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Evaluation of Effectiveness of Letrozole-Based Ovulation Induction in Rural Women with Polycystic Ovary Syndrome

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Key words:
Letrozole, PCOS, ovulation induction, pregnancy outcomes.

Abstract

Background: *Polycystic ovary syndrome (PCOS) is a leading cause of anovulatory infertility, with letrozole emerging as an effective first-line ovulation induction agent. Evidence from rural populations remains limited, despite potential differences in clinical presentation, treatment responsiveness, and access to reproductive care. This study aimed to evaluate the effectiveness of letrozole-based ovulation induction in rural women with PCOS who achieved positive pregnancy outcomes.* ***Methods:*** *This prospective observational study included 60 women treated at Jahurunessa Hospital, Rupganj, Narayanganj, from June 2024 to July 2025. Baseline demographic, hormonal, and clinical features were recorded. Treatment characteristics, ovulatory response, and pregnancy outcomes were evaluated. Data were analyzed using SPSS version 25.0.* ***Results:*** *The mean age of the study population was 23.38 ± 3.1 years and a BMI of 26.42 ± 1.98 kg/m². Oligomenorrhea (90%) and hyperandrogenism (83.3%) were prevalent. All women achieved ovulation, with a median of 1 (IQR 1–2) mature follicles and a mean endometrial thickness of 10.5 ± 1.4 mm. Clinical pregnancy was confirmed in all cases, while biochemical pregnancy occurred in 70%. Live birth, ongoing pregnancy, abortion, and ectopic pregnancy rates were 76.7%, 15%, 6.7%, and 1.7%, respectively. Complications were minimal, including ovarian hyperstimulation syndrome (6.7%) and multiple pregnancy (5%).* ***Conclusion:*** *Letrozole-based ovulation induction demonstrated excellent ovulatory and reproductive outcomes in rural women with PCOS, supporting its use as an effective and feasible first-line therapy in resource-limited settings.*

Introduction

Polycystic ovary syndrome (PCOS) remains one of the most common endocrine disorders affecting reproductive-aged women worldwide and is a leading cause of anovulatory infertility. Characterized by hyperandrogenism, ovulatory dysfunction, and polycystic ovarian morphology, the syndrome manifests heterogeneously, influenced by metabolic, genetic, and environmental factors.[1,2] Global prevalence estimates vary due to differences in diagnostic criteria, but studies consistently suggest that PCOS affects up to one in five women, with substantial implications for reproductive and metabolic health.[3,4] Beyond infertility, the condition is associated with insulin resistance, menstrual irregularity, and long-term risks such as type 2 diabetes and cardiovascular complications.[5]

Ovulation induction is a cornerstone of infertility management in anovulatory PCOS, long dominated by clomiphene citrate (CC) as first-line therapy. Although effective, CC's anti-estrogenic effects on the endometrium and cervical mucus are well recognized, potentially reducing implantation rates.[6,7] Letrozole, a third-generation aromatase

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inhibitor, emerged as a promising alternative due to its ability to induce mono- or bi-follicular development with minimal peripheral anti-estrogenic effects.[8] Letrozole promotes ovulation by transiently reducing estrogen synthesis, thereby stimulating endogenous gonadotropin release without adversely affecting endometrial receptivity.[9] Over the past decade, accumulating evidence has positioned letrozole as a superior first-line agent in many clinical contexts, with higher ovulation, pregnancy, and live birth rates compared with CC.[10,11]

Randomized controlled trials and meta-analyses reinforced the advantages of letrozole, particularly in clomiphene-resistant women and those with pronounced hyperandrogenism.[12,13] Studies reported enhanced endometrial thickness, improved follicular recruitment, and lower rates of multiple gestations relative to CC, contributing to better overall reproductive outcomes.[14] While letrozole's effectiveness is well established in tertiary-care and urban populations, evidence from rural settings—where delayed presentation, lower health literacy, and limited access to specialist care may alter treatment responsiveness—remains sparse. In such populations, PCOS often presents with prolonged untreated menstrual dysfunction, metabolic derangements, and increased psychosocial burden, all of which may influence ovulatory response and pregnancy rates.[15,16]

Bangladesh, particularly its rural regions, faces unique reproductive health challenges. Sociocultural barriers, limited diagnostic facilities, and delayed access to fertility services contribute to prolonged infertility before treatment initiation. Despite these constraints, letrozole is widely used due to its affordability, favourable safety profile, and minimal need for intensive monitoring. However, empirical data on its real-world effectiveness in rural Bangladeshi women remain limited. Understanding treatment response in these populations is essential for optimizing fertility management and developing context-appropriate clinical guidelines.

