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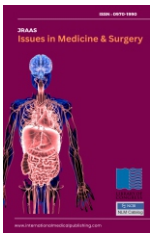

Research Article

Section: Obstetrics & Gynaecology

Comparative Study of Efficacy of Letrozole with Clomiphene Citrate in Anovulatory Women with Polycystic Ovarian Syndrome

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HIGHLIGHTS

- Better follicular maturation
- Improved endometrial thickness
- Enhanced hormonal response
- Shorter stimulation duration
- Effective first-line therapy

Key Words:
Polycystic Ovary Syndrome
Letrozole
Clomiphene Citrate
Ovulation Induction
Infertility

ABSTRACT

Introduction: Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine disorders among women of reproductive age and a major cause of anovulatory infertility. Ovulation induction remains the cornerstone of treatment for infertile women with PCOS. Among the available pharmacological agents, Letrozole and Clomiphene Citrate are widely used, with recent evidence suggesting superior reproductive outcomes with Letrozole. **Aim & Objective:** To compare the efficacy and safety of Letrozole and Clomiphene Citrate for ovulation induction in women with PCOS. **Materials & Methods:** This comparative study was conducted at Gandhi Hospital between July 2022 and September 2023 and included 100 women diagnosed with PCOS. Participants were randomly allocated into two equal groups. The Letrozole group received 2.5 mg twice daily, while the Clomiphene Citrate group received 100 mg daily for five days starting from day 3 of the menstrual cycle. Follicular development was monitored by ultrasonography, and endometrial thickness, hormonal profile, number of mature follicles, and duration of stimulation were assessed. **Results:** Letrozole showed significantly better outcomes than Clomiphene Citrate. Women treated with Letrozole demonstrated a higher number of mature follicles (>14 mm and >18 mm), greater endometrial thickness, and more favorable hormonal profiles. Although the Clomiphene Citrate group developed a higher total number of follicles, follicular quality and endometrial receptivity were superior in the Letrozole group. Furthermore, Letrozole required a shorter duration of stimulation, indicating improved treatment efficiency. **Conclusion:** Letrozole is more effective than Clomiphene Citrate for ovulation induction in women with PCOS, providing better follicular maturation, enhanced endometrial receptivity, and improved hormonal response. These findings support Letrozole as a preferred first-line therapy for managing anovulatory infertility associated with PCOS.

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INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine disorders affecting women of reproductive age worldwide. It is characterized by a triad of clinical features including menstrual irregularities, hyperandrogenism, and polycystic ovarian morphology. These manifestations vary widely in severity and combination, making PCOS a heterogeneous condition with diverse clinical presentations. A major consequence of PCOS is infertility, primarily due to chronic anovulation, which significantly reduces the likelihood of spontaneous conception and often necessitates medical intervention [1].

Ovulation induction represents a cornerstone in the management of infertility associated with PCOS. Among the pharmacological agents available, Letrozole and Clomiphene Citrate are widely used as first-line therapies. Letrozole, an aromatase inhibitor initially developed for breast cancer treatment, induces ovulation by suppressing estrogen synthesis, leading to increased follicle-stimulating hormone (FSH) secretion. In contrast, Clomiphene Citrate, a selective estrogen receptor modulator, acts by blocking hypothalamic estrogen receptors, thereby enhancing gonadotropin release and stimulating ovulation [2]. Although both agents are effective, differences in their efficacy and safety profiles have been increasingly recognized. Emerging evidence suggests that Letrozole may be associated with higher ovulation and pregnancy rates compared to Clomiphene Citrate, along with a lower risk of multiple gestations. Furthermore, Letrozole tends to have a more favorable side effect profile, with fewer vasomotor and psychological adverse effects such as hot flushes and mood disturbances commonly observed with Clomiphene Citrate. Despite these advantages, the selection of an appropriate ovulation induction agent remains complex & must be individualized based on patient characteristics, treatment goals, and clinician experience [3,4].

