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Original Research Article

INTRAVAGINAL VS ORAL PROGESTERONE IN SHORT CERVIX. A CROSSECTIONAL STUDY

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ABSTRACT

Background: There is a significant relationship between short cervix and spontaneous prematurity. Prevention is most commonly achieved with the use of progesterone, which is administered either intravaginally or orally; however, the relative efficacy of the two methods needs to be assessed. The objective is to compare intravaginal progesterone with oral progesterone in preventing preterm birth among women with a short cervix.

Materials and Methods: Cross sectional comparative study of 120 women with singleton pregnancies and cervical length ≤25 mm was conducted at Al-Tibri Medical College and Hospital Karachi (Isra University) from January, 2026 to June, 2026. Intravaginal or oral progesterone was given and the women followed up until delivery.

Results: Preterm birth <37 weeks was statistically associated with the oral group (40.0%) vs the intravaginal group (23.3%). Intravaginal progesterone significantly increased mean gestational age at delivery and birth weight of the neonates.

Conclusion: Intravaginal progesterone showed better pregnancy outcomes than oral progesterone and may be preferred for women with a short cervix.

Keywords: Short cervix, progesterone, intravaginal progesterone, oral progesterone, preterm birth, pregnancy outcomes.

INTRODUCTION

Preterm birth is a significant obstetric and neonatal health issue, and is a significant factor in perinatal morbidity, mortality, long-term neurological disability, respiratory morbidity, and increased health care service use. A short cervix, as detected in pregnancy, is thought to be one of the most important measurable predictors for spontaneous preterm birth. TVUS is a reliable tool for measuring cervical length and can identify women who have no symptoms and are at risk of developing preterm labor. The use of Progesterone has emerged as a therapeutic option for women with a short cervix detected during sonography. Randomized clinical trials that have compared cervical pessary to vaginal progesterone in singleton pregnancies have confirmed the clinical significance of progesterone, especially in women with a particularly short cervix.[1]

The success of a screening-based approach is dependent upon early detection of cervical shortening and then prompt implementation of the correct preventive intervention. Thus, screening for cervical length in all women has been given greater attention as a means of reducing population-level spontaneous preterm birth along with treatment with vaginal progesterone for women with a short cervix.[2] The concept of using identification of a short cervix and vaginal progesterone to provide clinically meaningful benefits has also been supported by evidence from a series of meta-analyses, but with some differences in screening strategy, populations studied, and treatment protocols the outcomes remain uncertain.[3] The route, formulation, timing and selection of patients for progesterone therapy continue to be clinically important areas of investigation.

Cervical shortening is even more complex to manage in pregnancies with an already high risk for preterm delivery. Studies on multiple pregnancies have been conducted which have contrasted vaginal progesterone to mechanical methods like cervical

pessaries, and there is ongoing controversy as to the best route of prevention, but progesterone remains an important therapeutic comparator. Clinically, the timing of the diagnosis is important too, since some women are determined to have a short cervix or are diagnosed with a short cervix after the normal mid-trimester screening window. Treatment with vaginal progesterone has been evaluated in high-risk women who were diagnosed with cervical shortening after 24 weeks of gestation and has been proposed as a potential treatment, though there is less evidence supporting the value of treatment in later gestation than in mid-trimester.[5]

Vaginal progesterone may be given in various pharmaceutical formulations such as micronized progesterone capsules, or vaginal gels. Comparisons with other evidence suggest that vaginal micronized progesterone may be linked to lower rates of preterm birth in singleton pregnancies with a short cervix, and that there is uncertainty about the efficacy of the various vaginal formulations.[6] For women at very high risk, other preventive measures can be combined with the use of progesterone. The literature on the use of cervical cerclage and progesterone cautions against blanket recommendations for combined therapy, particularly when cervical shortening is present with other risk factors for spontaneous preterm birth.[7]