This study addresses a critical gap by analyzing pregnancy-positive cases following letrozole-based ovulation induction in rural women with PCOS. Examining hormonal profiles, ovarian response, treatment characteristics, and pregnancy outcomes provides meaningful insights into the clinical performance of letrozole in a resource-limited setting. The findings contribute to the growing body of evidence supporting letrozole as an effective ovulation-induction agent and offer practical implications for clinicians working in rural reproductive health care.

Methods:

This prospective observational study was conducted at Jahurunessa Hospital, Rupganj, Narayanganj, from *June 2024 to July 2025*. This study included 63 reproductive-aged women diagnosed with polycystic ovary syndrome (PCOS) who underwent letrozole-based ovulation induction and subsequently achieved pregnancy. Three patients dropped out of the study; therefore, the final sample size was 60. All participants were residents of rural communities surrounding the hospital and were managed through the hospital's infertility clinic, following standardized diagnostic and treatment protocols.

Inclusion Criterias were women aged 18–35 years. Diagnosed with PCOS based on the Rotterdam criteria. History of anovulatory infertility (primary or secondary). Underwent ovulation induction with letrozole during the study period. Achieved biochemical or clinical pregnancy following treatment. Provided informed consent. Exclusion Criteria following were Known tubal pathology or hydrosalpinx. Male-factor infertility documented by abnormal semen analysis. Thyroid dysfunction, hyperprolactinemia, or uncontrolled metabolic disorders. Use of other ovulation-induction agents in the same cycle. Incomplete clinical, hormonal, or follow-up data.

Data collection followed a structured and standardized protocol to ensure completeness and consistency across all cases. At enrollment, each participant underwent a comprehensive clinical evaluation that included detailed reproductive history, menstrual patterns, and previous infertility treatments. Anthropometric

measurements such as height, weight, and BMI were recorded using calibrated equipment. Baseline hormonal assessment was performed on days 2–3 of the menstrual cycle, including serum FSH, LH, AMH, and evaluation of hyperandrogenism, using validated chemiluminescent immunoassay techniques available in the hospital's diagnostic laboratory. Transvaginal ultrasonography was conducted by an experienced gynecologist to document antral follicle count, ovarian morphology, and baseline endometrial thickness using a standardized imaging protocol.

Letrozole was administered at individualized doses of 5 mg or 7.5 mg based on clinician assessment and prior treatment response. Follicular monitoring was performed through serial ultrasonography beginning on cycle days 9–10, with tracking of dominant follicle development, endometrial changes, and timing of ovulation trigger when indicated. Data on treatment cycles, number of mature follicles, ovulation confirmation, and administration of hCG trigger injections were recorded. Pregnancy outcomes—including biochemical pregnancy, clinical pregnancy on ultrasound, and early complications—were documented during follow-up visits. Informed consent was obtained from all participants after explaining the study objectives, procedures, and confidentiality safeguards. The study adhered to the principles of the Declaration of Helsinki.

Data analysis was performed using SPSS version 25.0. Descriptive statistics summarized demographic, hormonal, and treatment variables using means, standard deviations, frequencies, and percentages. Inferential statistics, including median and interquartile ranges, were applied where appropriate. Results were organized in structured tables and figures to present ovulatory response and reproductive outcomes clearly and objectively.

Results:

Table I presents the baseline demographic and clinical characteristics of the study population (n=60). Most participants were between 18 and 24 years (66.7%), with a mean age of 23.38 ± 3.1 years. The mean BMI was 26.42 ± 1.98 kg/m². Primary infertility was more common (60%), and the mean duration of infertility was 2.4 ± 1.2 years. A majority (71.7%) were nulliparous, while previous pregnancy loss was reported in a small proportion (13.3%).

Table I: Baseline Demographic and Clinical Characteristics (n=60)

Characteristic		Frequency (%)	Percentage (%)
Age (years)	18-24	40	66.7
	25-31	20	33.3
	Mean ± SD	23.38 ± 3.1	
	BMI (kg/m²)	26.42 ± 1.98	
Type of Infertility	Primary	36	60.0
	Secondary	24	40.0
Mean Duration of Infertility (years)		2.4 ± 1.2	
Parity	Nulliparous	43	71.7
	Multiparous	17	28.3
Previous Pregnancy Loss	Abortion/Miscarriage	8	13.3

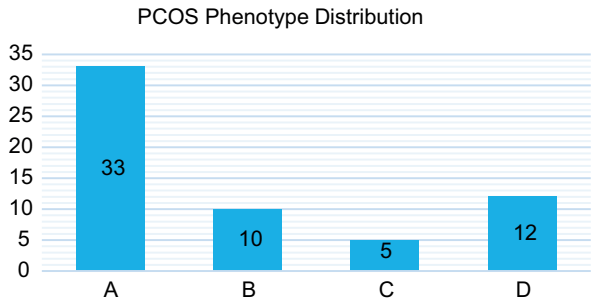

Figure 1: Distribution of PCOS Phenotypes (n=60)
A: Oligomenorrhea + Hyperandrogenism + PCOM
B: Oligomenorrhea + Hyperandrogenism
C: Hyperandrogenism + PCOM
D: Oligomenorrhea + PCOM

Figure 1 illustrates the distribution of PCOS phenotypes among all participants, showing the relative frequencies of varying phenotypic presentations as defined by clinical, biochemical, and ultrasonographic criteria.

