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USE OF NIFEDIPINE AS A TOCOLYTIC AGENT IN CASES OF PRETERM LABOUR

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ABSTRACT

Preterm birth is the most important cause of fetal morbidity and mortality. In our study total 75 patients with preterm labour between 28 to 34 weeks of gestation were given tocolytic drugs with Nifedipine to increase the intrauterine lifespan of fetus during which corticosteroid was given for lung maturity. Close monitoring was done to detect the known side effects of the tocolytic drugs like hypotension, headache, tachycardia, nausea, flushing and palpitation. It was found in this study that Nifedipine significantly arrests the preterm labour with minimal side effects both mother and fetus.

Keywords: Nifedipine, Tocolytic agent,Preterm birth

1.INTRODUCTION

Preterm labor is defined as the regular, painful, frequent uterine contraction which causes progressive effacement and dilatation of cervix, before 37 weeks of gestation. The period of viability varies from 20 weeks to 28 weeks depending on the facilities available for newborn care & likelihood of survival. Preterm labour is considered to be established if regular uterine contractions can be documented at least 4 in 20 minutes or 8 in 60 minutes with progressing changes in cervical score in the form of effacement of 80% or more and cervical dilatation of more than or equal to 1 cm.

Tocolytic therapy to delay preterm delivery is an important intervention in obstetrics. Although tocolytics have been shown to improve neonatal outcomes, they can delay preterm delivery long enough for antenatal corticosteroids to be administered or for the mother to be transported to a tertiary care facility. In premature neonates, antenatal corticosteroids reduce morbidity and mortality. Tocolytic therapy may therefore have an important role in improving outcomes from preterm delivery. With over 500000 preterm births in the united states alone (12.3% of all births in 2008) and 29% of these being less than 34 weeks gestation, preterm delivery is an important public health issue.

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Activity in the uterine muscle invitro is dependent upon extracellular calcium. It is inhibited by calcium antagonist. Our study is concerned with the role of calcium channel blocker, nifedipine in preterm labor as a tocolyic agent.

OBJECTIVES

AIMS

- Efficacy of the drug for prolongation of pregnancy for 48hrs to 7 days, so as to allow the steroids to act and help the lung maturity.
- To assess the maternal and fetal side effects of the drug.
- To study the speed of onset of uterine relaxation after administration of the drug.

2.METHODOLOGY

Type of study:
Prospective study
Sample size:
75
Study group:

The pregnant women who were admitted in Raja Muthiah Medical College and Hospital with preterm labour between 28 weeks to 34 weeks of gestation Oct 2014 to Oct 2015 was included in the study.

Nifedipine is given initially with the loading dose of 20mg orally. This was followed by 20mg given at intervals of 6hrs until complete cessation of uterine contraction. The patient was maintained by the usual dose of 20mg 6th hourly. If in between the 6th hourly dose there were any contractions then

the patient received 4th hourly dose upto a max of 160mg/day.

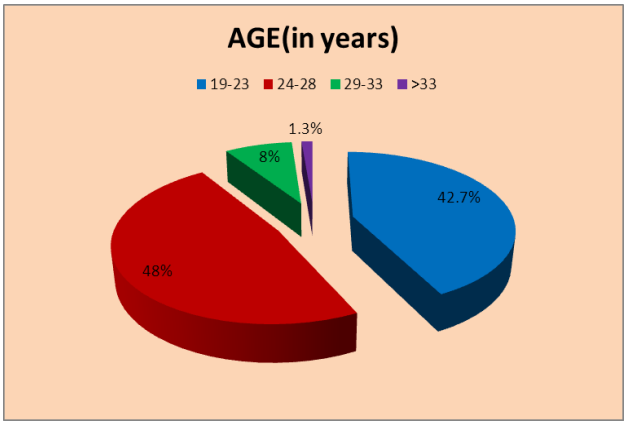
Administration of steroids for fetal lung maturity and antibiotic prophylaxis.

3.RESULTS

In the present study the efficacy of drug therapy on premature labour pain is studied. The impacts of drug on uterine relaxation, delivery status, maternal and fetal side effect were studied. The statistical tools used were basic descriptive statistics such as mean and standard deviation, frequency distributions, Pearson's correlation analysis and paired sample't'. For pre and post comparison of uterine contraction, paired't' test is used. Correlation using Pearson's test is used to study the relationship of drug usage with age and duration of relaxation. The graphical representation is also presented for the selected parameters. The statistical analysis is carried out using statistical package for social science (SPSS 21).

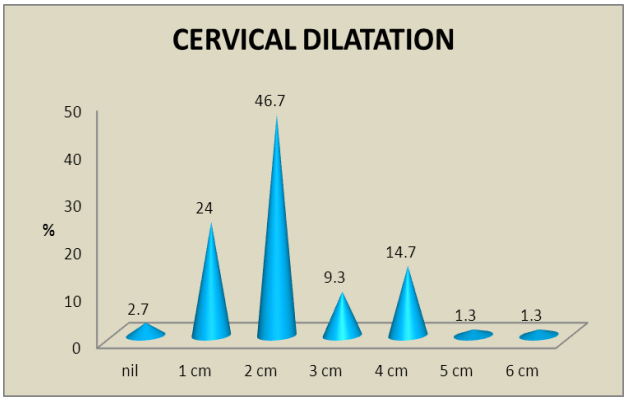
Age distribution of study women

Age (in years)	Number of patients	Percentage
19-23	32	42.7
24-28	36	48.0
29-33	6	8.0
>33	1	1.3



