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COMPARING VAGINAL, ORAL AND IM PROGESTERONE TO PREVENT PRETERM LABOUR

Obstetrics & Gynaecology

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ABSTRACT

Background: Preterm labour (PTL) remains a major contributor to perinatal morbidity and mortality worldwide, with India reporting the highest number of preterm births annually. Progesterone is a key agent in the prevention of PTL, but the optimal route of administration—oral, vaginal, or intramuscular—remains debated. **Objective:** To compare the efficacy of oral, vaginal, and intramuscular progesterone in preventing PTL among pregnant women at high risk. **Methods:** An interventional study was conducted over one year at RMCH, Bareilly, including 225 pregnant women divided into three groups (75 each) receiving oral, vaginal, or intramuscular progesterone from 20 weeks 'gestation. Participants were selected via random sampling. Outcomes such as NICU admissions, neonatal complications, and pregnancy duration were assessed across groups, stratified by cervical length and obstetric history. **Results:** Vaginal progesterone showed the best outcomes in women with a cervical length <25 mm, both in primigravida and in those with previous PTL. Intramuscular progesterone was more effective in those with cervical length >25 mm and a prior PTL history. Oral progesterone was associated with higher NICU admissions and more side effects. **Conclusion:** Vaginal and intramuscular progesterone are more effective than oral progesterone in PTL prevention. The route should be individualized based on clinical parameters.

KEYWORDS

progesterone, oral, vaginal, im, preterm labour.

INTRODUCTION

Preterm labour (PTL) is the significant cause of perinatal and neonatal mortality and dreariness, which is firmly connected with formative and neurological problems sometime down the life.[1] As per World Health Organization (WHO), a preterm baby is defined as a baby who is born alive before 37 weeks of pregnancy are completed. The rate of preterm birth ranges from 5-18% across 184 countries.[2] India has the highest number of preterm births as well as neonatal deaths due to prematurity. Out of an estimated 2.6 crore live births in India each year, 35 lakh babies are born preterm, and out of these, 3.03 lakh babies (10% approximately) die due to complications of preterm births.[2].

Untimely birth difficulties, like premature retinopathy, necrotizing enterocolitis, respiratory distress and sepsis, are not restricted to the neonatal period; they may likewise address sequelae, as unusual neurophysiological advancement in youth and school under-accomplishment.[3] Early determination of pregnant ladies who are at high risk of preterm work can be the best. Subsequently, bed rest, cervical cerclage, bacterial vaginosis treatment, and prophylactic utilization of progesterone could be one of the administrations in this high-risk population.[5] There is as yet impressive vulnerability about the best type of progesterone, way of organization, portion and timing of commencement of treatment in high risk ladies to keep away from PTL.[6]

Progesterone can be given through oral route, vaginal gel or suppository, or intramuscularly.[7,8] In oral route there are fluctuation in the plasma levels of the medication because of individual variety in gastric filling and enterohepatic course, additionally this course can be related with secondary effects like nausea, migraine, tiredness, etc. causing incompliance.[9,10] The vaginal course avoids the side effects of the oral route while progesterone given intramuscularly can cause injection site inflammation.[11,12]

The focus for this research has been to compare various routes of administration of progesterone that is oral, vaginal and intramuscular routes in preventing and managing preterm labour and in females in danger, especially with history of past spontaneous PTL .

Aim

To compare oral vs vaginal vs intramuscular progesterone in prevention of preterm labour.

Objectives

- To administer progesterone through oral, vaginal and intramuscular routes in separate cohorts of pregnant females.
- To compare the effects of progesterone through oral, vaginal and intramuscular routes in the study cohorts.

MATERIAL AND METHODS

An interventional study has been carried out pregnant females visiting in the OBGY department of RMCH, Bareilly for a period of 1 year. A total of 225 study subjects were enrolled through OPD and divided into three groups with 75 cases in each group through simple random sampling by lottery method.

The institutional evidence-based protocols are used as guidelines for the management of high-risk cases after obtaining the approval from institutional approval committee. Time period of study from 1st May 2022 to 1st May 2023. Data collected and analysed through MS excel spreadsheet.

Inclusion Criteria

- Singleton pregnancy in females aged 21-35 years
- Live fetus
- Willing to give consent for participating in the study.

Exclusion Criteria

- Severe liver disease
- With active bacterial vaginosis infection
- BMI> 30kg/m2
- Hypertension
- Diabetes
- Cardiovascular disease
- Thromboembolic disorder
- Not willing to give consent for participating in the study.

Group A received daily 200mg oral progesterone, group B was given vaginal progestogen 200 mg daily; group C was given intramuscular injection of 200 mg17 alpha hydroxyprogesterone caproate weekly during pregnancy. Treatment was started from 20 weeks of gestation . The patients were under follow up through their routine check ups and contact numbers.

