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COMPARATIVE STUDY OF NIFEDIPINE ISOXSUPRINE IN THE TREATMENT OF PRETERM LABOUR

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Nifedipine, Isoxsuprine, Preterm labour.

Abstract
Preterm labour complicates 5-10% of pregnancy and leading cause of neonatl mortality and morbidity worldwide. It is major health problem in terms of loss of life and long term disability. Tocolytics are pharmacological agents, they relax the uterine myometrium and inhibit contractions leading to abolition of preterm labour and is currently the principal preterm birth preventive measure. Study involved 120 patients with the diagnosis of preterm labour with gestational age of 28-36 weeks. They were divided in two groups treated with Nifedipine and I isoxuprine. Patients were follow up till delivery and outcome parameters measured. The prolongation of pregnancy was 31-68 days in Nifedipine and 27-54 days in Isoxuprine group which statistically significant. Success rate with Nifedipine was found to be 96% as compared to Isoxsuprine which was 75%.

INTRODUCTION

The WHO recommended that 'Preterm' be defined as a gestational age less than 259 days from the first day of the last menstrual period. In developed countries the incidence of preterm birth varies between 5% and 10%. In institutions serving as referral centers, the rate is often much higher than that as 15.5%.

Currently, the therapeutic foundation for treating preterm labour involves the use of tocolysis. Till date the degree of success has been less than optimal despite the availability and use of several different tocolytic agents with different modes of action. The lack of successful treatment may well stem from the paucity of information about the initiating factors that ultimately lead to preterm labour. The labour results from cascade of physiological events.

Consequently, to prevent preterm labour successfully the therapeutic approach should be to focus on the initial events of labour instead of attempting to inhibit the cascade of events culminating in preterm labour. It is believed that tocolytic therapy by prolonging pregnancy even for a short period of time may be useful in allowing these measures to be performed.

Aims And Objectives

1. To compare the efficacy of Nifedipine and Isoxsuprine in the treatment of preterm labour.
2. To evaluate the maternal side effects and neonatal outcome of the two drugs.

MATERIALS & METHODS

Materials

In this prospective study, 120 antinatal cases with 28-36 weeks gestation with painful intermittent uterine contraction diagnosed preterm labour, were randomly divided into two groups, Group A (Nifedipine).
Group B (Treat with Isoxsuprine)

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Methods

1. Nifedipine 30 mg was given sublingually 4-6 hours the last dose.
2. Nifedipine 10-20 mg was given orally every 6-8 hours, for 7 days.
3. Isoxsuprine – Oral 10 mg 8 hourly for 7 days.
4. Patients in both groups were given antibiotics and injection betamethasone 24 mg in 2 divided doses, 24 hours apart.

Inclusion Criteria

1. Gestational age between 28-36 weeks.
2. About 1-2 regular uterine contractions occurring in 10 min., each lasting for 30 seconds.
3. Cervical effacement of more than 80% with dilatation of less than 3 cms with intact membranes.
4. No previous administration of tocolytics.

Exclusion Criteria

1. Systemic complications.
2. Obstetric complications.
3. Foetal complication.
4. Multifoetal gestation**.**

OBSERVATIONS & RESULTS

Table No. 1 – Showing maternal changes in pre and post drug administration.

Statistics	Nifedipine group drug administration		Isoxsuprine group drug administration	
	Pre drug	Post drug	Pre drug	Post drug
Systolic blood pressure (mm/Hg)				
Mean	114.2	110.6	114.6	102.6
Minimum	104	90	104	80
Maximum	130	124	130	116
SD	6.10	7.00	9.15	9.60
P value	0.000			
Diastolic blood pressure (mm/Hg)				
Mean	73.06	72.06	74.73	70.93
Minimum	68	66	66	60
Maximum	86	84	86	80
SD	5.13	4.65	5.78	4.47
P value	0.000			
Maternal pulse rate (bpm)				
Mean	87.7	88.33	86.13	87.8
Minimum	70	78	60	70
Maximum	102	116	100	116
SD	6.30	7.05	8.69	10.75
P value	0.101			
Foetal heart rate (bpm)				
Mean	141.27	144	140.5	143
Minimum	130	136	128	126
Maximum	156	160	156	154
SD	5.98	7.37	7.25	6.64
P value	0.012			