Despite the widespread use of both drugs, there is still a lack of consensus regarding the optimal first-line therapy for ovulation induction in PCOS. Direct comparative studies between Letrozole and Clomiphene Citrate remain limited, contributing to variability in clinical practice. This gap in evidence creates challenges for clinicians in selecting the most effective and safest treatment for patients seeking conception. Therefore, well-designed comparative studies are essential to evaluate outcomes such as ovulation rates, pregnancy rates, live birth rates, and safety profiles to guide evidence-based decision-making [5,6].

The significance of such comparative research lies in its potential to improve clinical outcomes and standardize care. By identifying the superior agent in terms of efficacy and safety, clinicians can tailor treatment strategies more effectively, thereby enhancing reproductive outcomes while minimizing risks. These findings may also contribute to the development of updated clinical guidelines for infertility management in PCOS, ultimately benefiting patients through improved, personalized care [7,8].

The present study aims to compare Letrozole and Clomiphene Citrate through a randomized controlled trial design, focusing on ovulation induction as the primary outcome, along with secondary outcomes including pregnancy rates, miscarriage rates, live birth rates, and adverse events. Careful monitoring through hormonal assays and ultrasonography will ensure accurate assessment of treatment response. Such a design enables a robust evaluation of both efficacy and safety parameters across multiple treatment cycles [9–11].

Safety considerations remain integral to ovulation induction therapy. Both Letrozole and Clomiphene Citrate are generally well tolerated, though they may be associated with adverse effects. Letrozole can cause symptoms such as fatigue, dizziness, and headache, while Clomiphene Citrate is more commonly

