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Evaluation of nifedipine tocolysis in preterm labour

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Abstract
Background: Preterm Labour and delivery is one of the biggest challenges for obstetricians and any endeavor to reduce the perinatal mortality calls for a successful effort to reduce the problems of preterm birth for no single obstetrical misfortune is more wasteful as prematurity.
In many instances, delaying delivery till the fetus is sufficiently mature is a tremendous gain for the fetus at no disadvantage to the mother. All that we have achieved so far is the possibility of gaining a few days with use of tocolytic agents our study is concerned with the Efficacy of Nifedepine – a calcium channel blocker as a tocolytic agent.
Aim: 1. To evaluate the Tocolytic effects of Calcium channel blocker – NIFEDIPINE in preterm labour.
2. To study the maternal and fetal effects of NIFEDIPINE
Materials and Methods: It is prospective study conducted I Government RSRM Lying in Hospital, Stanley Medical College, Chennai from September 2012 to September 2013 The study population comprised of patients who attended the causality or outpatient department. There were 100 patients in Nifedipine group and 2 patients were lost to follow-up. There were 100 patients in Central group and 3 patients were lost to follow up. Study group received Nifedipine and control group were observed with bed rest. Both groups received intra muscular corticosteroid written informed consent obtained.
Results: 1. In our study, Preterm labour was common in Primigravida in age group 20 – 29 years accounting for 77.54% compared to 22.5% between 19 and 30 years.
2. Incidence of preterm labour in looked and unbooked cases were 80.6% and 19.38% in Nifedipine group when compared to 86.5% and 13.4% in control groups respectively.
3. The success of Nifedipine as indicated by prolongation of pregnancy beyond 48 hours was observed in 73.4% of cases compared with 57% in controls P value was significant (< 0.001).
Conclusion: In developing countries neonatal intensive care are usually found in tertiary referral hospitals but not all such units have the required treatment capabilities. The statistically significant benefits of nifedipine in suppressing the uterine contractions for in utero transfer, in reducing neonatal respiratory distress syndrome along with its reduced maternal side effects, and its low cost makes it to be considered as the first line tocolytic agents in these countries.

Keywords: Nifedipine tocolysis, preterm labour

Introduction

Preterm Labour and delivery is one of the biggest challenges for obstetricians and any endeavor to reduce the perinatal mortality calls for a successful effort to reduce the problems of preterm birth for no single obstetrical misfortune is more wasteful as prematurity In 2010, more than one in 10 of the world's infants, of more than 15 million children, were born prematurely [1] More than a million of those children died secondary to complications associated with premature birth. Prematurity is the single most important cause of death in the first month of life and is a factor in over 75% of pediatric deaths in the neonatal period. As the second leading cause of death in children under five years old [2], prematurity remains a global health problem. In addition, prematurity is associated with learning and motor disabilities and with visual and hearing impairment, contributing to approximately half of disabilities in children. Although preterm birth has actually decreased in the United States over the past five years (see below), worldwide rates have increased over the last decade [1-4].

In many instances, delaying delivery till the fetus is sufficiently mature is a tremendous gain for the fetus at no disadvantage to the mother. All that we have achieved so far is the possibility of gaining a few days with use of tocolytic agents our study is concerned with the Efficacy of Nifedepune – a calcium channel blocker as a tocolytic agent.

Aim of the Study

1. To evaluate the Tocolytic effects of Calcium channel blocker – NIFEDIPINE in preterm labour.
2. To study the maternal and fetal effects of NIFEDIPINE

Study Design

It is prospective study conducted I Government RSRM Lying in Hospital, Stanley Medical College, Chennai from September 2012 to September 2013 The study population comprised of patients who attended the causality or outpatient department. There were 100 patients in Nifedipine group and 2 patients were lost to follow-up. There were 100 patients in Central group and 3 patients were lost to follow up. Study group received Nifedipine and control group were observed with bed rest. Both groups received intra muscular corticosteroid written informed consent obtained.

