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Original Article

Maternal and Pregnancy Outcomes Following Vaginal Progesterone Use in Threatened Preterm Labour: A Descriptive Case Series

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ABSTRACT

Threatened preterm labour is a key contributor to neonatal morbidity and mortality worldwide. Progesterone supplementation has been investigated for its role in prolonging pregnancy and reducing the risk of preterm birth. **Objectives:** To share insights into pregnancy prolongation among women receiving vaginal progesterone at a tertiary care hospital and to examine how these outcomes vary across demographic and clinical groups. **Methods:** This descriptive case series was carried out at the Department of Obstetrics and Gynecology, Imran Idrees Teaching Hospital, Sialkot, from August 2025 to January 2026. A total of 100 pregnant women aged 18–45 years with parity <5 and gestational age between 28 and 36 weeks presenting with threatened preterm labour were recruited using consecutive non-probability sampling. All participants received 200 mg natural micronized progesterone vaginally once daily until delivery. Delivery beyond 36 completed weeks was considered a favorable pregnancy prolongation outcome. Data were analyzed using SPSS version 25.0. **Results:** The mean maternal age was 32.13 ± 8.41 years, while the mean gestational age at presentation was 32.11 ± 2.22 weeks. Delivery beyond 36 weeks of gestation was observed in 76% of participants (95% CI: 66.6%–83.5%). No significant statistical association was identified between pregnancy prolongation outcomes and "maternal age, body mass index, cervical dilatation, gestational age at presentation", parity, lifestyle status, anemia, diabetes, hypertension, previous preterm labour, or antepartum haemorrhage ($p>0.05$). **Conclusions:** A majority of women receiving vaginal progesterone delivered beyond 36 weeks of gestation. Due to the descriptive single-arm design, causal conclusions regarding treatment effectiveness cannot be established.

INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, accounts for approximately 10–11% of all live births globally and remains a leading cause of neonatal mortality and long-term morbidity [1]. It causes approximately 35 percent of neonatal mortality rates all over the globe and is a primary cause of "respiratory distress syndrome", intraventricular hemorrhage, and neurodevelopmental impairment. "Preterm birth is a main cause of neonatal morbidity and mortality in the world", and it causes major long-term neurodevelopmental issues and health costs [2]. Threatened preterm labor is a time-sensitive condition that needs prompt treatment because early intervention has the potential to extend the gestation period and enhance childbirth outcomes. Progesterone is important for maintaining uterine quiescence by inhibiting myometrial contractility, modulating inflammatory pathways, and supporting cervical integrity [2]. The key physiological role of progesterone in pregnancy is that it suppresses myometrial contractility and regulates the inflammatory pathway which is involved in cervical ripening. The pathogenesis of spontaneous preterm labor has been associated with functional progesterone withdrawal, which provides a good biological explanation for exogenous supplementation [3]. Several randomized controlled trials have established the effectiveness of vaginal progesterone in reducing preterm birth rates.

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Yadav et al. reported a significant reduction in preterm delivery among women treated with vaginal progesterone, with improvement in gestational age at delivery compared to controls [4]. In a randomized controlled trial involving women with preterm labor, Sirisangwon and Phupong demonstrated that progesterone supplementation significantly prolonged pregnancy duration, with a higher proportion of women delivering beyond 37 weeks compared to placebo [5]. A recent systematic review and meta-analysis by Breuking *et al.* which included multiple randomized controlled trials, reported that progestogen maintenance therapy after arrested preterm labor reduced recurrent preterm birth with a pooled relative risk reduction and significantly prolonged pregnancy latency [6]. Similarly, Ferrari *et al.* in a meta-analysis, concluded that progestogens used as maintenance tocolysis significantly prolonged the interval following treatment to delivery and reduced the risk of early preterm birth [7]. Kabiri *et al.* specifically evaluated vaginal progesterone in women with threatened labor and a shortened cervix diagnosed after 24 weeks and demonstrated a statistically significant reduction in preterm birth before 34 weeks compared with controls [8]. Comparative trials have also evaluated progesterone against conventional tocolytics. Hafeez et al. conveyed that vaginal progesterone was at least as effective as oral nifedipine in inhibiting threatened preterm labor, with comparable pregnancy prolongation rates [9]. Mohamed and Wafa, similarly demonstrated significant efficacy of vaginal progesterone in reducing uterine contractions and delaying delivery compared to nifedipine [10].

