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Efficacy of Oral Progesterone Treatment in Women with Unexplained Recurrent First Miscarriages

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ABSTRACT

Recurrent miscarriage in the first trimester is a difficult and emotionally draining problem, affecting nearly 1–2% of women. In many cases, no clear cause can be found. Progesterone is known to help support early pregnancy by stabilizing the endometrium and reducing uterine contractions. **Objective:** To assess how effective oral progesterone is in women who have had repeated unexplained first-trimester miscarriages. **Methods:** This was a prospective, non-randomized single-arm interventional study conducted in the Department of Obstetrics and Gynecology, Combined Military Hospital, Bahawalpur, between August 02, 2024, and February 01, 2025. A total of 152 women aged 20–40 years, each with a history of ≥2 unexplained consecutive first-trimester miscarriages and a confirmed intrauterine viable pregnancy of <12 weeks, were included. All participants received oral dydrogesterone (10 mg twice daily) until completion of 12 weeks' gestation, with follow-up assessments every two weeks. Data were analyzed using SPSS version 26.0. **Results:** Efficacy was defined as pregnancy continuation beyond 12 completed weeks of gestation following therapy; live birth (where available) was recorded as an additional outcome. Associations were examined using chi-square tests and multivariable binary logistic regression, with $p<0.05$ considered statistically significant. **Conclusions:** In this single-arm cohort, oral dydrogesterone was associated with continuation of pregnancy beyond 12 weeks or live birth in 78.9% of women with unexplained recurrent first-trimester miscarriages. As no untreated comparator group was included, this study cannot determine whether dydrogesterone improves live birth outcomes compared with no progesterone therapy; randomized controlled studies are needed to confirm comparative effectiveness.

INTRODUCTION

Recurrent miscarriage (RM) refers to the loss of two or more consecutive pregnancies before twenty weeks of gestation. It affects around 1–2% of women in their reproductive years and is both emotionally and clinically challenging [1]. In almost half of these cases, no clear reason can be found even after a complete work-up [2]. Progesterone, a key steroid hormone that prepares the endometrium for implantation and helps maintain early pregnancy, has long been considered a possible treatment to reduce miscarriage risk [3, 4]. Various progesterone preparations have been used in clinical practice, including oral micronized progesterone and dydrogesterone. Several studies have reported potential benefits of progesterone supplementation in selected women with unexplained RM; however, results have been inconsistent across trials and populations [5, 6]. Progesterone may support early pregnancy through multiple mechanisms, including modulation of immune tolerance, facilitation of trophoblastic invasion, and reduction of uterine contractility processes that are particularly important during the first trimester [7]. The use of progesterone has also been investigated in large randomized controlled trials, such as PROMISE and PRISM. Although the overall effect was small, some subgroups, especially women with early pregnancy bleeding and a history of multiple prior miscarriages, showed higher rates of live births with

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progesterone supplementation [8, 9]. This trend was further supported by a Cochrane meta-analysis suggesting a probable reduction in miscarriage risk, particularly among women with three or more prior losses [10]. Oral dydrogesterone is commonly used due to its convenient oral route and established clinical use in early pregnancy support; however, direct head-to-head comparisons with other progesterone formulations (such as vaginal micronized progesterone) remain limited and have reported mixed findings [6, 11]. In addition, a recent double-blind RCT did not show a statistically significant reduction in miscarriage rates with oral progestogen compared with placebo among women with threatened miscarriage [12].

Taken together, these findings highlight ongoing uncertainty regarding the magnitude of benefit and the populations most likely to respond, indicating the need for further evidence. Recurrent first-trimester miscarriage remains a distressing condition with many contributing factors, and in nearly half of women, no definite cause can be identified. Because progesterone plays a central role in implantation and early pregnancy maintenance, helping stabilize the endometrium, reduce uterine contractility, and regulate immune tolerance, some researchers propose that subtle luteal phase insufficiency may contribute to unexplained RM in a subset of patients. Progesterone supplementation may help support early gestation in such cases. Despite increasing international evidence, data from local populations remain scarce. This study aimed to assess pregnancy outcomes and tolerability among women with unexplained recurrent first-trimester miscarriages treated with oral dydrogesterone, aiming to provide locally relevant evidence to inform clinical practice.