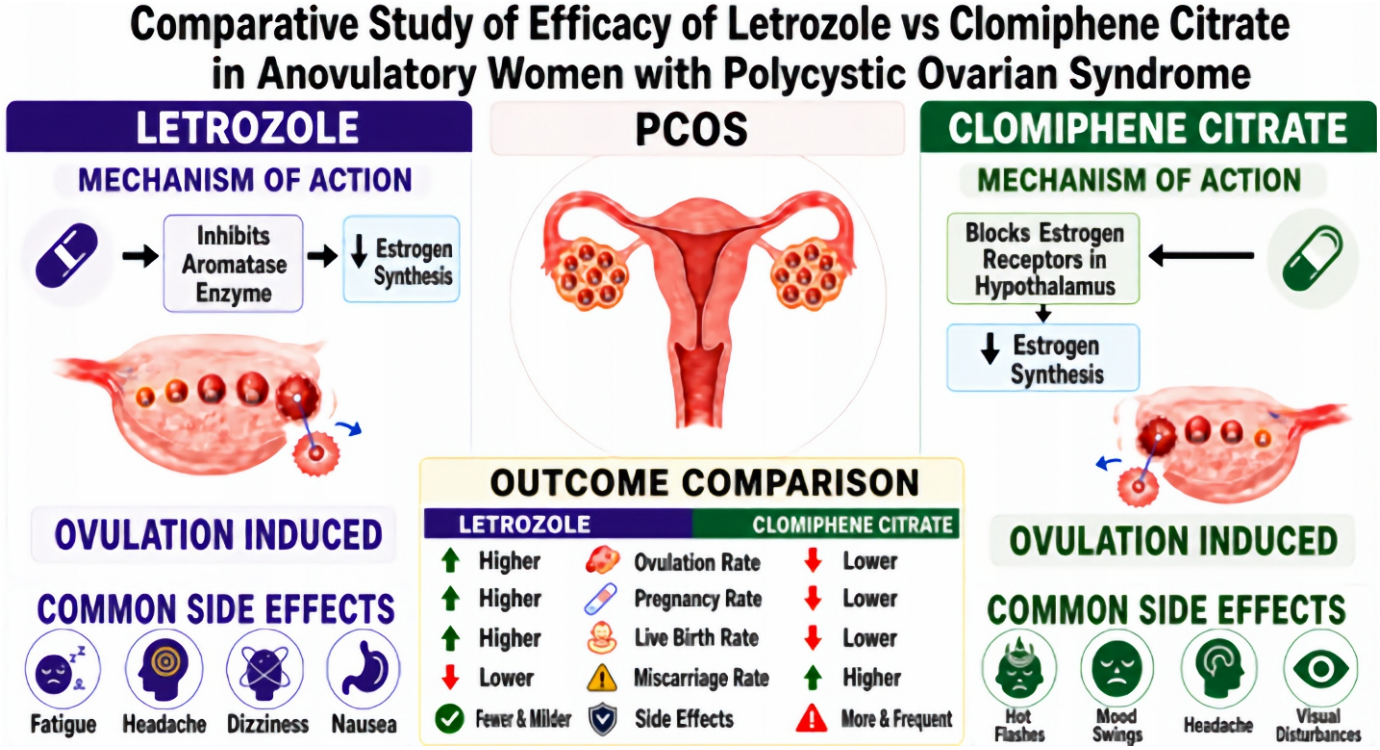

Figure 1: Comparison of letrozole and clomiphene citrate for ovulation induction in PCOS.

linked to hot flashes, mood swings, and, in rare cases, ovarian hyperstimulation syndrome and multiple pregnancies. Variations in tolerability and discontinuation rates further highlight the importance of individualized treatment selection [12–15]. Historically, concerns regarding the safety of Letrozole led to its temporary ban for infertility treatment in India in 2011; however, subsequent evidence supporting its safety and efficacy resulted in its reapproval in 2021. Current research increasingly supports the hypothesis that Letrozole may offer superior outcomes compared to Clomiphene Citrate, particularly in terms of ovulation and pregnancy rates with fewer adverse effects. If validated, this could significantly influence clinical practice and improve fertility outcomes in women with PCOS [16,17]. Graphical comparison of the mechanisms of action, efficacy outcomes, and side-effect profiles of letrozole and clomiphene citrate for ovulation induction in women with polycystic ovarian syndrome (PCOS) **(Figure 1).**

This study is delimited to women diagnosed with PCOS within a defined setting and timeframe, ensuring a homogeneous study population and minimizing confounding variables. While this may limit generalizability, it enhances internal validity and allows for a more precise comparison between the two treatment modalities [18–20].

In summary, PCOS-related infertility remains a significant clinical challenge requiring effective and safe ovulation induction strategies. A direct comparison of Letrozole & Clomiphene Citrate is essential to determine the optimal therapeutic approach. The findings of this study aim to provide evidence-based guidance for clinicians, ultimately improving reproductive outcomes & patient care in women with PCOS [21,22].

MATERIALS & METHODS

This comparative study was conducted in the Department of Obstetrics & Gynecology at Gandhi Hospital from July 2022 to September 2023, involving 100 women diagnosed with Polycystic Ovary Syndrome. Participants were equally randomized into two groups: one receiving Letrozole (2.5 mg twice daily for 5 days from day 3 of the menstrual cycle) and the other receiving Clomiphene Citrate (100 mg daily for 5 days from day 3). Inclusion criteria comprised women of reproductive age with PCOS, at least one patent fallopian tube, normal partner semen analysis, and regular intercourse, while women without PCOS were excluded. Diagnosis of PCOS was based on the revised 2003 consensus criteria, including oligo/anovulation, hyperandrogenism, and polycystic ovarian morphology on ultrasound. A double-blind randomization protocol was followed, and participants were monitored for follicular development (number and size), endometrial thickness, and pregnancy rates. Data collected included demographic variables (age, parity), clinical features, anthropometric parameters (BMI), hormonal profiles (FSH, LH), and treatment outcomes such as number of mature follicles, endometrial thickness at baseline and at human chorionic gonadotropin administration, serum estradiol, progesterone levels, & duration of stimulation.

Statistical analysis was performed using appropriate tests, with p-values calculated to determine the significance of differences between the two groups. used to summarize categorical data, while mean values were calculated for continuous variables such as hemoglobin and blood loss to assess severity and clinical trends.

