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Original Article

Preterm Birth Frequency among Women with Risk Factors Presenting at 28–34 Weeks and Receiving Oral Micronized Progesterone: A Prospective Single-Arm Study

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ABSTRACT

Preterm birth (PTB) remains a major cause of neonatal morbidity and mortality. Evidence regarding oral progesterone in women presenting with risk factors later in gestation remains limited. **Objectives:** To determine the frequency of PTB before 37 completed weeks among women presenting at 28–34 weeks with risk factors for PTB and receiving oral micronized progesterone. **Methods:** This prospective single-arm study included 100 women aged 18–40 years with singleton pregnancies at 28–34 weeks and a previous spontaneous PTB, cervical length <25 mm, or both. Oral micronized progesterone 100 mg was given twice daily until 36+6 weeks or delivery. Participants were followed until delivery. Data were analyzed using IBM SPSS Statistics version 26.0. Quantitative variables were summarized as median and interquartile range. Categorical variables were reported as frequencies and percentages. Mann–Whitney U and Fisher exact tests were used where appropriate. **Results:** Median age was 30.0 years and median cervical length was 23.4 mm. PTB occurred in 15 (15.0%) women (95% CI: 8.6–23.5), while 85 (85.0%) delivered at term. Five (5.0%) delivered before 34 weeks and 10 (10.0%) at 34 to <37 weeks. Median gestational age at delivery was 38.2 weeks. Compliance was good in 93 (93.0%) women. Twenty women reported adverse effects, with one recorded adverse effect per affected participant. **Conclusion:** PTB occurred in 15.0% of women receiving oral micronized progesterone, while 85.0% reached term gestation.

INTRODUCTION

Preterm birth (PTB), defined as birth before 37 completed weeks of gestation, remains a cause of neonatal morbidity and mortality. Its burden is high in low- and middle-income countries. A global analysis reported approximately 15 million neonatal PTB cases in 2019, with a high burden in South Asia [1]. A multicentre study of 215,254 singleton births reported a PTB prevalence of 7.4%, with risk varying by gestational age and maternal characteristics [2]. PTB has a multifactorial origin. Maternal disease, infection, cervical changes, and previous obstetric history can contribute to its occurrence. Vaginal bleeding in early pregnancy and urinary tract infection has been associated with spontaneous preterm birth (sPTB) [3]. Previous sPTB and a short cervix are important predictors of recurrence. In women with cervical length ≤25 mm diagnosed after 24 weeks, progesterone treatment has been associated with fewer births before 34 weeks and fewer neonatal intensive care admissions [4]. Progesterone is used to reduce PTB risk, but outcomes vary by formulation, route, timing, and indication. Oral treatment avoids injections and vaginal

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administration. A Pakistani randomized study found both oral and vaginal progesterone useful, although vaginal progesterone was more effective [5]. Another randomized trial found similar preterm labour and neonatal outcomes with oral and intramuscular progesterone [6]. A 2024 cohort reported no overall significant reduction in recurrent sPTB with progesterone, suggesting variation across risk groups [7]. The study hypothesized that most women receiving oral micronized progesterone would reach term, although some would still experience PTB.

Most evidence for progesterone prophylaxis is based on treatment started earlier in pregnancy, while evidence for women presenting with risk factors at 28–34 weeks is limited. This creates a local knowledge gap regarding PTB frequency in women treated during this later gestational window. This study aimed to determine the frequency of PTB before 37 completed weeks among women presenting at 28–34 weeks with risk factors for PTB and receiving oral micronized progesterone.