Table II: Overall Clinical, Hormonal and Baseline TVS Findings

Variable	Value
Oligomenorrhea, n (%)	54 (90.0%)
Hyperandrogenism, n (%)	50 (83.3%)
AMH (ng/mL)	8.78 ± 2.1
FSH (D2/D3) (mIU/mL)	5.4 ± 1.4
LH (D2/D3) (mIU/mL)	12.0 ± 2.4
Mean AFC	42.8 ± 7.4
Right Ovary AFC	21.5 ± 4.9
Left Ovary AFC	21.3 ± 4.6
Baseline Endometrial Thickness (mm)	5.5 ± 0.5

Table II describes the hormonal and biochemical profile. Oligomenorrhea was reported in 90% of women, and hyperandrogenism in 83.3%. Mean AMH was 8.78 ± 2.1 ng/mL. Baseline gonadotropin levels measured on day 2/3 demonstrated a mean FSH of 5.4 ± 1.4 mIU/mL and LH of 12.0 ± 2.4 mIU/mL. The mean antral follicle count (AFC) was 42.8 ± 7.4, with similar right and left ovarian distributions. Baseline endometrial thickness averaged 5.5 ± 0.5 mm.

Table III: Treatment and Cycle Characteristics (n=60)

Variable	Value
Letrozole Dose	
5.0 mg	28 (46.7%)
7.5 mg	32 (53.3%)
Follicles >18 mm, Median (IQR)	1 (1 – 2)
Endometrial Thickness (mm)	10.5 ± 1.4
Trigger Injection Administered, n (%)	21 (35.0%)
Number of Treatment Cycles, Median (IQR)	3 (2 – 4)
Ovulation Achievement Rate, n (%)	60 (100.0%)

Table III shows treatment and cycle characteristics. Letrozole at 5 mg was used in 46.7% of cycles, whereas 53.3% received 7.5 mg. The median number of follicles >18 mm was 1 (IQR 1–2), and the mean endometrial thickness at trigger was 10.5 ± 1.4 mm. Trigger injection was administered in 35% of cycles. The median number of treatment cycles was 3 (IQR 2–4), and the ovulation achievement rate was 100%.

Table IV: Pregnancy and Reproductive Outcomes (n=60)

Outcome	Frequency (n)	Percentage (%)
Biochemical Pregnancy (B-hCG+)	42	70.0
Clinical Pregnancy (Ultrasound)	60	100.0
Live Birth	46	76.7
Ongoing Pregnancy	9	15.0
Abortion	4	6.7
Ectopic Pregnancy	1	1.7

Table IV presents pregnancy and reproductive outcomes. Biochemical pregnancy occurred in 70% of cases, while clinical pregnancy was confirmed in all participants. Live birth rate was 76.7%, with ongoing pregnancies at 15%. Abortion occurred in 6.7% and ectopic pregnancy in 1.7%.

Table V: *Complications During Pregnancy (n=60)*

Complications	Frequency (n)	Percentage (%)
Ovarian Hyperstimulation Syndrome	4	6.7
Multiple Pregnancy	3	5.0
Preterm/Premature Birth	3	5.0
Gestational Diabetes Mellitus	1	1.7

Table V summarizes pregnancy-related complications. Ovarian hyperstimulation syndrome occurred in 6.7% of participants, multiple pregnancy in 5%, and preterm birth in 5%. Gestational diabetes mellitus was documented in 1.7%.

Discussion:

The present analysis evaluated the effectiveness of letrozole-based ovulation induction among rural women with PCOS who achieved pregnancy, providing insight into clinical and reproductive responses in a resource-limited context. The findings demonstrated consistently favourable ovulatory, endometrial, and pregnancy outcomes, aligning with established evidence that positions letrozole as an effective first-line treatment for anovulatory PCOS. Letrozole's mechanism—transient suppression of estrogen synthesis leading to enhanced follicle-stimulating hormone (FSH) secretion—has been widely recognized to promote mono-follicular recruitment with minimal anti-estrogenic peripheral effects.[8] The complete ovulation rate observed in this study corroborates previous randomized trials reporting superior ovulatory responsiveness with letrozole compared with clomiphene citrate.[17]

The participants exhibited a high baseline antral follicle count (AFC), elevated anti-Müllerian hormone (AMH), and an increased LH:FSH ratio—biochemical features typical of PCOS phenotypes described in earlier studies.[1] The predominance of oligomenorrhea and hyperandrogenism mirrors prevalence patterns reported in Asian populations, where menstrual dysregulation is noted as the most frequent presenting feature.[3] These endocrine characteristics are known to influence treatment response, with several studies suggesting that women with high ovarian reserve indicators may display heightened sensitivity to ovulation induction agents.[18] The favourable follicular recruitment observed in the current cohort is consistent with such trends.