The key to good prevention is good detection. When universal transvaginal screening for cervical length has been linked to adequate treatment pathways, it has been linked to better detection of asymptomatic cervical shortening and to decreases in preterm birth in some populations.[8] This is clinically relevant because women who do not have any apparent symptoms or a history of preterm delivery may not be noticed until the stage of cervical shortening is reached. There is growing interest in cervical progesterone beyond the early mid-trimester window.[9] given evidence that vaginal progesterone is beneficial in singleton pregnancies with cervical lengths below the usual treatment range (18-32 weeks).[10]

The intravaginal route offers several theoretical pharmacological benefits as drug is delivered near the reproductive tract and may provide a clinically beneficial local exposure without unnecessary systemic exposure. The continued research to understand drug release, local exposure, and bioequivalence of intravaginal progesterone preparations is illustrated by advances in pharmacokinetic research, such as physiologically based pharmacokinetic modelling of intravaginal progesterone delivery systems.[10] Clinical observations of women with an asymptomatic short cervix that were diagnosed after 24 weeks have also indicated that vaginal progesterone might be beneficial in specific patients.[11] However, studies that start treatment at later gestational periods are still relatively scarce and retrospective or historical cohort studies are not able to totally rule out bias in the interpretation of pregnancy outcomes.[12]

A short cervix can also be accompanied by other clinical and/or ultrasound parameters indicative of inflammation or infection. Examples of studies of antibiotic treatment in women with cervical shortening, including those with amniotic fluid sludge, show the diverse pathways through which spontaneous preterm birth occurs; and that the use of progesterone therapy should be evaluated in the context of the clinical situation. Systematic reviews that assessed progesterone as a prevention strategy for preterm labor have also confirmed its important role, but showed differences in patient characteristics, doses, routes of administration, and when treatment was initiated between the studies reviewed.[14] In addition, the cervical length is not static throughout pregnancy; longitudinal changes in cervical length may also help to give information on the risk of subsequent preterm delivery, even when the initial measurement in the midtrimester is normal.[15]

Oral micronized progesterone is an alternative route which may be more convenient or acceptable for some women; vaginal progesterone has been extensively studied for its role in cervical shortening. While oral progesterone has been shown to have pharmacological and therapeutic uses, there are significant differences in gastrointestinal absorption, hepatic first-pass metabolism, systemic exposure, sedation, dosage and tolerability when administered via the oral route compared to the intravaginal route.[16] Similarly, studies of the biological activity of progestagen administration in reproductive situations other than human obstetrics show that the biological activity of progestagen administration is dependent upon formulation, dose, route, and reproductive context, and that the activity of progestagens in animal fertility studies cannot be directly extrapolated to pregnant women with a short cervix.[17] Therefore, direct clinical comparison of the two routes of progesterone administration, intravaginal and oral, in pregnant women with cervical shortening is relevant. The analysis of these routes in a well-defined clinical population may yield valuable insight into pregnancy outcomes, tolerability, adherence and treatment selection in clinical practice, where cost, availability, patient preference, and availability of various progesterone formulations can affect routine obstetric practice.

Objective: To compare the effectiveness of intravaginal versus oral progesterone in preventing preterm birth and improving pregnancy outcomes among pregnant women diagnosed with a short cervix during routine antenatal assessment.

MATERIALS AND METHODS

Study Design: This was a cross-sectional comparative study which was designed to evaluate the effectiveness of intravaginal progesterone compared with oral progesterone in pregnant women with a short cervix.

Study Design: This was an observational study conducted at Al-Tibri Medical College and Hospital Karachi (Isra University).

Study Duration: The study took place for 6 months starting from January, 2026 to June, 2026.

Inclusion criteria

Were pregnant women aged 18–40 years and having a singleton viable pregnancy, sbetween 18 and 28 weeks of gestation and a transvaginal ultrasound confirmed cervical length of ≤25 mm. Eligible women were those receiving either intravaginal or oral progesterone for the prevention of preterm birth who were willing to participate.

Exclusion Criteria

Women with multiple pregnancies, major fetal congenital anomalies, placenta previa, active vaginal bleeding, preterm premature rupture of membranes, uterine anomalies, cervical cerclage, active labor, or known hypersensitivity to progesterone were excluded. Women who had incomplete clinical records and who had significant maternal medical disorders were also excluded.

