

Use of Nifedipine and Isoxpurine Hydrochloride in Prevention of Preterm Labor – A Prospective and Comparative Study

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ABSTRACT

Background: The study was done in Obstetric & Gynaecology Department of Dr. VRK Women's Medical college to prevent the preterm labor which one is better either Nifedipine or Isoxpurine hydrochloride. **Methods:** In one month period total 1884 patients attended OPD of Obstetric & Gynaecology. Out of 416 patients came with preterm labor. 200 patients chosen for tocolysis. 100 patients were given Nifedipine and 100 patients Isoxpurine hydrochloride. **Results:** Preterm labor incidence was 22% while preterm delivery incidence was 20.9%. Nifedipine was more effective than Isoxpurine hydrochloride for preterm labor whether it is diagnosed either in early stage or late stage. In early-diagnosed preterm labor, Nifedipine had higher efficacy than Isoxpurine (P value 6.45×10^{-6}) and also higher efficacy than its own in late diagnosed preterm labor (P value 2.08×10^{-5}). **Conclusions:** In India preterm labor incidence is very high. So Nifedipine is better option than Isoxpurine hydrochloride especially when patient is having early signs of preterm labor.

Key words: Uterine contractions, Betamethasone, prematurity, nifedepine, isoxpurine, preterm labor

INTRODUCTION

Preterm labor and preterm delivery is a very big challenge to both obstetrician and paediatrician even in Developed Countries incidence is 10-15%.^[1] & in our country it is 22.9%.^[2] and in account neonatal deaths are 40-75%. Incidence of preterm delivery trends is going to increase due to ART, Mental stress and, induction of labor before maturity data are available.^[1-4]

Prediction and prevention is not possible even after so many research on this topic. We have to face the problem especially Foetal lung maturity before 34 weeks of gestational age. If patients come early and there is no sign of infection, we can postpone the labor for 48 hours till lung

maturity occurs by giving 2 doses of Betamethasone (12mg) 12 hours apart. If the patient delivered in between 34 weeks to 37 weeks reduces the incidence of respiratory distress syndrome but other complications of prematurity we cannot avoid. Obstetrician for prevention of preterm labor oftenly used Beta-adrenergic receptor agonist Isoxpurine hydrochloride and calcium channel blocker -Nifedipine. This study also shows the outcome of preterm labor in India after using tocolytics.

METHODS

412/4500 antenatal patients came with preterm labor in OPD of Obstetric Department were included in our study, Written consent has been taken from all the patients before commencement of the study.

Detailed history, clinical examination and USG done for every patient. In this study patient was having pregnancy in between 22 and 37 weeks. According to ACOG guideline, patients having uterine contractions 4 in 20 min with or without cervical dilations >1 cm were selected. P/V amniotic membrane status was also noted.

Patients with gestational age more than 36 weeks, cervical dilation > 4 cm, any signs of chorioamnitis, fetal distress, contraindication for tocolytics were allowed for delivery (Total 216 patient).

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200 patients were chosen for study. Two groups had made each of 100 patients. Group I patients received 20mg Nifedipine initially followed 10 mg at 4 hourly intervals for 48 hours. Drug dose was tapered gradually every 24 hours and then stopped. If contractions persisted at 90 minutes, again 10 mg was started. Group ii were given 10 mg Isoxpurine IM. at the interval of 6 hr for 48 hrs. Patients, who responded very well started oral retard 20mg tablet at 12 hrs interval for 1 week as maintenance therapy. In both groups patients were strictly monitored for uterine contraction. pulse, BP, any discharge P/V and FHS. In case of any serious side effects. the respective drug was stopped. All the patients were divided in subgroups A and B. Subgroup A was having uterine contraction < 30s & cervical dilation < 2 cm and subgroup B uterine contraction >30s & cervical dilation >2 cm.

All patients were investigated for CBP, CUE and vaginal swab culture. Antibiotics had to those patients having pus cells in urine and positive swab culture. Betamethasone 12mg given to those patient's pregnancy < 34 weeks.

The purpose of giving tocolytics is to delay the delivery at least for 48 hrs so lung will become mature. If patient was not delivered till 48 hrs means whatever tocolytics was used was effective, then transferred the patient in antenatal ward and after 2 days patient was discharged to home with advice of Bed Rest. Patient were followed till delivery for good and adverse outcome.

RESULTS

Total 462 patients admitted for preterm labor out of 1882 antenatal admission. Total live birth was 1614 out of 338 were preterm deliveries (20.9%)200 were given tocolysis out of 416.