METHODS

This prospective single-arm study was conducted in the Department of Obstetrics and Gynecology, Fatima Memorial Hospital, Lahore. All 100 participants were recruited from April 2026 to May 2026 and were then followed prospectively until delivery. Final follow-up was completed on August 2026, by which time outcome data were available for all participants, with no loss to follow-up. Women presenting to the outpatient or emergency department were enrolled through non-probability consecutive sampling. Ethical approval was issued by the Institutional Review Board/Ethical Review Committee of Fatima Memorial Hospital & Allied Institutions, Lahore (Ref. No. FMH/ERC/2026/04-1082 dated 4 April 2026). Written informed consent was obtained before enrolment. The minimum sample size was calculated using a single-population proportion formula. Ashoush et al. reported a PTB frequency of 44.7% among women receiving oral micronized progesterone [8]. With 95% confidence and 10% absolute precision, the minimum sample was 95; 100 eligible women were analyzed. Women aged 18–40 years with singleton pregnancies at 28–34 weeks were eligible if they had a previous spontaneous preterm birth (sPTB), cervical length <25 mm on transvaginal ultrasonography, or both. Multiple pregnancy, polyhydramnios with amniotic fluid index >25 cm, gestational or chronic hypertension, diabetes mellitus, asthma, and known cardiac disease were excluded. Gestational age was assigned using the best obstetric estimate from the last menstrual period (LMP) and earliest available ultrasound. When LMP was uncertain, the earliest reliable ultrasound was used. If LMP- and ultrasound-based estimates differed, ultrasound dating was used when the discrepancy exceeded 5 days before 9 weeks, 7 days at 9–15+6 weeks, 10 days at 16–21+6 weeks, 14 days at 22–27+6 weeks, or 21 days at ≥28 weeks. Once established, the estimated date of delivery was not revised by later scans. At enrolment, demographic and obstetric data were recorded. Body mass index was calculated as kg/m^2. Cervical length was measured transvaginally with an empty bladder; three technically adequate measurements were obtained, and the shortest was recorded. Participants were classified as having short cervix only, previous sPTB only, or both. All women presented at 28–34 weeks and received oral micronized progesterone 100 mg twice daily from enrolment until 36+6 weeks or delivery, whichever occurred first. Participants were followed routinely until delivery. Compliance was estimated from the proportion of prescribed doses reported as taken; ≥80% was classified as good compliance. Dizziness, sleepiness, and weariness were assessed at follow-up, and only one adverse-effect category was recorded per participant; therefore, affected participants were counted once, and categories were mutually exclusive. PTB was defined as delivery before 37 completed weeks and was further classified as <34 weeks or 34 to <37 weeks.

Data were analyzed using IBM SPSS Statistics version 26.0. Quantitative variables were summarized as median and interquartile range, and categorical variables as frequency and percentage. Exact two-sided 95% confidence intervals were calculated using the Clopper–Pearson method. Mann–Whitney U and two-sided Fisher exact tests compared term and preterm groups. A p-value <0.05 was significant. Multivariable analysis was not performed because only 15 PTB events occurred, limiting reliable model estimation.

RESULTS

The analysis included 100 women at risk of PTB. The median age was 30.0 years (IQR 27.3–34.0), while the median gestational age at presentation was 30.0 weeks (IQR 28.3–33.0). Median parity was 2.0 (IQR 1.3–3.0), median BMI was 27.9 kg/m^2 (IQR 26.7–30.3), and median cervical length was 23.4 mm (IQR 21.4–27.8). A previous sPTB was present in 55 (55.0%) women. Regarding the qualifying risk profile, 45 (45.0%) had a short cervix only, 40 (40.0%) had a previous preterm birth only, and 15 (15.0%) had both risk factors (Table 1).

Table 1: Baseline Maternal and Obstetric Profile of the Study Participants (n=100)

Characteristics	Median (IQR) / n (%)
Age (years)	30.0 (27.3–34.0)
Gestational Age at Presentation (weeks)	30.0 (28.3–33.0)
Parity	2.0 (1.3–3.0)
BMI, kg/m^2	27.9 (26.7–30.3)

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Cervical Length (mm)	23.4 (21.4–27.8)
Previous sPTB	55 (55.0%)
Short Cervix Only	45 (45.0%)
Previous sPTB Only	40 (40.0%)
Both Risk Factors	15 (15.0%)

The median gestational age at delivery was 38.2 weeks (IQR 37.4–39.7). PTB before 37 completed weeks occurred in 15 (15.0%) women, with an exact 95% CI of 8.6%–23.5%. Five (5.0%) women delivered before 34 weeks and 10 (10.0%) delivered from 34 to <37 weeks. Good compliance with oral progesterone was documented in 93 (93.0%) women. Adverse effects were reported by 20 (20.0%) women. Each affected participant had one recorded adverse effect: dizziness occurred in 8 (8.0%), sleepiness in 7 (7.0%), and weariness in 5 (5.0%) women. No participant was counted in more than one adverse-effect category (Table 2).