The improved endometrial thickness following letrozole treatment observed here aligns with evidence that aromatase inhibitors preserve endometrial receptivity more effectively than agents with anti-estrogenic properties. Findings from Wang et al. and Al-Obaidi et al. documented significantly greater endometrial thickness and improved implantation potential in women treated with letrozole compared with clomiphene citrate.[9,18] This enhanced endometrial environment may partly explain the high clinical pregnancy rate found in this study. Notably, even in the absence of extensive gonadotropin supplementation, the endometrium achieved satisfactory development, supporting the clinical utility of letrozole in low-resource settings where intensive monitoring and adjunct hormonal therapy may be limited.

The biochemical pregnancy rate of 70% and live birth rate of 76.7% are comparable to previous clinical trials in similar populations. Meta-analyses by Liu et al. and Tsiami et al. consistently reported higher pregnancy and live birth rates with letrozole compared with clomiphene citrate.[10,11] Furthermore, studies evaluating sequential or dose-escalation protocols have demonstrated that increasing the letrozole dose may benefit women with high BMI or pronounced hyperandrogenism.[19] In the present analysis, more than half of the participants received a 7.5 mg dose, which may partly contribute to the robust pregnancy outcomes observed.

Regarding reproductive outcomes, the study recorded low rates of multiple pregnancy (5%) and ovarian hyperstimulation syndrome (6.7%). These findings are consistent with previous observations that letrozole promotes controlled follicular development and minimizes the risk of multiple

gestations.[7] The low complication rates are noteworthy given the rural setting, where access to emergency obstetric care may be constrained. Other studies, including Kuang et al., have emphasized the safety advantages of letrozole, particularly its lower stimulatory effect on the endometrium and reduced likelihood of excessive estrogen exposure.[20]

The high clinical pregnancy rate (100%) observed in this analysis may reflect the preselected sample of women who achieved positive conception, which differs from intention-to-treat populations in clinical trials. However, the reproductive outcomes, including live births and ongoing pregnancies, support the consistent effectiveness of letrozole in inducing ovulation and sustaining early gestation. The low miscarriage rate is also in line with prior evidence suggesting that aromatase inhibitors do not adversely affect luteal function.[13]

The findings underscore the relevance of letrozole-based therapy in rural contexts, where affordability, ease of administration, and reduced monitoring requirements are essential considerations. Earlier studies from South Asian and resource-limited environments, such as study by and Mile et al., similarly reported favourable responses among women with limited access to advanced reproductive technologies.[21] The present results reinforce the applicability of letrozole as a feasible first-line agent for optimizing fertility outcomes in such populations. Although socio-cultural delays in seeking care are common in rural Bangladesh, the high ovulatory response and favourable pregnancy outcomes observed highlight the underlying biological receptivity to treatment once initiated.

Overall, this study contributes meaningful data demonstrating that letrozole remains a highly effective and safe ovulation induction agent for rural women with PCOS. Its favourable endometrial effects, controlled follicular response, and strong pregnancy performance support its continued use as a primary therapeutic option, particularly in low-resource settings.

Conclusion:

This study demonstrates that letrozole-based ovulation induction is highly effective in rural women with PCOS, yielding strong ovulatory, endometrial, and pregnancy outcomes with minimal complications. High clinical pregnancy and live birth rates underscore its reliability as a first-line agent in resource-limited settings. The findings reinforce the clinical value of letrozole for optimizing fertility care where access to advanced reproductive technologies is limited.

Limitations:

Limited sample diversity and inclusion of only pregnancy-positive cases restrict generalizability. Future studies should incorporate larger, multi-center cohorts and compare different dosing strategies. Strengthening early diagnosis and optimizing follow-up systems in rural settings may further improve reproductive outcomes.

Data Availability:

The datasets analysed during the current study are not publicly available due to the continuation of analyses but are available from the corresponding author on reasonable request.

Conflicts of interest:

There are no conflicts of interest.

Financial support and sponsorship:

No funding sources.

Ethical Consideration:

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Institutional Review Board from Sir Salimullah Medical College, Dhaka. The written informed consent was taken from all the patients before taking part of the study.

Author Contributions:

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; had agreed on the journal to which the article had been submitted; and agreed to be account able for all aspects of the work.

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