Inclusion Criteria

1. Gestational age between 28 and 34 as determined by menstrual dates, chemical examination, ultra sonogram abdomen.
2. Uterine contraction 4 contractions in 20 minute period lasting for 40 – 45 seconds.
3. Progressive verve cal effacement upto 75%
4. Cervical dilation upto 3 cm
5. Intact membranes.

Exclusion Criteria

Maternal Conditions

GA > 34 Weeks Rupture of membranes Evidence of chorioamniotis Cervical dilatation greater than 4cm Antepartum hemorrhage Polyhyramnios / oligohydramnios Pregnancy induced hypertension Chronic hypertension Previous caesarean section Cardiac disease Renal disease Uncontrolled diabetes mellitus Asthma, Adult Respiratory distress Syndrome History of allergy Liver disease

Fetal Condition

Multiple gestation Fetal death / distress IUGR Congenital anomalies Investigations Urine analysis Complete blood count High vaginal swab USG Abdomen ECG (Electrocardiogram)

Drug Protocol

On admission, patients were put in left lateral position. Temperature, pulse rate and blood pressure recorded cardiovascular system and Respiratory system examined steroids gain.

Group A

Tab. Nifedipine 20 mg was given orally. If uterine contractions persisted after 90 minutes another 10 mg dose given. If the dosage suppressed uterine activity then maintenance of 10 mg given 6^{th} hourly for 3 days.

If uterine contractions did not cease within 1-1/2 hours patient was deemed failure and treatment stopped treatment considered success if there was abolition of uterine contractions and progress of cervical dilation and postponement of labour for at least 48 hours.

Group B

Patients observed with bed rest Both the groups given intramuscular corticosteroids Monitoring of vitals – Temperature, Pulse rate Blood pressure Respiratory rate Systolic BP<100 mm Hg or pulse rate > 100,

Temperature > 37.5 °C is important

Careful watch for side effects like facial flushing Tachycardia, Hypertension, Nausea, vomiting After initial reactive CTG (Cardio topography), Fetal heart rate monitored hourly during stabilization phase and there after fourth hourly for first 48 hours Success and Failure There are several studies by various authors suggesting several factors for assessment of success of tocolysis.

In our study, successful locolysis was defined as the delay of delivery with suppression of contractions for more than 48 hours from initiation of therapy.

Failure of therapy is said to occur, when patient delivered within 48 hours of initiation of therapy and tocoysis was stopped when cervical dilation progressed to > 3 cm or when there was spontaneous rupture of membranes.

Hence our studies confined about idiopathic spontaneous preterm labour and comparing the efficacy of Nifedipine with that of control in delaying delivery for 48 hours and regarding the maternal fetal effects of Nifedipine.

Results and Discussion

1. In our study, Preterm labour was common in Primigravida in age group 20 – 29 years accounting for 77.54% compared to 22.5% between 19 and 30 years.
2. Incidence of preterm labour in looked and unbooked cases were 80.6% and 19.38% in Nifedipine group when compared to 86.5% and 13.4% in control groups respectively.
3. The success of Nifedipine as indicated by prolongation of pregnancy beyond 48 hours was observed in 73.4% of cases compared with 57% in controls P value was significant (< 0.001).
4. 78.57% of patients required 30 mg to suppress uterine contractions whereas 21.4% required 20 mg to stop contractions.
5. The prolongation of pregnancy more than 48 hours was found to be more in 31 -34 weeks of gestational age in Nifedipine and control groups.
6. Cervix was 1 cm dilated in 81.92% 2 cm dilated in 87.12% and 3 cm dilated in 30.74% respectively.
7. The cervical effacement was 25% in 24.6% 50% in 55.3% and 75% in 20% of cases respectively.
8. Prolongton of pregnancy more than 48 hours is 94.7% and 8.8% between 31 and 34 weeks gestational age group. 5.2% and 11.1% in 28-30 weeks gestional age group in control and Nifedipine groups respectively
9. Prolongation of delivery beyond 1 week in Nyedepine group is 11.2% compared to 2.06% in control groups
10. Incidence of vaginal deliveries between Nifedipine and control group were 97.2% and 98.2% respectively P value < 0.001 was insignificant. 3 cases underwent Lower segment caesarean section.
11. About 56.1% of parents in Nifedipine group had side effects which were reversed on discontinuation Headache material tachycardia were the common side
12. There was no maternal mortality effects observed
13. About 5.5% and 38.46% of neonatal complications occurred in Nifedipine success and failure groups respectively. About 10.5% and 32.46% of Neonatal complications occurred in control success and failure groups.
14. Neonatal morality was 6.12% and 15.4% among Nifedipine and control groups respectively.
15. Apgar score of ≤5 was seen in 4.12% and 46.1% of Nifedipine success and failure groups respectively.