METHODS

This prospective, non-randomized single-arm interventional (quasi-experimental) study was conducted in the Department of Obstetrics and Gynecology, Combined Military Hospital, Bahawalpur, from August 02, 2024, to February 01, 2025. The study was approved by the IRB (EC-6-2023). The sample size was calculated using the standard formula for estimation of a single population proportion: $n = Z^2 \times p \times (1 - p) / d^2$, where Z = 1.96 for a 95% confidence level, p=0.889 (expected efficacy rate of oral progestogen reported by Shinwari *et al.*), and d = 0.05 (margin of error). The calculated sample size was 152 patients [13]. A non-probability consecutive sampling technique was used, and all eligible women presenting during the study period and fulfilling the inclusion criteria were enrolled until the required sample size was achieved. Women aged 20–40 years with a history of ≥2 consecutive first-trimester miscarriages without an identifiable cause and a confirmed intrauterine pregnancy of <12 weeks on ultrasound were included after obtaining informed written consent. Patients with miscarriages due to known causes such as uterine anomalies, chromosomal abnormalities, uncontrolled endocrine disorders, antiphospholipid syndrome, or thrombophilia were excluded. Women with multiple or ectopic pregnancies, those using other hormonal or immunologic therapies, and those with an allergy to progesterone or serious systemic illness were also excluded. Intervention: All enrolled participants received oral dydrogesterone 10 mg twice daily, started at confirmation of intrauterine pregnancy and continued until completion of 12 weeks of gestation. No randomization and no comparator arm were used. Outcome definitions: The primary efficacy outcome was pregnancy continuation beyond 12 completed weeks of gestation following oral dydrogesterone therapy. Pregnancy was labeled effective if it continued beyond 12 completed weeks and not effective if miscarriage occurred before 12 weeks despite treatment. Live birth (where available) was recorded as an additional pregnancy outcome measure. As all enrolled participants received dydrogesterone, no untreated control group was available; therefore, comparative effectiveness versus no progesterone therapy could not be assessed. All eligible participants were identified from antenatal clinics and gynecology wards. After consent, baseline demographic and obstetric information, including age, BMI, gravidity, and parity, was recorded on a structured proforma. Compliance was reinforced through counseling and follow-up every two weeks until 12 weeks of gestation. At each visit, participants were assessed for fetal viability by ultrasound and for adverse effects such as nausea, dizziness, or breast tenderness. Data regarding dose, duration of therapy, gestational age at outcome, and adverse effects were documented. All data were entered and analyzed using SPSS version 26. Quantitative variables such as age, BMI, duration of therapy, and gestational age at outcome were expressed as mean ± standard deviation (SD). Qualitative variables, including efficacy and adverse effects, were presented as frequencies and percentages with 95% confidence intervals (CI). The primary outcome (efficacy) was analyzed as a proportion with 95% CI. For inferential analysis, the association between efficacy and categorical variables such as age group and BMI category was assessed using the chi-square test. For continuous predictors (e.g., duration of therapy), the independent-sample t-test was applied as appropriate. To identify independent predictors of efficacy, binary logistic regression analysis was performed, including relevant demographic and clinical variables. Adjusted odds ratios (AOR) with 95% confidence intervals were reported. A p-value of <0.05 was considered statistically significant.

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RESULTS

A total of 152 women were included in the study. The mean age of the participants was 29.53 ± 5.97 years. The mean BMI was 25.91 ± 4.20 kg/m^2, while the mean duration of progesterone therapy was 10.07 ± 1.42 weeks. The mean gestational age at outcome was 23.72 ± 10.31 weeks. Out of 152 women included in the study, 120 (78.9%) achieved pregnancy continuation beyond 12 completed weeks following oral dydrogesterone therapy (95% CI: 71.8%–84.7%), while 32 (21.1%) experienced miscarriage before 12 weeks (Figure 1).

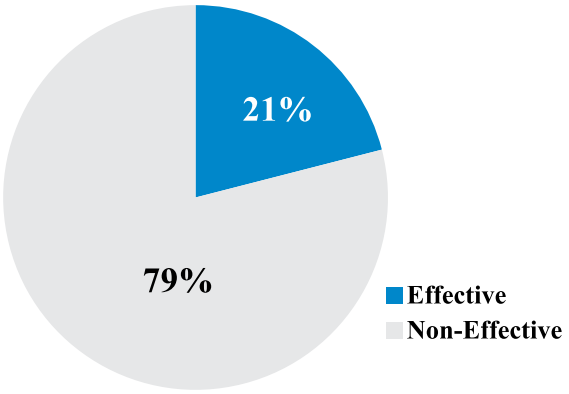

Figure 1: Frequency of Efficacy

The study summarizes the association between baseline/clinical characteristics and treatment efficacy, defined as pregnancy continuation beyond 12 completed weeks among women receiving oral dydrogesterone. Efficacy was numerically higher among women aged ≤30 years (83.1%) compared with those aged >30 years (73.9%); however, this difference was not statistically significant (p = 0.165). Gravidity and parity were not significantly associated with efficacy (p = 0.605 and p = 0.204, respectively). Likewise, BMI category showed no significant association with response (non-obese: 82.8% vs obese: 76.6%; p = 0.365). Women who reported mild adverse effects had a higher observed efficacy rate (88.2%) than those without adverse effects (76.3%), but this difference was also not statistically significant (p = 0.132). Overall, none of the evaluated demographic or clinical variables demonstrated a statistically significant association with efficacy in univariate analysis (Table 1).