While several randomized trials and meta-analyses have looked into progesterone therapy for preterm labor, there's a lot of variation in the types of progesterone used, how patients are selected, and the methods for assessing the cervix. Additionally, there's limited local data on how well pregnancy is prolonged when women with threatened preterm labor receive vaginal progesterone in everyday clinical practice, especially in resource-limited settings where cervical length measurement isn't always available. That's why this study aimed to share insights into pregnancy prolongation among women receiving vaginal progesterone at a tertiary care hospital and to examine how these outcomes vary across demographic and clinical groups.

METHODS

This descriptive case series was conducted in the Department of Obstetrics and Gynecology, Imran Idrees Teaching Hospital, Sialkot, after approval from the Institutional Review Board of Sialkot Medical College (IRB No. MRC/IRB/24044, dated 18 September 2024). The research was conducted for 6 months, between August 2025 and January 2026, and informed consent was obtained from all participants before enrollment. A total of 100 pregnant women were recruited through consecutive non-probability sampling, who were brought to the hospital with a history of threatened preterm labor. The WHO sample size calculator was used to determine the sample size with a level of confidence of 95 per cent and a 10 per cent margin of error and an expected level of effectiveness of 60 percent, based on already published values. Women aged 18–45 years with parity less than five and gestational age ≥28 weeks presenting with threatened preterm labor were included. Threatened preterm labour was defined as regular uterine contractions occurring at least four times in 20 minutes or eight times in 60 minutes, accompanied by cervical effacement and/or cervical dilatation between 28 and 36 completed weeks of gestation [11]. Women with multiple pregnancies, abnormally located placenta on ultrasound, morbid obesity (BMI >35 kg/m^2), underweight status(BMI <18 kg/m^2), cervical dilatation greater than 3 cm, known hypersensitivity to progesterone, or those who had already received progesterone therapy during the current pregnancy were excluded. Following informed consent, data on demographic and clinical aspects were collected, such as maternal age, body mass index, parity, and lifestyle status (categorized based on self-reported daily physical activity, Participants performing regular moderate physical activity for at least 150 minutes per week were categorized as having an active lifestyle, while those not meeting this criterion were categorized as sedentary.), gestational age at the time of presentation, cervical OS dilatation, and history of anemia, diabetes, hypertension, previous preterm labor, and antepartum hemorrhage. Anemia was defined as a hemoglobin level <11 g/dL according to WHO criteria for pregnancy [12]. Hypertension was defined as blood pressure ≥140/90 mmHg. Gestational diabetes mellitus was defined according to the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria using a 75-g oral glucose tolerance test, including fasting plasma glucose ≥92 mg/dL, 1-hour value ≥180 mg/dL, or 2-hour value ≥153 mg/dL [13]. All participants received standard institutional care for threatened preterm labour in addition to vaginal progesterone. Standard care included: [list all that apply, e.g., hospitalization, bed rest, intravenous hydration, tocolysis with nifedipine or ritodrine, antenatal corticosteroids (betamethasone) for fetal lung maturity if gestational age <34 weeks, antibiotics if infection was suspected, magnesium sulphate for fetal neuroprotection if gestational age <32 weeks, and treatment of any underlying condition such as anaemia or hypertension]. The decision to administer these interventions was made by the attending obstetrician according to institutional protocols. Data on co-interventions were collected from

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medical records and are reported in the Results. Gestational age at the time of delivery was documented for all participants. Gestational age at delivery was classified using standard obstetric definitions: early preterm (<34+0 weeks), late preterm (34+0 to 36+6 weeks), and term (≥37+0 weeks). The primary outcome was favorable pregnancy prolongation, defined as delivery at ≥37+0 completed weeks. Delivery at 36+0 to 36+6 weeks was classified as late preterm and reported separately; it was not included in the term group. Because this was a single-arm descriptive case series, the term 'treatment failure' was not used. Neonates were managed according to institutional protocols. All enrolled participants were followed until delivery. No participants were excluded after enrollment or lost to follow-up during the study period. Data collection forms were reviewed for completeness before data entry and statistical analysis, and no significant missing data were identified

Data were entered and analyzed using SPSS version 25.0. The Shapiro–Wilk test was applied to assess the normality of quantitative variables. Quantitative variables were presented as mean ± standard deviation, while qualitative variables were expressed as frequencies and percentages. Exploratory subgroup analyses and stratification, as pre-specified in the approved FCPS Part-II synopsis, were performed to describe the distribution of pregnancy prolongation outcomes across demographic and clinical variables. Expected cell count assumptions were assessed before application of the Chi-square test. Fisher's exact test was applied where expected cell counts were less than 5. A p-value ≤0.05 was considered statistically significant. The participant flow diagram is shown (Figure 1).