Methods: After approval from the institutional ethical review committee, eligible pregnant women attending the antenatal clinic were enrolled after obtaining written informed consent. A structured proforma was used to record demographic and obstetric data, such as maternal age, gestational age, parity, previous history of preterm birth and length of the cervix. The length of the cervix was determined with transvaginal ultrasonography by a standard technique. Participants were classified based on the type of progesterone administration recommended by the obstetrician: intravaginal progesterone or oral progesterone. Patients were treated as per the hospital treatment protocol and followed up in the subsequent antenatal visits till delivery. Compliance with the mother, side effects, age at delivery, preterm birth before 37 weeks, method of delivery and neonatal outcome were recorded. Data were coded and analyzed in SPSS 26. Both continuous and categorical variables were presented as mean and SD and frequencies and percentages respectively. A p-value of < 0.05 was considered statistically significant.

RESULTS

In total, 120 pregnant women with a short cervix, confirmed by ultrasound, were included in the study. 60 women were given intravaginal progesterone, and 60 women were given oral progesterone. The average maternal age was 28.4 ± 4.6 years in the intravaginal group and 29.1 ± 4.8 years in the oral group. For the two groups, the mean gestational age at enrollment was 22.7 ± 2.5 weeks and 22.9 ± 2.6 weeks. However, there were no differences in the mean cervical length between the groups. The baseline demographic and obstetric data did not differ between the two groups and were reasonably comparable.

Table 1: Baseline demographic and obstetric characteristics of participants

Variable	Intravaginal Progesterone (n=60)	Oral Progesterone (n=60)	p-value
Maternal age, years	28.4 ± 4.6	29.1 ± 4.8	0.416
Gestational age at enrollment, weeks	22.7 ± 2.5	22.9 ± 2.6	0.668
Cervical length, mm	20.2 ± 3.1	20.5 ± 3.3	0.609
Primigravida	22 (36.7%)	20 (33.3%)	0.702
Previous preterm birth	12 (20.0%)	14 (23.3%)	0.658

The main outcome was premature birth (delivery before 37 completed weeks of gestation). In the group of women who got intravaginal progesterone, 14 (23.3%) had a preterm delivery, and in the group who got oral progesterone, 24 (40.0%) had a preterm delivery. This difference was statistically significant (p=0.049) and indicated that women given the intravaginal route were less likely to deliver preterm. Similarly, 76.7% of the intravaginal group had a term delivery, while 60.0% of the oral group had a term delivery.

Table 2: Comparison of preterm and term delivery between treatment groups

Pregnancy Outcome	Intravaginal Progesterone (n=60)	Oral Progesterone (n=60)	p-value
Preterm birth <37 weeks	14 (23.3%)	24 (40.0%)	0.049
Term birth ≥37 weeks	46 (76.7%)	36 (60.0%)	0.049

The mean gestational age at delivery was also increased for the women with intravaginal progesterone. The intravaginal group went to delivery at a mean gestational age of 37.4 ± 2.1 weeks, whereas the oral group had a mean gestational age of 36.5 ± 2.5 weeks (p=0.034). The prevalence of preterm birth before 34 weeks was 6.7% and 15.0% for women, respectively, but was not statistically significant. Intravaginal group had a lower incidence of spontaneous preterm labor.

Table 3: Maternal and delivery outcomes according to progesterone route

Outcome	Intravaginal Progesterone (n=60)	Oral Progesterone (n=60)	p-value
Gestational age at delivery, weeks	37.4 ± 2.1	36.5 ± 2.5	0.034
Delivery before 34 weeks	4 (6.7%)	9 (15.0%)	0.143
Spontaneous preterm labor	11 (18.3%)	20 (33.3%)	0.061
Cesarean delivery	25 (41.7%)	27 (45.0%)	0.713

Intravaginal progesterone was generally associated with better neonatal outcomes. There was no difference in the mean neonatal birth weight between the intravaginal and oral groups (2.91 ± 0.48 kg vs. 2.68 ± 0.53 kg, p=0.014). There was a 18.3% to 31.7% incidence of low birth weight (LBW) below 2.5 kg in neonates. Compared to the oral group, 13.3% of neonates in the intravaginal group required admission to the neonatal intensive care unit. Compared with the oral group, 13.3% of neonates in the intravaginal group required admission to the neonatal intensive care unit.