RESULTS

Table 1 shows that the mean age was 27.6 ± 2.6 years in the Clomiphene citrate group and 29.34 ± 2.8 years in the Letrozole group, with no significant difference (p=0.1). Parity was similar in both groups (0.49 ± 0.61; p=0.3). The incidence of oligo/anovulation and hyperandrogenism was comparable between groups (p=0.3 and p=0.6, respectively). The Clomiphene group had significantly greater height (167.26 ± 8.56 cm vs 165.44 ± 5.7 cm; p=0.008) and weight (90.26 ± 9.68 kg vs 85.42 ± 9.4 kg; p=0.009). BMI showed no significant difference (p=0.1). FSH levels were similar (p=0.2), while LH levels were significantly higher in the Clomiphene group (11.72 ± 1.87 vs 11.22 ± 1.06 IU/ml; p=0.0002). **Figure 2.** The average number of follicles observed was slightly higher in the clomiphene citrate group (6.24 ± 1.36) compared to the letrozole group (5.88 ± 0.79). The p-value of 0.016 suggests this difference is statistically significant, indicating that clomiphene may induce a slightly higher number of follicles overall. **Figure 3** shows that the mean number of follicles larger than 14mm was significantly higher in the clomiphene group (2.97 ± 0.71) compared to the letrozole group (1.60 ± 0.49), with a p- value less than 0.001. **Figure 4** examines the number of follicles exceeding 18mm, which was higher in the clomiphene group (3.93 ± 1.26) than in the letrozole group (1.52 ± 0.50), with a p-value of <0.001. **Figure 5** focuses on Letrozole, which also showed a statistically significantly higher pretreatment endometrial thickness (5.98 ± 1.08 mm) compared to clomiphene (5.42 ± 1.15 mm), with a p-value less than 0.001. A thicker endometrium is often associated with better implantation potential. **Figure 6.** At the time of hCG administration, endometrial thickness was notably higher in the letrozole group (11.86 ± 1.2 mm) than in the clomiphene group (9.5 ± 1.15 mm), with a p-value < 0.001. This result further underscores letrozole's superior profile in enhancing endometrial receptivity. The serum E2 levels were higher in the letrozole group (491.54 ± 49.01 pg/mL) compared to the clomiphene group (462.1 ± 46.04 pg/mL), with a significant p-value of less than 0.001. Higher E2 levels might indicate more robust follicular development (**Figure 7**). **Figure 8** Serum progesterone levels were also higher in the letrozole group (10.62 ± 1.14 ng/mL) compared to the clomiphene group (9.38 ± 1.03 ng/mL), with a p-value of less than 0.001, which may suggest better corpus luteum function post-ovulation. The duration of stimulation was shorter in the letrozole group (10.94 ± 1.42 days) compared to the clomiphene group (11.68 ± 1.98 days), with a p-value of 0.043. This indicates that letrozole may achieve ovulation readiness in a shorter period, which could be advantageous for patient convenience and cycle management (**Figure 9**).