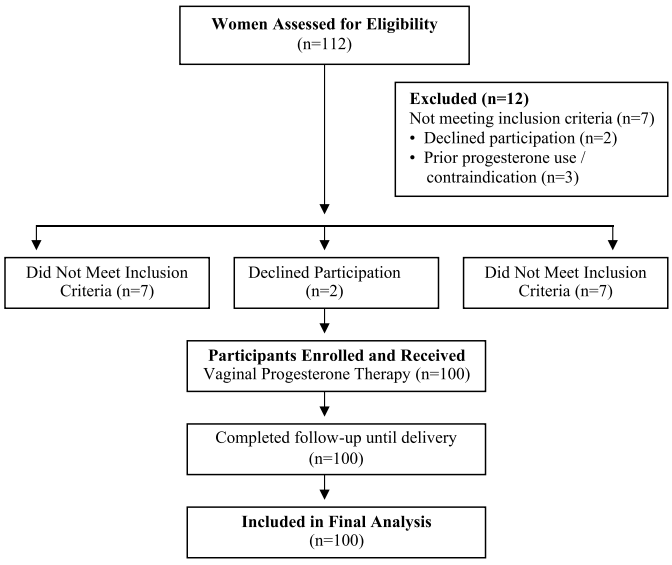


Figure 1: Participant Flow Diagram

RESULTS

A total of 112 women presenting with threatened preterm labour were initially assessed for eligibility. Twelve participants were excluded due to not fulfilling inclusion criteria or meeting exclusion criteria. Finally, 100 eligible participants were enrolled and received vaginal progesterone therapy. All enrolled participants completed follow-up until delivery and were included in the final analysis. Normality assessment using the Shapiro–Wilk test was performed before statistical analysis (Table 1).

Table 1: Shapiro–Wilk Normality Test Results for Quantitative Variables

Variables	Shapiro–Wilk Statistic (W)	p-value	Interpretation
Maternal Age (years)	0.981	0.184	Normally distributed
Body Mass Index (kg/m^2)	0.976	0.112	Normally distributed
Cervical OS Dilatation (cm)	0.972	0.086	Normally distributed
Gestational Age at Presentation (weeks)	0.984	0.241	Normally distributed
Gestational Age at Delivery (weeks)	0.979	0.153	Normally distributed

Normality was considered present at p-value >0.05

The mean maternal age was 32.13 ± 8.41 years, and the mean body mass index (BMI) was 27.64 ± 4.67 kg/m^2. The mean cervical OS dilatation at presentation was 1.88 ± 0.57 cm. The mean gestational age at presentation was 32.11 ± 2.22 weeks, and the mean gestational age at delivery was 36.50 ± 2.54 weeks. Delivery beyond 36 weeks of gestation (defined as effectiveness) was achieved in 76 (76%) participants, whereas 24 (24%) delivered before 36 weeks. Regarding baseline characteristics, anemia was present in 43 (43%) participants, diabetes in 21 (21%), hypertension in 18 (18%), previous history of preterm labor in 25 (25%), and antepartum hemorrhage in 10 (10%). Most participants had a sedentary lifestyle (72%). Baseline "demographic and clinical characteristics of the study participants are presented (Table 2).

