Original Research Article

A study of role of micronized progesterone in preterm labour at tertiary health care centre

Surabhi Tomar Sharma[1*], Eshan Sharma[2]

[1,2]Associate Professor, Department of Obstetrics and Gynecology, NIMS Medical College and Hospital Jaipur, Rajasthan, INDIA.
Email: surabhit@gmail.com

Abstract

Background: Preterm labour is one of the common complications in pregnancy. It remains a major cause of perinatal morbidity and mortality. **Aim and Objective:** To study the role of micronized progesterone in preterm labour **Methodology:** Total 100 pregnant women with period of gestation between 24-36 weeks, who were admitted with preterm labour were studied. They were studied in 2 groups (50 patients each). Group A received micronized progesterone vaginally and group B received no drug. Data collected for maternal and foetal outcome. **Results and Discussion:** Mean period of gestation at delivery in group A was significantly more (36.23± 1.5 weeks) than group B (33.14± 1.4weeks). Mean prolonged days of pregnancy in group A were significantly more (33.14± 11.2 days) than in group B (25.43± 8.9 days.) ($p<0.05$) 62% of neonates in Group A had birth weight significantly more than 2500 grams as compared to 30% in Group B.($p<0.05$)

Key Words: progesterone.

[*]**Address for Correspondence:**
Dr. Surabhi Tomar Sharma, Associate Professor, Department of Obstetrics and Gynecology, NIMS Medical College and Hospital Jaipur, Rajasthan, INDIA.
Email: surabhit@gmail.com

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INTRODUCTION

Preterm birth, according to WHO, is defined as birth before 37 completed weeks of gestation. In India, the incidence of preterm delivery is 10%-69%.[1] There are various causes of pre term labour like intra amniotic infection, preterm premature rupture of the membranes (PPROM),iatrogenic (done for preeclampsia, placenta previa, prior classical cesarean delivery,) and spontaneous preterm labour.[2,3] 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.[4] Almost 50 years ago, Csapo *et al.*[(5)]promoted the progesterone see-saw theory, which is that high progesterone levels prevent uterine contractions and low levels facilitate such contractions. It is now clear that, although levels of progesterone in the maternal circulation do not change significantly in the weeks preceding labor, the onset of labor both at term and preterm is associated witha functional withdrawal of progesterone activity at the level of the uterus.[6-8] Present study was conducted to assess the role of micronized progesterone in preterm labour at tertiary care centre.

MATERIAL AND METHODS

A prospective randomized control study was conducted in the tertiary care centre. Study population included the pregnant women with period of gestation between 24-36 weeks, who were admitted with preterm labour.

Inclusion Criteria

1. Singleton pregnancy
2. Intact fetal membranes
3. Cervical dilatation less than 3 cms

Exclusion Criteria

1. Foetal malformation
2. History of sensitivity to progesterone
3. Multiple pregnancy

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4. Preterm premature rupture of membranes at presentation,
5. Pregnancy with medical complications like hypertension, seizures.

Study was approved by ethical committee of institute. A valid written consent was taken after explaining study to the patients. Data was collected with pretested questionnaire. It included detailed history, clinical examination and routine ANC investigations including ultrasound. Preterm labour was defined as the presence of regular and painful uterine contractions at the rate of more than or equal to 2 contractions in 10 minutes with evidence of cervical changes such as effacement and/or dilatation, by manual examination. All patients were initially managed for preterm labour with tocolytics, steroids and antibiotics prophylaxis. Once the labour got arrested, which was defined as a 12 hour contraction free period with tocolytics, these patients were enrolled in study. Patients were randomly divided in group A and B 50 each. Patients in group A received daily doses of 200 mg natural micronized progesterone administered vaginally from the time of randomization until 36 weeks gestation or until the delivery of the fetus if sooner. Group B received no drug. Once the subjects in both the groups became stabilized and had relaxed uterus, they were discharged and monitored on outdoor basis by regular antenatal checkups till delivery. Maternal and foetal outcome were recorded. Data analysis was done with appropriate statistical tests.