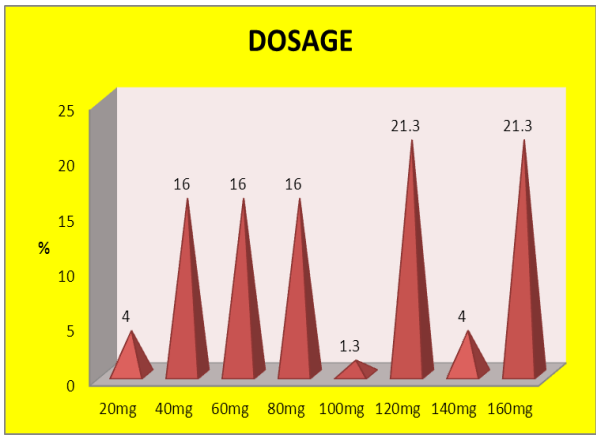
Cervical dilatation

Dilatation (in cm)	Number of persons	Percentage
0	2	2.7
1	18	24.0
2	35	46.7
3	7	9.3
4	11	14.7
5	1	1.3
6	1	1.3
Total	75	100



Drug Dosage Required

Dosage (mg)	Number of persons	Percentage
20	3	4.0
40	12	16.0
60	12	16.0
80	12	16.0
100	1	1.3
120	16	21.3
140	3	4.0
160	16	21.3
Total	75	100



Relationship of drug dosage Vs Duration of relaxation

	'r' value	'p' value
Pearson's correlations	0.560	0.001

Descriptive statistics

	Mean	S.D
Dosage	96.27	45.64
Duration of relaxation	30.40	15.48

Nifedipine which is a calcium channel blocker has been tried in the present study to know its efficacy in inhibiting preterm labour and to study its associated side effects and benefits. In this study, preterm labour were common in the age group 24 – 28 years. The majority of women (73.3%) are multiparous. Most of the women (81.3%) were from poor socio-economic status. Women with gestational age of 34 weeks (38.7%) were common and 32 weeks (36%) were second most common.

The clinical findings were, the majority of women had cervical dilatation of 2 cm (46.7%) and cervical effacement of 80%. The common drug usage required was 160 mg (21.3%) and 120 mg (21.3%) The majority of women (85.3%) had normal vaginal swab, and in 6.7% E coli organisms were found. The changes to other drugs were 9 cases that is 12%. Delivery occurred in 12 cases (16%). Effectiveness of the drug was seen in 54 cases that is 72%. The common duration of relaxation of drugs is 36 hours (21.3%) and 48 hours (21.3%). The common maternal side effect was headache (66.66%). No side effects for the baby except for low birth weight.

- ❖ There is insignificant relationship (r=0.216) between dosage of drugs and age.
- ❖ Uterine contraction is significantly reduced following treatment't'=9.45, p=0.001.

- There is significant relationship between drug dosage and duration of relaxation (r=0.560, p=0.001). Therefore when drug dose in more, the duration of relaxation is more and vice versa.
- Cost effect
- Easy route of administration
- Easy availability of drug

4.DISCUSSION

Nifedipine was first reported in 1980 in an observational study to be an effective tocolytic agent with minimal side effects.[1]

The Royal hospital for women 2012[2] also says nifedipine is indicated in suppression of threatened or established preterm labour before 34 weeks gestation where it is not contraindicated. In Cochrane meta analysis by king jf et al in 2003, inclusion range of gestational age was from 20 to 26 weeks, upto a maximum of 33.5 to 36 weeks. In other studies, it was 26 to 34 weeks (Bekkari et al) and 24 to 32 weeks (Nikoloy et al).[3]

This study group includes patients from 28 to 34 weeks of gestational age. The dosage of nifedipine used is 20 mg of loading dose and repeated at 6 hours till contraction subsided or if contraction had not subsided to repeat after 4 hours with total dose not to exceed 160mg and a maintenance dose of 20 mg 6^{th} hourly for 3 days. A loading dose of 30mg of oral nifedipine was used by bekkari et al. A loading dose of 4 x 10 mg of oral nifedipine was used by nikoloy et al in his study.

A Cochrane meta analysis in 2003, the maximum dose used was 40mg of oral nifedipine in the first hour followed by 20mg of slow release nifedipine at t = 90 (papatsonis el al)[4]. In the present study maximum dose used was 160mg of oral nifedipine for 48hours, with the first hour maximum dose of 20mg of nifedipine followed by 20mg 6^{th} hourly.

When the bishop's score was less than 4, the success of tocolysis was 95% when more than 4 the success for 65%. Association of bishop's score and the success of the tocolytic agent was also noted in other study. In the present study the cervical dilatation was upto 4 cm more than 4 cm is excluded

Bekkari et al and Nikoloy et al[5] reported a success of 84% and 86.4% respectively. In the present study the effectiveness was found to be 72 %.

The most common side effect was head ache in Cochrane meta analysis and the side effect in the present study were similar to Cochrane meta analysis. No maternal side effects and good patient tolerance were reported by Mikolov et al and Bekkari et al respectively in their studies.

There was a reduction in respiratory distress syndrome and improved apgar scores at 5 minutes in Cochrane meta analysis 2005, because of intrapartum corticosteroid administration[6]. In present study, babies born had no respiratory distress syndrome and had good apgar scores at 5 minutes and no side effect babies, except the weight of the baby was small. The mean duration of relaxation was 36 hours and 48 hours in my study.

This study supports nifedipine as an ideal tocolygtic agent for treatment of preterm labour in low risk women.

5.CONCLUSION:

In developing countries, better neonatal intensive care is usually available in tertiary care hospitals. The statistically significant benefits of Nifedipine in suppressing the uterine contraction for in utero transfer, is best for good neonatal outcome, reducing the neonatal morbidity and mortality along with reduced maternal side effects. Henceforth accounting to its low cost and benefits, Nifedipine is considered as first line of drug for tocolysis in preterm term labour in developing countries.

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