Table 2: Baseline Demographic and Clinical Characteristics of Study Participants (n=100)

Variables	Mean ± SD / n (%)
Age (years)	32.13 ± 8.41
BMI (kg/m^2)	27.64 ± 4.67
Cervical OS (cm)	1.88 ± 0.57
Gestational Age	
At Presentation (weeks)	32.11 ± 2.22
At Delivery (weeks)	36.50 ± 2.54
Parity	
0	23 (23%)
1	14 (14%)
2	21 (21%)
3	19 (19%)
4	23 (23%)

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Lifestyle	
Sedentary	72 (72%)
Active	28 (28%)
History	
Anemia	43 (43%)
Diabetes	21 (21%)
Hypertension	18 (18%)
Previous Preterm Labor	25 (25%)
Antepartum Hemorrhage	10 (10%)
Effectiveness Achieved (>36 weeks)	76 (76%)

Stratified analysis showed "no statistically significant association between treatment effectiveness and maternal age (p=0.389), BMI (p=0.303), cervical OS dilatation (p=0.680), gestational age at presentation (p=0.633), parity (p=0.164), lifestyle (p=0.909), anemia (p=0.698), diabetes (p=0.756), hypertension (p=0.913), previous preterm labor (p=1.000), or antepartum hemorrhage (p=1.000). Delivery beyond 36 weeks of gestation was observed in 76% of participants (95% CI: 66.6%–83.5%), whereas 24% delivered before 36 weeks. Exploratory subgroup analysis of the distribution of pregnancy prolongation outcomes by demographic and clinical variables is presented (Table 3).

Table 3: Exploratory Subgroup Analysis of Pregnancy Prolongation Outcomes According to Demographic and Clinical Variables (n=100)

Variables	Category	Not Effective, n (%)	Effective, n (%)	95% CI for Effective Group	p-value
Age	≤30 years	8 (18.6%)	35 (81.4%)	66.6%–91.6%	0.389
	>30 years	16 (28.1%)	41 (71.9%)	58.5%–82.5%	
BMI	≤30 kg/m^2	13 (20.0%)	52 (80.0%)	68.2%–88.9%	0.303
	>30 kg/m^2	11 (31.4%)	24 (68.6%)	50.7%–83.1%	
Cervical OS	≤2 cm	16 (26.2%)	45 (73.8%)	61.2%–84.8%	0.680
	>2 cm	8 (20.5%)	31 (79.5%)	63.5%–90.7%	
GA at Presentation	≤32 weeks	10 (20.8%)	38 (79.2%)	65.0%–89.5%	0.633
	>32 weeks	14 (26.9%)	38 (73.1%)	59.0%–84.4%	
Parity	0	5 (21.7%)	18 (78.3%)	56.3%–92.5%	0.164
	1	1 (7.1%)	13 (92.9%)	66.1%–99.8%	
	2	3 (14.3%)	18 (85.7%)	63.7%–97.0%	
	3	7 (36.8%)	12 (63.2%)	38.4%–83.7%	
	4	8 (34.8%)	15 (65.2%)	42.7%–83.6%	
Lifestyle	Active	6 (21.4%)	22 (78.6%)	59.0%–91.7%	0.909
	Sedentary	18 (25.0%)	54 (75.0%)	63.4%–84.5%	
Anemia	No	15 (26.3%)	42 (73.7%)	60.3%–84.5%	0.698
	Yes	9 (20.9%)	34 (79.1%)	64.0%–90.0%	
Diabetes	No	20 (25.3%)	59 (74.7%)	63.7%–83.6%	0.756
	Yes	4 (19.0%)	17 (81.0%)	58.1%–94.6%	
Hypertension	No	19 (23.2%)	63 (76.8%)	66.0%–85.3%	0.913
	Yes	5 (27.8%)	13 (72.2%)	46.5%–90.3%	
Previous Preterm Labor	No	18 (24.0%)	57 (76.0%)	64.7%–84.9%	1.000
	Yes	6 (24.0%)	19 (76.0%)	54.9%–90.6%	
Antepartum Hemorrhage	No	22 (24.4%)	68 (75.6%)	65.4%–83.9%	1.000
	Yes	2 (20.0%)	8 (80.0%)	44.4%–97.5%	

Values are presented as n (% within row). Chi-square test or Fisher's exact test was applied, where appropriate, according to expected cell count assumptions. p ≤0.05 was considered statistically significant

The mean gestational age at delivery was higher among participants achieving favorable pregnancy prolongation outcomes (>36 weeks) compared with those delivering before 36 weeks (Table 4).