Table 2: Pregnancy Outcome, Compliance, and Treatment Tolerability (n=100)

Outcome/Characteristics	n (%)	Exact 95% CI
Gestational Age at Delivery, weeks	Median 38.2 (IQR 37.4–39.7)	–
Delivery <34 Weeks	5 (5.0%)	1.6–11.3
Delivery 34 to <37 Weeks	10 (10.0%)	4.9–17.6
Preterm Birth <37 Weeks	15 (15.0%)	8.6–23.5
Term Birth ≥37 Weeks	85 (85.0%)	76.5–91.4
Good Compliance	93 (93.0%)	86.1–97.1
Poor Compliance	7 (7.0%)	2.9–13.9
Any Adverse Effect	20 (20.0%)	12.7–29.2
Dizziness	8 (8.0%)	3.5–15.2
Sleepiness	7 (7.0%)	2.9–13.9
Weariness	5 (5.0)	1.6–11.3

Adverse-effect categories were mutually exclusive; each affected participant was counted once

None of the evaluated maternal, obstetric, or treatment-related factors showed a statistically significant association with PTB. However, only 15 PTB events occurred, and the subgroup analyses therefore had limited statistical power. Age, gestational age at presentation, parity, BMI, and cervical length were comparable between women with term and preterm delivery (all p>0.05). Preterm birth was numerically more frequent among women with a short cervix, poor compliance, or any adverse effect, but these differences were not statistically significant. A previous spontaneous preterm birth was present in 33.3% of women who delivered preterm compared with 58.8% of those who delivered at term, although this difference also did not reach statistical significance (p=0.092) (Table 3).

Table 3: Factors Associated with Preterm Birth (<37 Completed Weeks)

Variable/Positive Category	Term (n=85), Median (IQR) / n (%)	Preterm (n=15), Median (IQR) / n (%)	Statistical Test, Median (IQR) / n (%)	p-value
Age (years)	30.0 (28.0–34.0)	29.0 (26.0–35.0)	Mann–Whitney U=699.0	0.550
Gestational Age at Presentation (weeks)	30.0 (28.5–33.0)	30.0 (28.0–33.0)	Mann–Whitney U=649.0	0.910
Parity	2.0 (1.0–3.0)	2.0 (2.0–3.0)	Mann–Whitney U=617.0	0.838
BMI, kg/m^2	27.8 (26.8–30.4)	28.4 (26.7–30.1)	Mann–Whitney U=641.5	0.969
Cervical Length (mm)	23.4 (21.5–27.9)	23.0 (21.4–26.1)	Mann–Whitney U=669.0	0.761
Previous sPTB: Yes	50 (58.8)	5 (33.3)	Fisher exact	0.092
Short Cervix <25 mm: Yes	49 (57.6)	11 (73.3)	Fisher exact	0.392
Both Risk Factors: Yes	14 (16.5)	1 (6.7)	Fisher exact	0.457
Poor Compliance	5 (5.9)	2 (13.3)	Fisher exact	0.282
Any Adverse Effect	15 (17.6)	5 (33.3)	Fisher exact	0.173

DISCUSSION

PTB occurred in 15.0% of participants, while 85.0% reached term gestation. Ilyas *et al.* reported PTB in 24% of women receiving oral micronized progesterone [9], whereas Rafiq *et al.* reported a PTB frequency of 12.5% with vaginal progesterone [10]. Differences in clinical presentation, baseline risk, and treatment route may explain variation across these local studies. The observed PTB frequency of 15.0% was substantially lower than the 44.7% anticipated for the sample-size calculation. The anticipated value came from a population at high risk of recurrent PTB, whereas the present cohort included women with previous sPTB, short cervix, or both. Differences in baseline risk, population characteristics, gestational age at treatment initiation, clinical setting, and antenatal care may explain the discrepancy. The lower observed frequency should not be interpreted as evidence of greater treatment efficacy because no untreated comparison group was included. The observed estimate also had greater precision than originally planned: the calculation assumed 10% absolute precision, whereas the observed PTB frequency had an exact 95% CI of 8.6%–23.5%. However, only 15 PTB events occurred; therefore, subgroup analyses had limited statistical power and Type II error cannot be excluded. Median gestational age at delivery was 38.2 weeks, and 5.0% delivered before 34 weeks. Sultana *et al.* reported longer pregnancy prolongation with vaginal progesterone than nifedipine in women with preterm labour [11]. Differences in study