Table 1 shows the distribution of preterm labor cases according to gestational age. Table 2 shows the there was no much difference in both groups like parity, uterine contraction, cervical dilatation and status of membrane.

Table 3 shows the overall success effect of two types of the tocolysis i.e 74%. In Nifedipine group it was 80% and in Isoxpurine group it was 68%.Tocolytic effect in Nifedipine group was higher (pvalue0.006) in comparison to Isoxpurine. Out of 200 cases ,122 belonged to subgroup A and 78 belonged to subgroup B. After analysis the success rate of Nifedipine (56/62) was significantly higher than that of Isoxpurine(40/120) in subgroup A. In subgroup B efficacy of both drugs were almost same.

Total 108 cases were admitted with rupture of membranes, 31 cases received tocolysis, in this group failure was (14/31) 45.2% i.e quite high . With intact membrane only (38/169) 22.5% either with Nifedipine or Isoxpurine. Maternal side effects were less in Nifedipine (17%) in comparison to Isoxpurine(23%) Maternal side effects were Nausea, Vomiting, headache and palpitation in both groups. No pulmonary edema was found in any groups. Out of 338 preterm deliveries neonatal mortality was 101 before 34 weeks of gestation as compared to 11 after 34 weeks of gestation even after taken 2 doses of

Betamethasone(12mg) 12 hrs apart. RDS was less in those who had received Betamethasone but overall other morbidity in the form of septicemia, encephalitis and IUD were same in both groups.

Table 1: distribution of preterm labor cases according to gestational age

Pregnancy in weeks	Cases of preterm labor	Nifedipine	Isoxpurine	Total	Preterm deliveries
<28 wks	15	5	4	9	12
28-34wks	157	50	46	96	111
34-36wks	202	45	50	95	173
>36wks	42				42
Total	416	100	100	200	338

Table 2: Maternal factors in both groups

Factors	Nifedipine	Isoxpurine
Mean age	24.5	25.6
Primi	48	45
Multi	52	55
Cases of subgroup A	62	60
Cases of subgroup B	38	40
Rupture of membrane	16	15

Table 3: Tocolytic effects comparison

Admission delivery interval	Nifedipine group			Isoxpurine group			Total	Pvalue
	A	B	Overall	A	B	Overall		
Failure rate								
<48 hrs	6	14	20 (20%)	12	20	32	52	
>48hrs- <37 wks			36			34	70	
>37wks			44			34	78	
success rate	56	24	80 (80%)	48	20	68 (68%)	148 (74%)	0.006

DISCUSSION

In India incidence of preterm labor is high (22%) in comparison to developed countries(11%).^[2] Obstetrician always face the problem how to manage it, which drug is having less side effects on mother as well as on foetus. Selection of drug is also challenge for inhibition of uterine contraction and arrest of preterm labor.

Beta mimotectics act through cyclic GMP for inhibition of uterine contraction while calcium channel blocker directly inhibits the influx of calcium across cell membrane, thus decreasing the smooth muscle tone. Nifedipine is calcium channel blocker and Isoxpurine is B mimotectics drug. Cochrane *et al*^[5] concluded that before 34 weeks of gestation administration of tocolytics is compulsory for the prevention premature delivery, neonatal morbidity and complication in neonates due to preterm birth. In our study due to tocolysis delayed delivery was 39% of total cases. In the meantime patient has got Betamethasone for lung

maturation and neonatal survival was improved.

In the present study Nifedipine efficacy was much better (80%) than Isoxpurine (48%) for delaying the delivery at least for 48 hrs. In Nifedipine group up to 36 weeks pregnancy was prolonged till 36 weeks in 36% cases while in Isoxpurine in 29% only.

Preterm premature rupture of membrane is one of the most common cause of preterm labor. Tocolytics in such cases are less effective than with intact membranes. In 55% cases delivery can be delayed for 48 hrs with PROM against 78% in intact membranes. No significant difference was noted in efficacy of two drugs in this respect.

The RCOG^[6] recommends that the choice of tocolytic drug, which could improve neonatal outcome with no maternal or neonatal side effect, has not yet come.

CONCLUSION

Nifedipine has been found to be more effective than Isoxpurine in this large-scale study. In subgroup A, (early PTL) significant difference can be seen in success rates among the two tocolytics agents, indicating thereby that early initiation of tocolysis with Nifedipine is definitely

beneficial in cases of preterm labor.

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