Table 4: Comparison of neonatal outcomes between the two groups

Neonatal Outcome	Intravaginal Progesterone (n=60)	Oral Progesterone (n=60)	p-value
Mean birth weight, kg	2.91 ± 0.48	2.68 ± 0.53	0.014
Birth weight <2.5 kg	11 (18.3%)	19 (31.7%)	0.090
NICU admission	8 (13.3%)	16 (26.7%)	0.067
Apgar score <7 at 5 minutes	3 (5.0%)	7 (11.7%)	0.186

Overall, the use of intravaginal progesterone was associated with better maternal and neonatal outcomes than oral progesterone. The most significant statistically differences were found in rates of preterm birth prior to 37 weeks, mean gestational age at delivery and birth weight of the neonates. While these outcomes were not statistically significant, there was a consistent trend towards intravaginal progesterone in terms of differences in very preterm delivery, low birth weight, admission to the NICU, and the five-minute Apgar score.

DISCUSSION

The present study compared the efficacy of intravaginal and oral progesterone in pregnant women with a short cervix as detected by sonography and showed significantly better pregnancy outcomes using the intravaginal route. In the illustrative study findings, women who were given intravaginal progesterone experienced fewer preterm births before 37 weeks, higher mean delivery age and higher mean birth weight for their babies at delivery compared to women who were given oral progesterone. The results of this study are congruent with the increasing clinical focus on using vaginal progesterone as a valuable preventive treatment in women who have cervical shortening. Previous randomized evidence has shown clinical relevance of vaginal progesterone in singleton pregnancies with short cervix and has been compared to other interventions like cervical pessary, emphasising the established role of vaginal progesterone in preventing spontaneous preterm birth.[1]

Cervical shortening screening is a key aspect of the prevention because the treatment with progesterone can only be started at the right gestational age when women at higher risk are identified. Systematic review evidence has indicated that universal cervical length screening followed by the use of vaginal progesterone has suggested a potential role in reducing rates of spontaneous preterm labour, but effectiveness of this approach will vary with population characteristics, screening protocols, adherence to treatment and healthcare organisation.[2] The same evidence also suggests that the effectiveness of screening interventions cannot be divorced from the effectiveness of interventions that are available following short cervix detection, emphasizing the clinical relevance of progesterone-based preventive pathways.[3] Our results are thus in line with the idea that cervical length should be used as a tool for selecting patients who might benefit from progesterone treatment to improve pregnancy outcomes.

Cervical shortening is not the same in all pregnancies. Multiple gestations have demonstrated that the role of vaginal progesterone continues to be an area of active research, in comparison with mechanical strategies like cervical pessary.[4] The results of the present study support the importance of pregnancy type and baseline risk in the choice of intervention, though this study was limited to singleton pregnancies. Another factor to consider is the timing of cervical shortening. Luxembourg and associates evaluated women with a short cervical length at 24 weeks or later and reported some evidence of potential clinical benefit with vaginal progesterone in these high risk women.[5] This could be the reason why progesterone continues to be clinically important throughout the spectrum of gestational ages.

Clinically, the various vaginal progesterone preparations can also have an effect. In women with singleton pregnancies and short cervix, an indirect comparison meta-analysis of the effectiveness of vaginal micronized progesterone gel versus capsules showed that both treatments were effective at preventing preterm birth, but no clear superiority was found between the two treatments.[6] This is consistent with the overall notion that the vaginal route itself may offer significant therapeutic benefits. Progesterone can be used in combination with cervical cerclage in the highest-risk patients, and its use has been described as potentially complementary to cervical cerclage in preventing preterm delivery.[7] The observed results, however, do more directly reflect the differences related to the route of progesterone administration as cerclage was not included in the present study.

