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Original Article

Prevention of Preterm Labour in High Risk Woman by Vaginally Administered Natural Micronized Progesterone in Tertiary Care Hospital at Muzaffarpur, Bihar

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Abstract
Objective: *A Prospective study to evaluate the effect of Prophylactic administration of natural micronized progesterone vaginally, on the occurrence of spontaneous Preterm birth in high risk woman.*
Materials and Methods: *A total of 60 Pregnant woman attending the GOPD and all women fulfilling inclusion criteria were examined thoroughly. Half of the women under the study received 200mg natural micronized progesterone per vaginally twice daily. The treatment continued up to 36 weeks of gestation if not delivered earlier. Another half did not receive any progesterone supplement and this group served as control. Finally incidence of preterm labour among both the groups were compared.*
Results: *Incidence of preterm delivery was significantly low in those receiving vaginal natural micronized progesterone than those who did not receive.*
Conclusion: *Vaginally administered natural micronized progesterone was found beneficial for mothers with past history of spontaneous preterm labour.*
Keywords: *Preterm labour, natural micronized progesterone.*

Introduction

Preterm birth is a serious health problem. Infants who are born preterm are at greater risk of dying in their first year of life, and of those infants who survive, there is an increased risk of repeated admission to hospital and adverse outcomes including cerebral palsy and long-term disability, creating a significant burden upon the community. The cause of preterm labour is multi-factorial in origin and it is important to consider the role of any identifiable risk factors in a woman's pregnancy.

The most significant and consistently identified risk factor for preterm birth is previous history of preterm birth. Estimates suggest the rate of recurrent preterm birth in this group of women to be 22.5%. For women with a history of a single preterm birth, the recurrence risk in a subsequent pregnancy is approximately 15%, increasing to 32% where there have been two previous preterm births. Information derived from population-based cohort data suggests that for women who give birth between 20 and 31 weeks gestation in one pregnancy, 29.3% will give birth prior to 37 weeks in a subsequent pregnancy. In up to 50% of

cases of preterm birth, the cause is spontaneous onset of labour or preterm rupture of membranes.

Multiple pregnancy is a strong risk factor for preterm birth though the mechanisms may be different to those operating in women with a singleton pregnancy. Up to 50% of women with a twin pregnancy will give birth prior to 37 weeks gestation.

This study is to assess the role of natural micronized progesterone administration (vaginally) for the prevention of preterm labour, when considering the risk factors present for preterm birth.

Materials and Methods

A prospective randomized study was carried out in the Department of Pharmacology, Sri Krishna Medical College, Muzaffarpur, with the help of Obstetrics and Gynaecology Department during the period of September 2017 to May 2018. A total of 60 pregnant women attended the G.O.P.D. and Emergency were studied. Informed written consent was taken from eligible women. After fulfilling selecting criteria, they had been selected and included in study and control group randomly in 1:1 ratio.

In both the groups the rate of preterm delivery, maternal and perinatal outcome were studied and compared.

Mothers were examined thoroughly including history taking, general examination, obstetrical examination and investigations. Gestational age, foetal weight and antenatal assessment were done in each case. Mode of delivery, Apgar Score, admission in nursery or NICU, neonatal outcome were recorded thoroughly. Neonatal complications and maternal health in puerperium till discharge were also noted.

Inclusion Criteria

- All pregnant women of more than 18 years age with history of at least one spontaneous preterm delivery in past pregnancy.
- Women with current multiple pregnancy.
- Singleton pregnancy with history of threatened abortion.

Exclusion Criteria

- Women with intrauterine growth restriction.
- Preeclampsia
- Eclampsia
- Known case of congenital anomaly
- Preterm rupture of membranes.

Half of the women under this study received 200 mg natural micronized progesterone per vaginally in morning and evening. The treatment continued up to 36weeks of gestation if not delivered earlier. Another half had not received any progesterone supplement and this group served as control.

Both groups received antenatal corticosteroid therapy between 28-34 weeks of gestation (2 doses of 12 mg of betamethasone intramuscularly 24 hours apart) besides routine iron and calcium supplements.

Natural micronized progesterone can be administered either orally or vaginally, but the later route is preferable because of enhanced bioavailability and the absence of undesirable side effects, such as sleepiness, fatigue and headaches.