Table 1: Association of Demographic and Clinical Variables with Efficacy of Oral Progesterone Treatment (n=152)

Variables	Category	Not Effective n (%)	Effective n (%)	Total	p-value	Odds Ratio (95% CI)
Age Group	≤30 Years	14 (16.9%)	69 (83.1%)	83	0.165	0.58 (0.26–1.26)
	>30 Years	18 (26.1%)	51 (73.9%)	69		
Gravidity	Primigravida	6 (25.0%)	18 (75.0%)	24	0.605	1.31 (0.47–3.62)
	Multigravida	26 (20.3%)	102 (79.7%)	128		
Parity	Nulliparous	11 (28.2%)	28 (71.8%)	39	0.204	1.72 (0.74–4.00)
	Multiparous	21 (18.6%)	92 (81.4%)	113		
Obesity (BMI Group)	Non-obese (<25)	10 (17.2%)	48 (82.8%)	58	0.365	0.68 (0.30–1.57)
	Obese (≥25)	22 (23.4%)	72 (76.6%)	94		
Adverse Effects	No	28 (23.7%)	90 (76.3%)	118	0.132	2.33 (0.76–7.20)
	Yes	4 (11.8%)	30 (88.2%)	34		

Binary logistic regression was performed to identify independent predictors of treatment efficacy (defined as pregnancy continuation beyond 12 completed weeks) among women receiving oral dydrogesterone. The overall model was not statistically significant (χ^2 = 8.34, p=0.303), and the Hosmer–Lemeshow test indicated good model fit (p=0.925). The Nagelkerke R^2 value (0.083) suggested that approximately 8.3% of the variation in efficacy was explained by the variables included in the model. None of the predictors reached statistical significance at p<0.05. Women aged ≤30 years had higher odds of efficacy than those >30 years (AOR = 1.78, 95% CI 0.79–4.00; p=0.162). Gravidity (AOR = 1.43, 95% CI 0.33–6.11; p=0.631), parity (AOR = 0.41, 95% CI 0.12–1.39; p=0.152), obesity (AOR = 1.64, 95% CI 0.68–3.95; p=0.271), duration of therapy (AOR = 0.90, 95% CI 0.68–1.21; p=0.491), and gestational age at outcome (AOR = 1.01, 95% CI 0.97–1.05; p=0.547) were not independently associated with efficacy. With respect to adverse effects, the model used "Yes" as the reference category; therefore, women with no adverse effects had lower odds of efficacy compared with those reporting adverse effects (AOR = 0.37, 95% CI 0.12–1.19; p=0.095), although this was not statistically significant (Table 2).

Table 2: Binary Logistic Regression Analysis for Factors Associated with Efficacy of Oral Progesterone Treatment (n=152

Variables	B	S.E.	p-value	AOR (Exp B)	95% CI for AOR
Age ≤ 30 Years vs > 30 Years	0.577	0.413	0.162	1.78	0.79 – 4.00
Gravidity (Primigravida vs Multigravida)	0.356	0.742	0.631	1.43	0.33 – 6.11
Parity (Nulliparous vs Multiparous)	-0.902	0.629	0.152	0.41	0.12 – 1.39
Obesity (Non-obese vs Obese)	0.494	0.448	0.271	1.64	0.68 – 3.95
Duration of Therapy (Weeks)	-0.101	0.147	0.491	0.90	0.68 – 1.21
Gestational Age at Outcome (Weeks)	0.012	0.020	0.547	1.01	0.97 – 1.05
Adverse Effects (No vs Yes)	-0.997	0.596	0.095	0.37	0.12 – 1.19
Constant	2.603	1.691	0.124	13.50	—

(AOR = Adjusted Odds Ratio; CI = Confidence Interval; Reference categories => 30 years, Multigravida, Multiparous, Obese, Adverse effects = Yes). Model fit: χ^2 = 8.34 (df = 7, p=0.303); Hosmer-Lemeshow χ^2 = 3.14 (df = 8, p=0.925); Nagelkerke R^2 = 0.083.