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design and baseline risk limit direct comparison. Yadav *et al.* studied women with established preterm labour and reported term delivery in 82% receiving vaginal progesterone versus 60% without maintenance treatment [12]. Hyett *et al.* evaluated vaginal progesterone after successful arrest of preterm labour with parenteral tocolysis and reported later delivery with progesterone than placebo [13]. Their findings relate to maintenance treatment after preterm labour and should not be directly compared with this risk-factor-based cohort. Previous sPTB was present in 55.0% of participants but was not significantly associated with PTB. Boelig *et al.* reported recurrent PTB before 37 weeks in 31% with vaginal progesterone and 38% with intramuscular treatment [14], while Pacagnella *et al.* demonstrated persistent PTB risk despite progesterone in women with high underlying obstetric risk [15]. The non-significant association in the present study should be interpreted cautiously because of the small number of PTB events. The gestational age at progesterone initiation is an important limitation. Most evidence supporting prophylactic progesterone, particularly for a short cervix, is based on treatment started earlier in pregnancy. In this study, treatment began at 28–34 weeks, representing later presentation rather than conventional early prophylaxis. The findings should not be interpreted as evidence that oral progesterone started at 28–34 weeks is equivalent to guideline-supported earlier treatment. Kabiri *et al.* evaluated vaginal progesterone in women with threatened preterm labour and short cervix diagnosed at 24+0–33+6 weeks [16]. Because their population, route, and indication differed, direct efficacy comparison is inappropriate. Danieli-Gruber *et al.* examined neonatal outcomes among women who delivered preterm despite prophylactic vaginal or intramuscular progesterone [17]; their study addressed neonatal outcomes after PTB rather than PTB frequency. Nachum *et al.* evaluated vaginal micronized progesterone after arrested preterm labour at 24–34 weeks and found no significant prolongation of pregnancy in singleton gestations [18]. This represents a different clinical situation because participants had already experienced preterm labour. Wang *et al.* studied women with short cervix and reported PTB frequencies of 18.8% with progesterone and 21.2% without treatment [19], with effects varying by timing of cervical shortening. Residual PTB risk has also been reported in treated short-cervix populations. He *et al.* observed sPTB in 11.4% of singleton pregnancies receiving progesterone [20]. In the SuPPoRT trial, Hezelgrave *et al.* reported PTB before 37 weeks in 32 of 132 women allocated to vaginal progesterone [21]. Hart *et al.* assessed vaginal progesterone as an adjunct to cerclage in women with a markedly short or dilated cervix [22], a combined intervention not directly comparable with oral progesterone alone. These studies highlight heterogeneity in populations, routes, timing, and indications. Most women in the present cohort reached term gestation; however, the single-arm design means the observed PTB frequency cannot be attributed directly to oral progesterone. The findings should therefore be interpreted as descriptive outcomes in women presenting at 28–34 weeks with PTB risk factors rather than evidence of preventive efficacy.

The study had several limitations. Its single-centre, prospective single-arm design without a comparison group prevented direct estimation of oral progesterone efficacy. No efficacy can be inferred because there was no comparison group. Treatment began at 28–34 weeks, later than the period supported by most prophylaxis evidence, limiting comparison with earlier treatment. Only 15 PTB events occurred, reducing subgroup power, increasing the risk of Type II error, and precluding reliable multivariable analysis. Self-reported compliance and adverse effects were susceptible to recall and reporting bias. Future multicentre comparative studies should assess earlier initiation, treatment route, adherence, maternal adverse effects, and neonatal outcomes.

CONCLUSIONS

PTB occurred in 15.0% of women presenting at 28–34 weeks with risk factors for PTB and receiving oral progesterone, while 85.0% reached term gestation. Most participants showed good treatment compliance, and adverse effects were reported in 20.0%. None of the evaluated maternal, obstetric, or treatment-related factors showed a statistically significant association with PTB. The findings describe pregnancy outcomes during oral progesterone use but do not establish its preventive efficacy because the study had no comparison group.

Authors' Contribution

Conceptualization: FKK, SZ, FA, AT, SK, SA
Methodology: FKK, SZ, FA, AT, SK, SA
Formal analysis: FKK, SZ, FA, AT, SK, SA
Writing and Drafting: FKK, SZ, FA, AT, SK, SA
Review and Editing: FKK, SZ, FA, AT, SK, SA

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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