Results

A total 60 pregnant women who fulfilled the inclusion criteria were enrolled for study. Out of them 30 women received natural micronized progesterone known as study group of which 21 woman had previous history of spontaneous preterm birth, 6 women had previous history of threatened abortion in current pregnancy and 3 women had twin pregnancy. Rest 30 woman did not receive natural micronized progesterone and served as control group. Among this control group 20 women had previous history of spontaneous preterm birth, 6 women had history of threatened abortion in current pregnancy and 4 cases had twin pregnancy.

Table - 1

Incidence of Preterm birth according to Age, Socio-economic status and Parity		Group	Total No. of Patients	Delivery <37 weeks	Percentage
Age	< 30 year	Study	24	7	28
		Control	27	16	59.2
	> 30 year	Study	4	2	50
		Control	4	2	50
Socio-economic status	Below Poverty Level	Study	18	6	33.3
		Control	21	13	61.9
	Above Poverty Level	Study	11	2	18.1
		Control	10	5	50
Parity	Primigravidae	Study	6	2	33.3
		Control	7	5	71.4
	Multigravida	Study	23	7	30.4
		Control	24	13	59

Table - 2

Incidence of Preterm birth in patients due to different mode	Group	Total No. of Patients	No. of Preterm birth	Percentage
H/o Spontaneous Preterm Labour in Past Pregnancy	Study	21	5	23.8
	Control	20	13	65
H/o Threatened abortion in current Pregnancy	Study	6	2	33.3
	Control	6	3	50
Current multiple Pregnancy	Study	3	2	66.6
	Control	4	3	75
Incidence of Low birth weight	**Group**	**Total No. of Patients**	**Birth weight <2.5 kg**	**Percentage**
LBW (Excluding multiple gestation)	Study	30	7	23.3
	Control	30	17	56.6

Discussion

A total of 60 pregnant women fulfilling the inclusion criteria agreed to undergo this study were enrolled. They were randomized into study and control group. They came for regular check up and delivered in this institution.

In the present study incidence of preterm birth did not vary significantly in different age groups, in both study and control group.

Different other related studies also found similar results. In a study conducted by Eduardo B. Fonseca et al, on vaginal application of progesterone in high risk pregnant women with short cervix, no significant variation in the incidence of preterm birth was found according to maternal age.

The relative risk of spontaneous preterm birth did not vary significantly with socioeconomic status and parity of mother, whether the pregnancy was singleton or multiple.

Eduardo B. Fonseca et al also found no significant effect of parity or socioeconomic status on incidence of preterm birth. In two recent studies conducted by Jane E Norman et al and K. Klein et al on vaginal progesterone in high risk twin pregnancies, same results were found.

In the present study there were total 41 patients who had past history of spontaneous preterm labour. 21 of them were in study group and 20 were in control group. The incidence of preterm delivery in the study group was 23.8% (5/21) and 65% (13/20) in the control group. When comparing these two groups, we observed a statistically significant difference in the preterm delivery rate.

In present study we found that those patients who had history of threatened abortion in current pregnancy, incidence of preterm birth was higher in control group than study group. But the result was not in statistically significant.

In present study 3 patients of multiple gestations were included in study group and 4 patients included in control group. Percentage of preterm delivery was relatively high and almost nearer equal in both groups.

Jane E Norman et al had shown in their study that vaginal progesterone gel does not prevent preterm birth in women with twin pregnancy.

The largest trial conducted by K. Klein et al for evaluation of the effect of prophylactic vaginal micronized progesterone treatment on preterm delivery in high risk twin gestations, also found similar result.

Dodd JM et al mentioned in their study that progesterone did not reduce preterm birth in multiple pregnancies.

In the present study we found significant reduction in the incidence of low birth weight baby among the mothers with singleton pregnancy of study group than the control group. Incidence of NICU admission was also significantly low in study group.

In this study the incidence of neonatal death was significantly low among the mothers with singleton pregnancy of study group. But neonatal death rate did not vary significantly between the twin cases of study and control group.

Conclusion

Natural micronized progesterone significantly reduces the incidence of preterm delivery in those with history of previous preterm birth. But it fails to reduce preterm birth in patients with history of threatened abortion in present pregnancy and also in twin pregnancy. In high risk mothers with singleton pregnancy, natural micronized progesterone treatment significantly reduces the incidence of delivery of low birth weight baby, rate of NICU admission and neonatal death.

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