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DISCUSSION

In this study, oral dydrogesterone was associated with an efficacy rate of 78.9% in women with unexplained recurrent first-trimester miscarriages. This outcome is consistent with previous literature suggesting that progesterone supplementation may support early pregnancy in selected women with recurrent miscarriage. Shinwari *et al.* reported higher success rates with oral progestogens (88.9%) than with vaginal preparations (66.7%) [13]. However, as those findings arise from a different study design and population, and because our study did not include a vaginal progesterone comparator arm, our data do not allow conclusions regarding the superiority of the oral route. Nevertheless, our results indicate that pregnancy continuation beyond the first trimester was observed in a substantial proportion of women receiving oral dydrogesterone in routine clinical settings. Clinical guidance has also discussed the role of oral dydrogesterone in threatened miscarriage and recurrent pregnancy loss. The Thai interest group guideline supports the use of oral dydrogesterone in threatened miscarriage and unexplained recurrent pregnancy loss, primarily citing ease of dosing and tolerability [14]. The guideline also highlights concerns related to variable absorption and patient discomfort with vaginal micronized progesterone when used in high or unnecessary doses [14]. While these recommendations align with common clinical practice, our findings should be interpreted as observational outcomes in a single-arm cohort rather than evidence of preference over alternative formulations. However, not all studies have demonstrated a clear benefit of progesterone in recurrent miscarriage. The PROMISE trial by Coomarasamy *et al.* reported no significant difference between vaginal progesterone and placebo in women with recurrent miscarriage [15]. Such discrepancies across studies may reflect differences in progesterone formulation, route of administration, timing of initiation, dosing regimens, and heterogeneity in underlying patient characteristics. In this context, our findings contribute local data on outcomes among women treated with oral dydrogesterone; however, direct comparisons with vaginal progesterone or placebo cannot be made within this study. Guo and Lu provide mechanistic insight into why dydrogesterone may be beneficial in some patients [16]. They reported that dydrogesterone may promote a more favorable immune environment by increasing anti-inflammatory cytokines (IL-4 and IL-10) and reducing IFN-γ levels. Because immune dysregulation has been implicated in unexplained recurrent miscarriage, this immunomodulatory pathway may partly explain the favorable outcomes observed in some cohorts, including ours. In their meta-analysis, Saccone *et al.* also reported that first-trimester progestogen use may reduce recurrent miscarriage and improve the likelihood of live birth [17]. They discussed the potential role of synthetic progestogens (including dydrogesterone and hydroxyprogesterone caproate) in early pregnancy support. While such findings are encouraging, it remains important to distinguish pooled evidence from individual cohort outcomes and to consider differences in study design and comparator groups when interpreting effectiveness. Pandya *et al.* described potential advantages of dydrogesterone, including good oral absorption, receptor selectivity, and a generally favorable tolerability profile, and noted its use in threatened and recurrent miscarriage [18]. Similarly, Kriplani *et al.* supported its acceptability in clinical practice and reported favorable safety observations [19]. In our cohort, treatment was generally well tolerated, and no major safety concerns were observed, supporting its practical feasibility in this setting. Ranjan *et al.* reported lower miscarriage rates and higher live birth rates among women who received progesterone compared with those who did not [20]. While this supports the broader hypothesis that progesterone may be beneficial in recurrent pregnancy loss, our study design does not permit causal inference or definitive comparison against no progesterone therapy. Influence of BMI on response: In our dataset, the BMI category was not significantly associated with treatment response. Efficacy was 82.8% among non-obese women and 76.6% among obese women (p = 0.365). In multivariable logistic regression, obesity was also not an independent predictor of efficacy (AOR = 1.64, 95% CI 0.68–3.95; p = 0.271). These findings suggest that the observed pregnancy continuation beyond 12 completed weeks after dydrogesterone therapy was broadly similar across BMI groups in this cohort.

Limitations of the Study: Non-randomized, single-arm, no control group, single-center, short follow-up (12 weeks), no blinding, lack of confounder adjustment, and subjective measure of adherence. Future Recommendations: Multicenter RCTs with placebo comparators, longer postpartum follow-up to live birth, blinding, and oral versus vaginal progesterone should be carried out. Add subgroup analysis of the previous number of miscarriages, age, and BMI.

CONCLUSIONS

In this cohort of women with unexplained recurrent first-trimester miscarriage who received oral dydrogesterone, 78.9% of pregnancies continued beyond 12 weeks or resulted in live birth, and adverse effects were generally mild. However, because this study lacked an untreated control group, a definitive comparison with no progesterone therapy cannot be made. Comparative trials are recommended to confirm whether oral dydrogesterone

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improves live birth outcomes versus no treatment and to identify subgroups most likely to benefit.

Authors' Contribution

Conceptualization: MUAZ
Methodology: MUAZ
Formal analysis: SZ
Writing and Drafting: SZ
Review and Editing: MUAZ, SZ

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

Conflicts of Interest

All the authors declare no conflict of interest.

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