Parameters such as dose and route of administration of progesterone,

period of gestation, gestational risk factors, cervical length, type of pregnancy, PTL history, neonatal outcomes and complications if any were recorded by the researcher on proforma

RESULTS

Result:

Table 1: CX Length Vs Pregnancy Vs PTL Vs POG

Previous pregnancy-preterm history present	Cervical length		Group A 75	Group B 75	Group C 75
	<25mm	Very preterm	10	3	5
		Early preterm	7	5	8
		Late preterm	5	9	6
		Term	2	10	6
			24	27	25
	>25mm	Very preterm	8	7	3
		Early preterm	8	6	5
		Late preterm	4	5	7
		Term	5	7	10
			25	23	25
Primigravida	<25mm	Very preterm	9	5	9
		Early preterm	7	2	6
		Late preterm	5	8	5
		Term	5	10	5
			26	25	25

Table 1 depicts the various routes of progesterone administration according to different stages of PTL, cervical lengths and type of pregnancy of the study subjects.

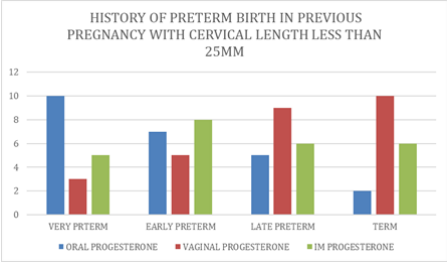


Figure 1 shows the comparison between various routes of progesterone administration in pregnant females with history of preterm birth in previous pregnancy and with cervical length less than 25 mm. Vaginal progesterone had best response in this group.

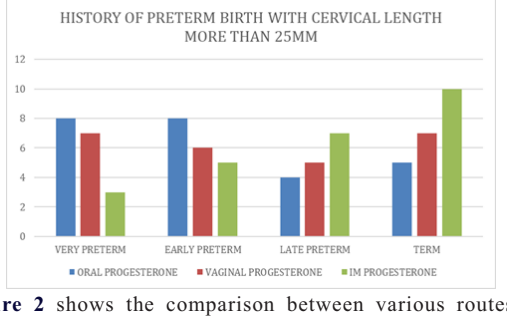


Figure 2 shows the comparison between various routes of progesterone administration in pregnant females with history of preterm birth in previous pregnancy and with cervical length more than 25mm. IM progesterone had best response in this group.

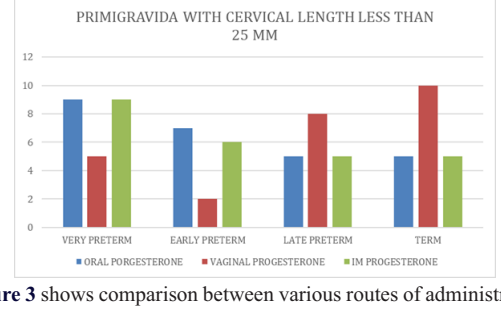
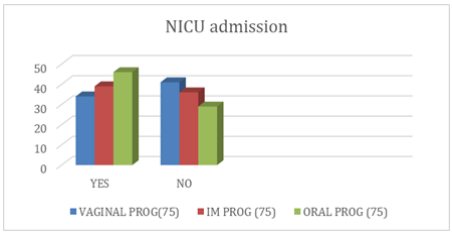


Figure 3 shows comparison between various routes of administration in primigravida female with cervical length less than 25mm . Again, Vaginal progesterone showed promising results.



NICU admission was higher in children whose mothers were given oral progesterone (81.99%) followed by intramuscular progesterone (68.36%) and lowest in cases of vaginal suppository (55.76%). Common complications in neonates were HIE (45.96%), Hyperbilirubinemia (62.73%), RDS (71.04%).

DISCUSSION

In the index study, vaginal progesterone had the best response in this study when the cervical length was less than 25 mm in both primigravida and females with history of preterm labour. As a result, the association between vaginal progesterone and a cervical length of less than 25 millimeters is statistically significant.

Additionally, intramuscular progesterone could prolong the duration of pregnancy in females with cervical length more than 25mm having a history of preterm birth.

Considering the side effects of treatment, 10 females (13.33%) complaint of nausea who were taking oral progesterone and 6 women (8%) reported bruising on injection site, which did not reoccur in the following weeks of treatment. None of the subjects experienced any severe complications such as thromboembolism.

CONCLUSION

According to our study, vaginal progesterone may be considered as a treatment option for patients who were primigravida or with a history of preterm birth, singleton gestation and cervical length less than 25mm. In the absence of shortened cervix with history of preterm birth, IM progesterone can be considered. Progesterone plays pivotal role in managing PTL and dose and route of administration should be decided according to the basis of period of gestation, gestational risk factors, cervical length, type of pregnancy and PTL history.

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