16. Apgar 6-7 was seen in 22.2% and 15.3% of Nifidipine success and failure groups.
17. Apgar more than 7 was seen in 73.6% and 38% of Nifedipine success and failure groups.
18. Apgar score of more than 73.6% was present in Nifedepine success group compared to 57.8% in control success group P value was significant <0.001
19. 87.5% CASES AMONG Nifedipine success group had birth weight of 2 to 2.5 kg when compared with 56.1% in control success group.
20. 5.5% in Nifedipine success group had birth weight > 2.5kg compared to 3.5% in control success group P value 0.001 statistically significant.
21. Incidence of Respiratory Distress syndrome is 2.7% and 15.38% in Nifidipine swess and Failure respectively compared to 3.5% and 15% in control success and failure groups P value is Significant (0.042)

Review

In our study the range of gestational age was 28 to 34 weeks. In other studies it was 24 to 32 weeks (Nikolov *et al*.) and 26 to 34 weeks (Bekkari *et al*.). In Cochrane meta analysis study, the inclusion range of gestational age was from 20 to 26 weeks upto a maximum of weeks. The trials in the Meta analysis excluded women with cervical dilation more than 4cm, while in our study the limit was 3cm.

In our study the dosage of Nifedipine used in 20 mg of loading dose followed by 10 mg at 90 minutes of uterine contraction persisted followed by maintenance dose of 10 mg of oral nifedipine 6 hourly for 3days. Similar to this a loading dose of oral nifedipine 3x10mg was used by bekkari *et al*. A loading dose 4x10 mg of oral nifedipine was used by Nikolov *et al*. in their study.

In Cochrane metaanalyis in the maximum dose used was 40 mg of oral Nifedipine in the first hour followed by 20mg of slow release Nifedipine at t=90 minutes (Papatsonis *et al*.).

Most of the trials in the Cochrane metaanalysis 2003 measured outcome primarily by delay in delivery for more than 48 hours as in our study. 9 out of 13 trials in this review reported a favourable outcome. Bekkari *et al*. and Nikolov *et al*. reported a success of 84% and 86.4% respectively, while in our study it was 73.4%

The most common side effects in the trials in Cochrane metaanalysis were hypotension and headache similar to our study. Similar to our study there was no maternal mortality in any of those trials. No maternal side effects and good patient tolerance were reported by Nikolov *et al*. and Bekkari *et al*. respectively in their studies.

Similar to our study there was a reduction in respiratory distress syndrome and improved Apgar scores at 5 minutes in Cochrane metaanalysis.

Conclusion

Labour inhibiting drugs may not treat the cause of preterm labour but they only treat the symptoms, that is contractions.

As these agents make the uterus refractory to contractile stimuli for a short time so that the perinatal outcome is improved. In this clinical study idiopathic spontaneous preterm labour whose onset was at 28 to 34 weeks has responded well to tocolytic therapy by oral nifedipine and neonatal outcome improved and no maternal mortality was observed. The maternal side effects were reverse on discontinuation of the drug. The drug has provided the fetus of its valuable opportunity of being inside the mothers womb for a period enough to make the lungs mature by administration of exogenous steroids.

However decrease in the incidence of preterm labour lies in identification of high risk patients, improving the socio-economic standards, better antenatal care, education and early detection of the onset of labour.

In developing countries neonatal intensive care are usually found in tertiary referral hospitals but not all such units have the required treatment capabilities. The statistically significant benefits of nifedipine in suppressing the uterine contractions for in utero transfer, in reducing neonatal respiratory distress syndrome along with its reduced maternal side effects, and its low cost makes it to be considered as the first line tocolytic agents in these countries.

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