RESULTS

Total 100 patients were studied. Mean age of patients in group A is 25.34± 1.4 years. Mean age of patients in group B was 24.79± 2.1 years. Parity of women in group A ranged from 0-4 while in group B it ranged from 0-3. Both the groups were comparable with respect to age and parity. Mean Period of gestation in group A was 32.25± 1.8 weeks while of group B was 31.86±1.7 weeks. Cervical characters like cervical dilation and cervical effacement in group A was 1.46± 0.4 and 45.26± 8.2 respectively and that of in group B was 1.44± 0.5 and 44.35± 6.8 respectively. Both the groups were comparable with respect to period of gestation, cervical dilatation and cervical effacement. Mean period of gestation at delivery in group A was more (36.23± 1.5 weeks) than group B (33.14± 1.4weeks). Difference between these two groups is statistically significant.(P<0.05) Mean prolonged days of pregnancy in group A were 33.14± 11.2 days and in group B were 25.43± 8.9 days. Difference between these two groups was statistically significant.(P<0.05) Table 3 shows comparison of group A and group B according to birth weight of newborn. Mean birth weight in group A was 2730.39±285.71grams and mean birth weight in group B was 24022.21±308.2grams. 62% of neonates in Group A had birth weight more than 2500 grams as compared to 30% in Group B. The difference between the mean birth weight of the two groups was statistically significant (p<0.05).

Table 1: Comparison of group A and group B according to age and parity

Sr no	Variables	Group A	Group B	P value
1	Age (years)	25.34± 1.4	24.79± 2.1	>0.05
2	Parity			
3	Range	0-4	0-3	>0.05
4	Median	1	1	>0.05

Table 2: Comparison of group A and group B according to variables during pregnancy and delivery

Sr no	Variables	Group A	Group B	P value
1	Period of gestation (weeks)	32.25± 1.8	31.86±1.7	>0.05
2	Cervical dilation (cms)	1.46± 0.4	1.44± 0.5	>0.05
3	Cervical effacement	45.26± 8.2	44.35± 6.8	>0.05
4	Period of gestation at delivery (weeks)	36.23± 1.5	33.14± 1.4	<0.05
5	Prolongation of pregnancy(days)	33.14± 11.2	25.43± 8.9	<0.05

Table 3: Comparison of group A and group B according to birth weight of newborn

Sr no	Variables	Group A	Group B
1	Birth weight (gms)		
2	<1500	1(2%)	1(2%)
3	1500-1999	2(4%)	7(14%)
4	2000-2500	16(32%)	27(54%)
5	>2500	31(62%)	15(30%)
6	Total	50(100%)	50(100%)
7	Mean birth weight (gms)	2730.39±285.71	24022.21±308.2

P value: <0.05 significant

DISCUSSION

A number of studies have established the high bioavailability of vaginal micronized progesterone.[9] We therefore conducted this study to evaluate the use of vaginal micronized progesterone to reduce the risk of preterm delivery. Both the groups were comparable with respect to age, parity, cervical characters like cervical dilatation, cervical effacement and period of gestation at the start of treatment. Mean period of gestation at delivery in group A was more (36.23± 1.5 weeks) than group B (33.14± 1.4weeks). Difference between these two groups is statistically significant.(P<0.05) similar findings were observed in Bomba-Opon *et al*[(10)]where they observed a significant reduction in delivery before 34 weeks with vaginal progesterone (9.8% in progesterone group versus 35.3% in control group; p =

0.002).Dodd *et al*[11] concluded that women who received progesterone were statistically significantly less likely to give birth before 37 weeks (RR 0.58; 95% CI 0.48–0.70). Mean prolonged days of pregnancy in group A were significantly more (33.14± 11.2 days) than in group B (25.43± 8.9 days.) ($p<0.05$) Gargari *et al* reported duration of prolongation of pregnancy to be 2.6 weeks.[12] Mean birth weight in group A was 2730.39±285.71grams and mean birth weight in group B was 24022.21±308.2grams. 62% of neonates in Group A had birth weight significantly more than 2500 grams as compared to 30% in Group B.($p<0.05$) similar results were observed in previous studies.[13-15]

CONCLUSION

Progesterone supplementation prolongs period of gestation in women presented with preterm births and it improves the birth weight.

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