Table 4: Mean Gestational Age at Delivery

Outcome Group	Mean Gestational Age at Delivery
Effective (>36 weeks)	38.1 ± 1.2 weeks
Not Effective (<36 weeks)	33.8 ± 1.1 weeks

DISCUSSION

In the present study, vaginal progesterone demonstrated a high effectiveness rate in prolonging pregnancy beyond 36 weeks in women presenting with threatened preterm labor. These findings are consistent with previous regional and international studies supporting progesterone's role in maintaining pregnancy. Sahoo *et al.* reported a "significant reduction in preterm birth rates" among women treated with vaginal progesterone [14]. On the same note, Sirisangwon and Phupong reported a longer gestation and better outcomes in newborns in their randomized

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controlled trial [5]. These findings are in line with the current study, and this supports the therapeutic use of vaginal progesterone in threatened preterm pregnancies. The practice of maintenance therapy after an acute event of preterm contractions is a controversial topic. In their systematic review and meta-analysis, Breuking *et al.* concluded that progestogen maintenance therapy effectively extends the duration of pregnancy [6]. Ferrari *et al.* also established better pregnancy continuation among the symptomatic women who were treated with progestogens [7]. These conclusions are supported by the high gestation age recorded in the current study. The mechanistic effect of progesterone is to keep the uterus quiescent via a down-regulation of the contraction-related proteins, suppression of prostaglandins, and the regulation of the inflammatory cytokine [15]. Comparative trials have been done between progesterone and other tocolytics, and the outcome is promising. According to Hafeez *et al.* vaginal progesterone was as effective as oral nifedipine at least in the treatment of threatened preterm labor [9]. The same case is reported by Mohamed and Wafa, which revealed similar inhibition of uterine contractions between nifedipine and progesterone [10]. The results of these studies indicate that progesterone can be used as a valid and well-tolerated alternative to the traditional tocolytics. The importance of progesterone in women who have a short cervix has been established. The study by Kabiri *et al.* showed a considerable decrease in spontaneous preterm babies among women with threatened labor and cervical shortening [8]. According to Romero et al. description of the PREGNANT trial, there is an additional emphasis on the significance of vaginal progesterone in preventing early preterm birth and neonatal outcomes [16]. The current study concurs with this evidence, particularly regarding the extension of gestation. Nonetheless, some studies indicate that progesterone may have little effect on twin gestation, as reported in the current meta-analyses [17]. As such, patient selection is critical. The current research studied singleton pregnancies, which may explain the positive results. Recent literature reports similar findings on progesterone and progestogens in preventing preterm birth. Hedawy *et al.* found oral dydrogesterone significantly reduced preterm birth risk and improved neonatal outcomes in high-risk pregnancies [18]. Di Renzo *et al.* noted progesterone helps maintain uterine quiescence, reduces inflammatory mediators, and prolongs pregnancy [19]. Dodd *et al.* in a Cochrane review, reported antenatal progesterone lowered preterm delivery rates and enhanced perinatal outcomes [20].

The present study has a few limitations that are important to keep in mind when looking at the results. First, because it was a descriptive single-arm study without a control group, it's difficult to determine the true effectiveness of vaginal progesterone in cases of threatened preterm labor. Second, because the research was conducted at a single specialized care center with a relatively small number of participants, the findings may not be widely applicable across settings. Third, cervical length was not routinely measured using transvaginal ultrasound, which could affect how these results compare to established, evidence-based methods. Additionally, the study did not include information on neonatal outcomes, maternal side effects, or a detailed safety analysis. To gain a clearer understanding of the role of vaginal progesterone in threatened preterm labor, larger studies involving multiple centers and long-term follow-up for both mothers and babies are needed.

CONCLUSIONS

In this descriptive case series, a majority of women receiving vaginal progesterone for threatened preterm labour delivered beyond 36 weeks of gestation. No statistically significant associations were observed between demographic or clinical variables and pregnancy prolongation outcomes. Due to the observational single-arm design without a control group, definitive conclusions regarding treatment effectiveness cannot be established. Further randomized controlled studies are recommended to evaluate the comparative efficacy of vaginal progesterone in threatened preterm labour.

Authors' Contribution

Conceptualization: HS
Methodology: HS, HA, HM
Formal analysis: HS
Writing and Drafting: HA, HM, FA
Review and Editing: HS, HA, HM, FA

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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