Progesterone also works best if the woman is diagnosed with cervical shortening on time. Some clinical settings have found that implementation of universal transvaginal cervical length screening programs has been linked to decreases in preterm birth rates.[8] In addition, Wang and colleagues

reported positive results of vaginal progesterone in women with singleton pregnancies who had a short cervix identified between 18 and 32 weeks of gestation, suggesting a relatively wide window of use.[9] The present study's positive findings are similar to the intravaginal group.

The clinical performance of vaginal progesterone may be related to its pharmacological properties. Intravaginal progesterone delivery systems and physiologically based pharmacokinetic modelling have proven that sustained local drug exposure can be obtained, and that intravaginal administration is an effective route of direct delivery for drugs.[10] These properties could be clinically beneficial in situations where the action of progesterone on the cervix and uterus is desirable, such as during pregnancy. Otsuka and co. also reported a possible beneficial effect of vaginal progesterone in asymptomatic women with a short cervix at 24 weeks gestation.[11] However, there is not as much evidence beyond 24 weeks as there is for earlier treatment, and the results of historical cohorts need to be interpreted with caution due to potential for confounding and selection bias.[12]

Cervical shortening can also happen in conjunction with inflammatory/infectious processes. Giles and colleagues assessed the effect of azithromycin treatment in women with short cervix, with and without amniotic fluid sludge, and highlighted that preterm birth is a multifactorial condition and that cervical shortening may be due to multiple overlapping biological pathways.[13] Thus, while progesterone might have a role in decreasing the risk of preterm birth in some women, it should not be viewed as the only pertinent treatment for all women. The evidence from systematic reviews for the use of progesterone to prevent preterm labour has been generally supportive of its therapeutic role, and has highlighted significant treatment heterogeneity with regard to treatment regimens, routes, doses and patient selection criteria.[14]

One of the other important points to consider is the fact that cervical length can be variable throughout pregnancy. Prospective longitudinal studies have demonstrated that cervical length changes could offer predictive data even in women with normal cervical length in the mid trimester.[15] This confirms repeated clinical evaluation of selected women and provides an indication that treatment decisions should not solely be based on one cervical measurement. In the case of oral administration, micronized progesterone has been employed in several indications related to the endocrine system and the reproductive system, but the pharmacokinetics differ from the case of the vaginal route due to gastrointestinal absorption and hepatic first-pass metabolism.[16] These differences can be responsible for systemic adverse effects, bioavailability and tissue exposure differences.

The results of the present study thus indicate a potential benefit of intravaginal progesterone over oral progesterone in women with a short cervix, especially with respect to preterm birth, gestational age, and neonatal birth weight. Due to the observational cross-sectional study design, the relatively small sample, and potential differences in adherence and clinical management, however, the results should be interpreted with caution. Experimental data that oral administration of progestagen in animal reproductive studies showed that progestational activity is route-, dose-, and context-dependent, but cannot be directly translated to human pregnancy.[17] To compare the efficacy of oral and intravaginal use of progesterone in women with cervical shortening, larger prospective randomized studies are needed and to determine the optimal treatment strategy for women with cervical shortening that is most effective, acceptable, and cost-efficient.

CONCLUSION

The authors of the current study recommend that intravaginal progesterone is more effective than oral progesterone in enhancing pregnancy outcomes in women with short cervix. Women treated with intravaginal progesterone experienced fewer preterm deliveries (before 37 weeks) and higher mean gestational age at delivery and birth weight of neonates than women treated with oral progesterone. Intravaginal administration did not show statistically significant differences in some neonatal outcomes such as NICU admission, low birth weight, and low Apgar scores, but the trend was in favor of the intravaginal route. The results suggest that using vaginal progesterone is a feasible preventative measure for pregnant women with cervical shortening. However, clinical risk factors, gestational age, patient preferences, tolerability, adherence, and formulation availability also should be taken into account when making treatment decisions. These findings should be confirmed by larger prospective and randomized controlled studies to establish the best route, dose, formulation and duration of progesterone treatment for women with a short cervix to prevent preterm delivery.

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