Table No. 2 – Total duration of prolongation of pregnancy in day

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Prolongation of pregnancy	Nifedipine group	Isoxsuprine group	P value
Mean	31.68	27.54	
Minimum	18	15	0.047
Maximum	47	42	

Table No. 3 – Mode of delivery.

Mode of Delivery	Nifedipine group		Isoxsuprine group	
	No. of patients	%	No. of patients	%
Vaginal	46	76.67	42	70
LSCS	04	6.66	06	10
Lost of follow up	10	16.67	12	20
Total	60	100	60	100

Table No. 4 – Perinatal outcome – Gestational age at delivery (weeks)

Statistics	Nifedipne group	Isoxsuprine	P value
Mean	37.12	36.375	
Minimum	36	33	0.003
Miximum	38	41	
Birth weight			
Mean	2.06	1.94	
Minimum	1.40	1.20	0.024
Miximum	3.46	3.10	

Apgar score

Apgar score at 1”	No. of patients	No. patients
< 7	4 (16%)	14 (48.34%)
> 7	21 (84%)	10 (41.66%)
Apgar score at 5”		
< 7	0 (0%)	4 (16.67%)
> 7	25(100%)	20(83.33%)

Table No. 5 – Maternal side effects.

Side effects	Nifedipine group		Isoxsuprine group	
	No. of patients	%	No. of patients	%
Tachycardia ≥110 bpm	01	3.33	02	6.67
Headache	00	00	00	00
Hypotension< 90/60	00	00	04	13.33
Nausea	00	00	00	00
Vomiting	00	00	00	00
Facial flushing	05	16.66	00	00

Table No. 6 – Side effects on neonates.

Mode of Delivery	Nifedipine group		Isoxsuprine group	
	No. of patients	%	No. of patients	%
Tachycardia	09	36	06	20
RDS	00	00	06	20

(RDS – Respiratory Distress Syndrome)

DISCUSSION

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- In present study significant drop in mean systolic blood pressure (SBP) 102.6 and diastolic blood pressure (DBP) 70.93 in Isoxsuprine and 110.6 SBP Isoxsuprine and 72.06 DBP in Nifedipine group, P value shows statistical significant.
  There was no significant difference in both group when maternal pulse rate and foetal heart rate was compared.
- Prolongation of pregnancy was more in Nifedipine group (mean) 31.68 days when compared to Soxsuprine group 27.54 days where P value statistically significant.
- The mean birth weight of infants delivered was 2.06 kg in Nifedipine group with Apgar scores of > 7 at 1" and 5" were 84% and 100% respectively. In Isoxsuprine group infants delivered had mean birth weight of 1.94 kgs with Apgar scores of > 7 at 1" and 5" were 41.66% and 83.33% respectively.
- In maternal side effects hypotension was noted in Isoxsuprine group while facial flushing was noted in Nifedipine group. No other serious side effects noted in both groups.
- The side effects of Nefedipine on neonate 09 (36%) patients had Tachycardia while compared with Isoxsuprine 06 (20%) patients had Tachycardia. There were higher incidences of RDS in Isoxsuprine group as compared to Nifedipine group (0%).

CONCLUSION

Prevention and treatment of preterm labour is essential to reduce adverse neonatal and infant outcome and to improve survival and quality of life. The achievable goal of tocolytic therapy may be expected to lead to further improvements in neonatal outcome found in present study with Nifedipine in this aspect (96% Vs 75%).

In the view of incrasing evidence of efficacy and safety, combined with its ease of administration it appears that Nifedipine play an expanded role in the suppression of preterm labour.

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