ORIGINAL RESEARCH

Oral versus vaginal natural micronized progesterone in preventing preterm labor

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ABSTRACT

Background: Since preterm labor and delivery (PTL) is still the leading cause of perinatal morbidity and mortality as well as its long-term consequences, it has a substantial effect on the health of the unborn child. The present study was conducted to compare oral and vaginal natural micronized progesterone in preventing preterm labor. **Materials & Methods:**90 pregnant women with gestational age between >24 weeks to <36 weeks were divided into 2 groups of 45 each. Group I patients were administered oral micronized progesterone 300 mg and group II were administered vaginal micronized progesterone. APGAR scoreat 5 minutes and birthweight were recorded. **Results:** Gestational age 24-28 weeks had 13 patients in group I and 15 in group II, 29-32 weeks had 24 in group I and 23 in group II and 32-36 weeks had 8 in group I and 7 in group II. Perinatal outcomes were asymptomatic at birth seen in 35 in group I and 38 in group II, neonatal sepsis in 2 and 1, hypoxemic ischaemic encephalopathy in 3 and 2, meconium aspiration syndrome in 1 and 2, and birth asphyxia in 4 and 2 in group I and II respectively. The difference was significant (P< 0.05). The mean birth weight <2.5 kgs was seen in 11 and 7, 2.5-3 Kgs in 20 and 14 and >3 kgs in 14 and 24 in group I and II respectively. NICU admission was seen in 4in group I and 2 in group II, APGAR score at 1 minute was 7.24 in group I and 8.19 in group II and at 5 minutes was 7.80 in group I and 8.61 in group II. The difference was significant (P< 0.05). **Conclusion:** Progesterone administered vaginally is thought to be more effective than progesterone taken orally. It is essential in lowering the rate of neonatal NICU admissions, neonatal death, and neonatal morbidity. It also lowers preterm labor.

Keywords:NICU, progesterone, Vaginal

INTRODUCTION

Since preterm labor and delivery (PTL) is still the leading cause of perinatal morbidity and mortality as well as its long-term consequences, it has a substantial effect on the health of the unborn child.[1,2] Although preterm births are becoming more commonplace worldwide, over 60% of them take place in South Asia and Sub-Saharan Africa. Compared to 9.1% in higher-income nations, the average percentage of preterm births in underdeveloped countries is 11.9%. One of the most vulnerable populations in the world may be newborns. Prematurity is currently the leading cause of death for children under the age of five, as well as the leading cause of disability and poor quality of life in later life worldwide.[3]

The two types of progesterone used to prevent PTB are 17-alpha hydroxyprogesterone caproate (17α-OHPC) and natural micronized progesterone. Natural progesterone is similar to that produced in the corpus luteum and placenta. When administered orally, it is metabolized in the liver and loses its potency, resulting in irregular blood concentration and more frequent side effects.[4] When administered through the vagina, however, it avoids the liver's first-pass effect, is absorbed quickly, has increased bioavailability, directly affects the uterus, and is maintained in a high concentration in the serum. A particular applicator is utilized to inject vaginal progesterone gel, and 90 mg of the drug was employed in all published investigations. Using clean hands or plastic gloves, the vaginal progesterone suppository is placed.[5]The present study was conducted to compare oral and vaginal natural micronised progesterone in preventing preterm labor.

MATERIALS & METHODS

The present study comprised of 90 pregnant women with gestational age between >24 weeks to <36 weeks. All gave their written consent for the participation in the study.

Data such as name, age etc. was recorded in case history file. Patients were randomly divided into 2

groups of 45 each. Group I patients were administered oral micronized progesterone 300 mg and group II were administered vaginal micronized progesterone. Pregnancies that lasted longer than 36 weeks were evaluated for possible delivery intervention. The APGAR score was collected in neonates at five minutes. There was a record of how many newborns needed to be admitted to the NICU. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Gestational age (weeks)	Group I	Group II
24-28	13	15
29-32	24	23
32-36	8	7

Table I shows that gestational age 24-28 weeks had 13 patients in group I and 15 in group II, 29-32 weeks had 24 in group I and 23 in group II and 32-36 weeks had 8 in group I and 7 in group II.

Table II Perinatal outcomes

Outcomes	Group I	Group II	P value
Asymptomatic at birth	35	38	0.54
Neonatal sepsis	2	1	0.82
Hypoxemic ischaemic encephalopathy	3	2	0.71
Meconium aspiration syndrome	1	2	0.82
Birth asphyxia	4	2	0.02

Table II, graph I show that perinatal outcomes was asymptomatic at birth seen in 35 in group I and 38 in group II, neonatal sepsis in 2 and 1, hypoxemic ischaemic encephalopathyin 3 and 2, meconium aspiration syndrome in 1 and 2, and birth asphyxia in 4 and 2 in group I and II respectively. The difference was significant (P< 0.05).

