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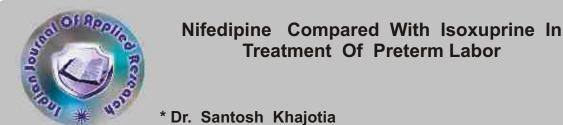
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## **Research Paper**

**Medical Science** 



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### ABSTRACT

Preterm labour and delivery remains a major cause of perinatal morbidity and mortality. Numerous drugs and interventions have been used to prevent and inhibit preterm labour but none have been found to be completely effective with the choice being further limited by troublesome side effects. This study compares in a prospective and randomised design the efficacy and safety of the calcium antagonist Nifedipine with the beta mimetic Isoxsuprine. 80% of patients receiving Nifedipine and 78% of those receiving Isoxsuprine achieved successful tocolysis. The mean prolongation of pregnancy with Nifedipine was 25+/-19.85 days and with Isoxsuprine it was 19.18+/-17.82 days. Nifedipine had significantly less side effects compared to Isoxuprine. These side effects are easily reversible with intravenous saline and calcium<sup>4</sup>. Hence It can be concluded that Nifedipine is a safe and effective alternative to Isoxsuprine for suppressing preterm labour.

## Keywords : Preterm labour, Tocolysis, Nifedipine, Bishopi's Score

#### Introduction

The incidence of low birth weight in India is around 30-40% of which 12-18% are associated with gestational age less than 37 weeks<sup>6</sup>. Between 30-36 weeks of gestation the incidence of Idiopathic Respiratory Distress (IRDS) is 15% to 20% <sup>1</sup>. It is a manor cause of perinatal Morbidity. If preterm labour can be delayed by 48 hours, fetal lung maturity can be accelerated with betamethasone<sup>3</sup>. If the pregnancy proceed to term the perinatal complications are significantly decreased. These facts are of special importance in developing countries where neonatal facilities are limited. Isoxuprine is an accepted tocolytic agent requiring initial parenteral administration and rigorous monitoring. Calcium channel blockers on the hand are good tocolytic agents with a few and easily reversible side effects and are easily administered. Hence the latter was compared with the former in this study.

#### **Meterial And Methods**

A prospective study was conducted in S.P. Medical college Bikaner during January 1,2010 to October 31,2010 on consecutive patients with preterm labour admitted in P.B.M. Hospital over a period of 10 months. The inclusion criteria were a) cases with known dates or where gestational age was confirmed by ultrasound scan before 20 weeks. b) gestational age berween 28-36 weeks. c) singleton pregnancies. d.) uterine contractions occurring atleast once every 10 minutes and lasting for 30 seconds or more e) cervical dilatation less than 2 cm. Women who had premature rupture of membranes, intrauterine infections, malformed and medical complications were foetus, hydramnios excluded from the trial. The patients were assigned to the two groups using a table of random numbers. All patients were rested in bed and sedated with Inj. Diazepam 10 mg Two doses of Inj. Betametnasone 12 mg each were given intramuscularly at 12 hourly interval. Nifedipine was administered as capsules orally, initially 30 mg, followed by 20 mg every 8 hours. Maternal bloods pressure and pulse rate and fetal heart rate were monitored every 15 min. for the

first 2 hours, hourly for 24 hours and subsequently before the drug administration. Calcium gluconate and IV fluids were kept ready at hand<sup>4</sup>. Isoxuprine 40 mg in 500 ml of GDW was started at a drip rate of 30 drops/mt and accelerated with close monitoring to achieve tocolysis, then continued for 4 hours. Subsequently the drug was administered intramuscularly at a dose of 30 mg /24 hours for 2 days. Maternal blood pressure

and pulse rate monitoring was done every 15 minute. while on the IV drip and subsequently before each intramuscular injection and oral dosing.

The treatment was considered successful if the pregnancy was prolonged for 48 hours from the beginning of therapy.

#### Results

Twenty eight patients received Nifedipine and 22 control Isoxuprine. The two groups were comparable for age,

Table	1-	CIII	lical	De	tai	IS

Particular	Nifedipine (n=28)	lsoxuprine (n=22)	Significance
Age (Years)	23.03 <u>+</u> 3.98		NS
Maternal wt (kg)	49.79 <u>+</u> 9.7	54.2 <u>+</u> 8.9	NS
Maternal Height (cm)	150.89 <u>+</u> 7.1	152.7 <u>+</u> 4.8	NS
Gestation at treatment (weeks)	33.7 <u>+</u> 1.7	33.7 <u>+</u> 4.8	NS
Bishop's Score	4.85 <u>+</u> 2.3	4.0 <u>+</u> 1.9	NS
Tocolytic Index	3.28 <u>+</u> 1.06	2.9 <u>+</u> 1.0	NS

NS- Not Significant.

Weight, height, parity gestational age, Bishop's score (1984) and Tocolytic index <sup>10</sup> (Table I). In the nifedipine group 22/28 patients had tocolysis while in the isoxuprine groups 20/22 had successful treatment (p=0.4 N.S.).

There were 8 primigravidae in the nifedipine group and 2 in the isoxuprine group. The mean Bishop's scores and Tocolytic indices of patients are shown in Table II. Lower indices were significantly associated with successful nifedipine tocolysis (Mann-Whitney U Test). Tachycardia was significantly higher in the isoxuprine group (10/22) compared to the nifedipine group (2/28) (p0. 04). Hypotension was recorded in two patient who had received isoxuprine. In the isoxuprine group, 20/22

Table- II	Bishop's Scores And Tocolytic Indices
-----------	---------------------------------------

Drug	Successful Tocolysis		Significance
		Tocolysis	
Bishop's S	Score		
Nifedipine	5,4,4,5,2,2,5,3,7,8,1 8,1,7,3,5,2,2,5,4,4,5	8,8,7,8,8,7	P .05
Isoxuprine	4,3,3,4,0,6,7,4,4,3 3,4,7,4,6,0,3,4,4,3,	6,6	NS
Tocolytic	Index		
Nifedipine	3,3,4,3,4,3,1,3,3,2,3, 2,3,1,3,3,4,3,4,3,4,3,3,3,	5,5,5,4,5,4	P .01
Isoxuprine	2,3,2,4,1,4,4,3,3,2 3,3,2,4,1,4,2,4,3,2	4,4	NS

patients were discharged following successful tocolysis after 72 hours, of these 16/20 delivered at term in this hospital, and 4/20 went elsewhere for delivery. Of the Nifedipine group 22/28 were discharged after

tocolysis. Of these 16 patients delivered at term, 2 delivered after 4 days, 4 delivered elsewhere. There were no neonatal complications in any of infants.

#### Discussion

Due to strict inclusion criteria the patients studied are limited as in previous studies <sup>12,13</sup> However the treatment and control groups were comparable for the mean Tocolytic index and Bishop's score. Successful Nifedipine tocolysis is associated with lower scorers as previously shown with tocolytic agents <sup>4,11</sup>. Fetal survival is directly related to fetal birth weight and age. Due to small number we did not experience IRDS or other complications in infants born preterm following unsuccessful tocolysis. 16 out of 20 (80%) patients in the isoxuprine group and 22 out of 28(78.6%) in the nifedipine group delivered at term following successful tocolysis. In this regard both the drugs were equally effective.

#### Conclusion

Nifedipine had significantly less side effects compared to Isoxuprine. These side effects are easily reversible with intravenous saline and calcium<sup>4</sup>. Hence It can be concluded that Nifedipine is a safe and effective alternative to Isoxsuprine for suppressing preterm labour therpy<sup>8,11</sup>

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