suffered from abruption (8%).

In a reproductive health library commentary by Fatima Paruk et al [25] the review states that the benefits and potential adverse effect so fusing anti-hypertensive agents for mild to moderately per tension in pregnancy are unclear.

In spite of this, the practice of using these drugs , particularly in under renounced regions , should not be abandoned until firm evidence becomes available to refute their role in the treatment of mild to moderate hypertension in pregnancy .

In addition there is little evidence that any particular antihypertensive agent is better than others. The review suggests that women should make the decision regarding the use of an antihypertensive agent in pregnancy in consultation with their obstetricians.

A pro-spective multi centrecohort study by LauraA. Mageeetal26 studied the safety of calcium channel blockers in human pregnancy to examine the potential teratogenicity.

They prospectively collected information and followed up 78 women with first trimester exposure to calcium blockers don't represent a major tera to genic risk.

A randomized multi center clinical trial comparing Nifedipine, given between 12 to 34 gestational weeks to delivery and expectant management for mild to moderate hypertension in pregnancy by Renata Bordellos et al 27 studied the safety of use of calcium channel blocker Nifedipine in pregnancy , children were followed up to 18 months of age .

Results suggest that the use of Nifedipine in pregnancy is safe with respect to the risk so fmal form action and Nifedipine or expectant management for mild – moderate hypertension in pregnancy do not affect major impairment in development at 18 months of age.

Victoria M Allen et al [28] conducted a population based study on the effect of hyper tensile disorder sin pregnancy on small for gestation aalge and still birth.

Study showed that, the women with any hyper tension in pregnancy were 1.6 (95% CI 1.5- 1.6) times more likely to have a live birth with **SGA** and 1.4 (95% CI 1.1-1.8) times more likely to have a still birth as compared with normotensive women.

Analysis showed that women with gestational hypertension without proteinuria and with proteinuria were more likely to have infants with SGA (RR 1.5, 95% CI 1.4 -1.6and RR 3.2.95% CI 2.8 -3.6, respectively).

Women with preexisting hypertension were also more likely to give birth to an infant with SGA (RR 2.5.95% CI 2.2-3.0) or to have a still birth (RR 3.2, 95% CI 1.9-5.4).

In the textbook of obstetrics and gynaecology by Arul Kumaran, Gita Arjun, Leonie Penna : The management of Labour 3rd edition29 states that : In treating severe hypertension it is crucial that hypotension is avoided, for it may lead to decrease dutero place ntal blood flow and hence fetal distress.

Labetalol,intravenous hydra lazine and oral Nifedipine are acceptable a gents for this in dictation.

Labetalol,a selective α_1 and a non selective β blocker decreases systemic vascular resistance, slows the heart rate, reducing myocardial oxygen demand. It doesn't reduce peripheral, renal, cerebral, corona ryandutero placental blood flow.

In the textbook of Practical Guide to high risk pregnancy and delivery, 3rd edition by Fernando Arias [30] states that ; the most commonly used non selective β blocker agent is Labetalol , which can be use dp are nterally to treat severe hyper tension and orally in less severe cases.

Labetalol is different from other β blockers as it acts By decreasing peripheral as cellarers is trance with little or no effect on cardiacout put.

One of its main obstetrical uses is for hypertensive emergencies with severe pre eclampsia.

In the textbook by James on High risk pregnancy management options 4th edition states that: Labet alollowers blood pressure by blocking α^1 adrenor eceptors in peripheral vessels there by reducing peripheral resistance, and the heart rate is reduced because of its β blocking effect.

Labetalol has become popular for the treatment of hyper tension in pregnancy and preeclampsia. It has been use dorsally and in ravenous for rapid blood pressure reduction.[31]

In the textbook of obstetrics and gynaecology by Mudaliar and Menon: Clinical Obstetrics 11th edition states that recently Labetalol (starting dose 100mgBD, max dose 2.4 g/day) is being recommended as the best drug to control blood pressure in severe pre eclampsia. Intra venous Labetalol is very useful for rapid control of hypertension.[32]

A textbook by Ian Donald on Practical Obstetric problems 6th edition states that Labetalol lowers blood pressure smoothly but rapidly without the associated tachycardia characteristic of hydralazine. No adverse fetal or neonatal effects have been seen in relation to Labetalol.[33]

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CONCLUSION

Both oral Nifedipine and oral Labetalol are ultimately effective in reaching the therapeutic goal, but Nifedipine achieve the target blood pressure more rapidly and with fewer doses than Labetalol.

Both drugs demonstrate a similar adverse effects profile.Nifedipine is also cheaper, easier to store, easier to administer, whereas oral Labetalol is more expensive and requires more dosage than Nifedipine.

Nifedipine is the preferred drug in case of hypertension in pregnancy 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.

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ABBREVATIONS

BP - Blood Pressure
PIH - Pregnancy Induced Hypertension
WHO - World Health Organization
HELLP - Haemolysis,Elevated liverenzymes and Low plateletcount
NICU - Neonatal Intensive Care Unit
RDS - Respiratory Distress Syndrome
IUD - Intra Uterine Death
APTT - Activated partial thromboplastin time
LMP - last menstrual period
EDD - Expected Date Of Delivery
Hb - Haemoglobin
IM - Intra Muscular
IV - Intra Venous
IUGR - Intra Uterine Growth Restriction
LFT - Liver Function Test
NST - Non Stress Test
PIH - Pregnancy Induced Hypertension
PR - Pulse Rate
PT - Prothrombin Time
RFT - Renal Function Test
SD - Standard Deviation
SGA - Small For Gest Ationalage
USG - Ultra Sound
SBP - Systolic Blood Pressure
DBP - Diastolic Blood Pressure
RCT - Randomized Control Trial