Graph I Perinatal outcome

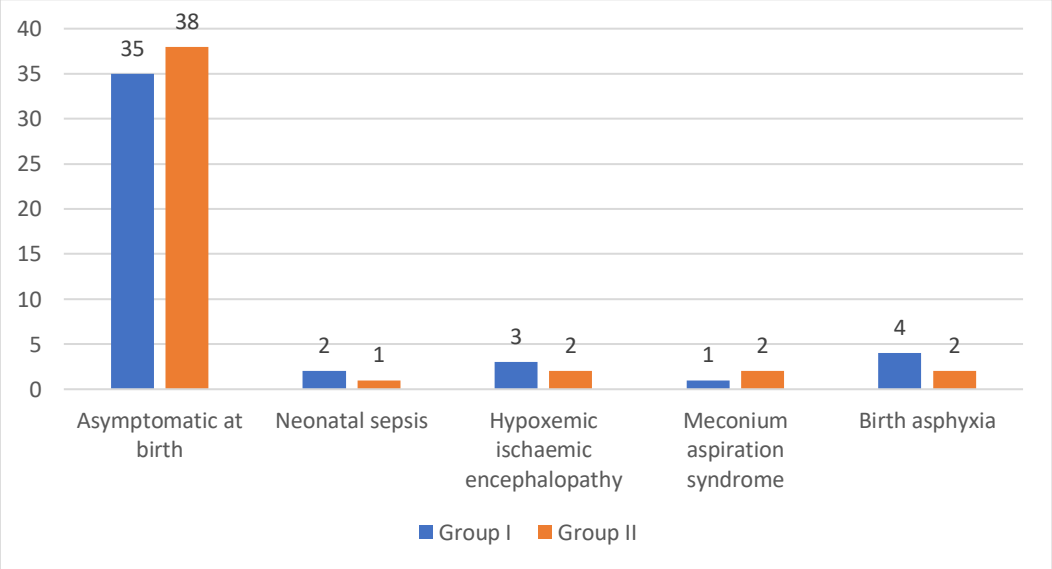

Table III Comparison of parameters

Parameters	Variables	Group I	Group II	P value
Birth weight (Kgs)	<2.5	11	7	0.05
	2.5-3	20	14	0.04
	>3	14	24	0.03
NICU admission	Yes	4	2	0.87
	No	41	43	
APGAR score	1 minute	7.24	8.19	0.05
	5 minutes	7.80	8.61	

Table III shows that the mean birth weight<2.5 kgs was seen in 11 and 7, 2.5-3 Kgs in 20 and 14 and >3kgs in 14 and 24 in group I and II respectively. NICU admission was seen in 4 in group I and 2 in group II, APGAR score at 1 minute was 7.24 in group I and 8.19 in group II and at 5 minutes was 7.80 in group I and 8.61 in group II. The difference was significant (P< 0.05).

DISCUSSION

PTL is a complex multifactorial etiopathogenesis that is caused by a number of maternal and fetal variables, including socioeconomic status, obstetric history, and maternal demographics.[6] Preterm birth results from the interaction of fetoplacental and maternal physiological parturition, which causes early cervical dilatation, effacement, and uterine contraction activation. Steroid coverage and tocolysis are used to treat preterm deliveries.[7,8] With the development of sophisticated NICUs and obstetric facilities, fetal survival can now occur in wealthy nations as early as 20 weeks of gestation, and in underdeveloped nations, with the best setups, as late as 28 weeks.10 PTL incidence is 23.3%, compared to 10–69% in India. The hazards related to PTL have increased as a result of ART procedures and contemporary world pressures.[9,10]The present study was conducted to compare oral and vaginal natural micronised progesterone in preventing preterm labor.

We observed that gestational age 24-28 weeks had 13 patients in group I and 15 in group II, 29-32 weeks had 24 in group I and 23 in group II and 32-36 weeks had 8 in group I and 7 in group II. Perinatal outcomes was asymptomatic at birth seen in 35 in group I and 38 in group II, neonatal sepsis in 2 and 1, hypoxemic ischaemic encephalopathy in 3 and 2, meconium aspiration syndrome in 1 and 2, and birth asphyxia in 4 and 2 in group I and II respectively. In a randomized, double-blind trial published by Meis et al[11], pregnant women with a history of spontaneous PTB were injected weekly between 16–20 weeks and 36 weeks of gestation with 250 mg of 17α-OHPC or a placebo. The 17α-OHPC treatment group had reduced incidences of PTB <37, <35, and <32 weeks of gestation than the placebo group, according to the results of this randomized research. Women whose previous PTB occurred before 34 weeks of gestation were the only ones in whom the 17α-OHPC therapy was successful in preventing recurrent PTB.

We found that the mean birth weight <2.5 kgs was seen in 11 and 7, 2.5-3 Kgs in 20 and 14 and >3 kgs in 14 and 24 in group I and II respectively. NICU admission was seen in 4in group I and 2 in group II, APGAR score at 1 minute was 7.24 in group I and 8.19 in group II and at 5 minutes was 7.80 in group I and 8.61 in group II.The results of a randomized, double-blind trial using vaginal natural micronized progesterone suppository therapy in a high-risk group were published by Fonseca et al.[12] Almost 90% of the participants had a history of PTB. The study's findings demonstrated that, in comparison to the placebo, daily use of a 100 mg vaginal progesterone suppository led to noticeably lower incidence of PTB <37 and <35 weeks of gestation.

The limitation of the study is the small sample size.

CONCLUSION

Authors found that progesterone administered vaginally is thought to be more effective than progesterone taken orally. It is essential in lowering the rate of neonatal NICU admissions, neonatal death, and neonatal morbidity. It also lowers preterm labor.

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