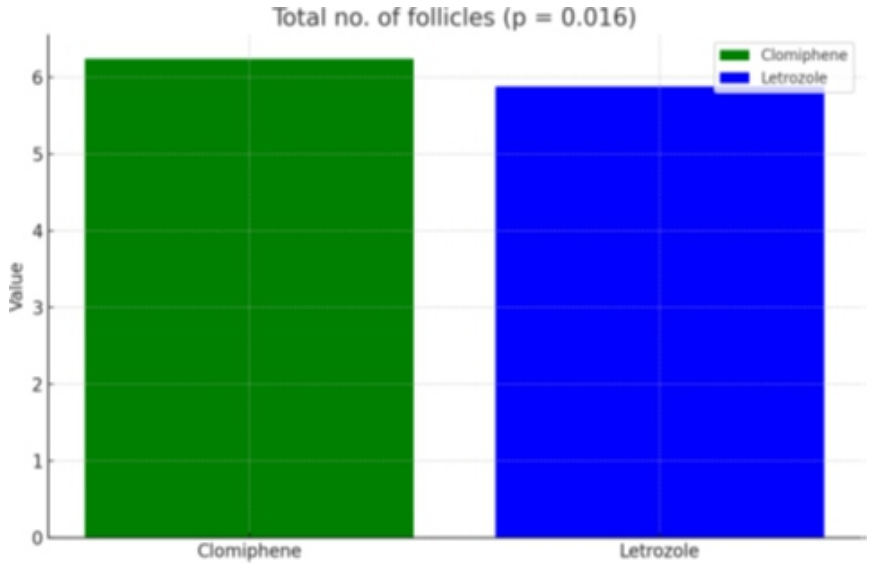

Figure 2: This chart compares the total number of follicles observed in patients treated with Clomiphene citrate versus Letrozole.

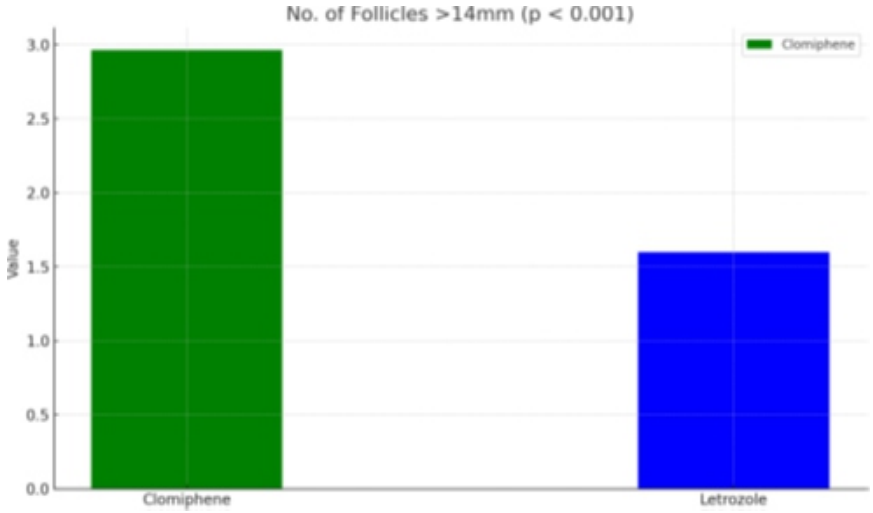

Figure 3: The count of follicles larger than 14mm for each treatment group, with a significantly lower p-value (<0.001), indicating a robust difference between the treatments

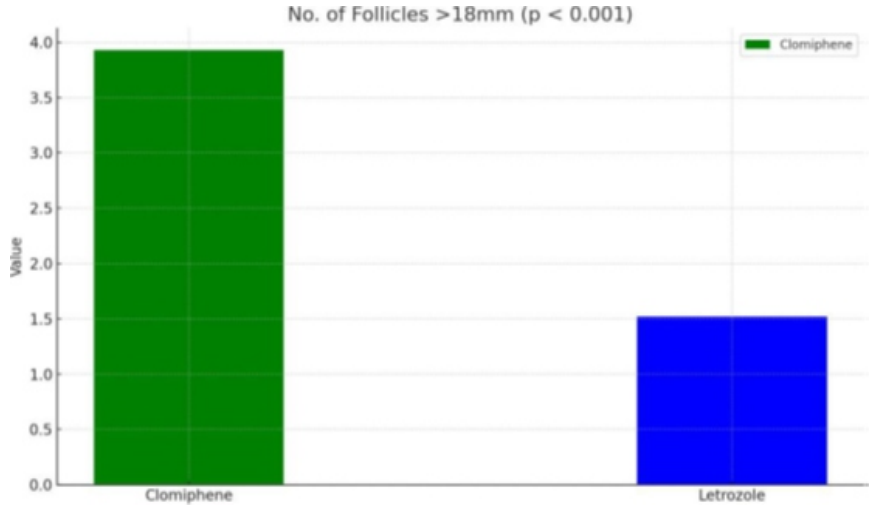

Figure 4: Number of follicles exceeding 18mm in diameter. The p-value of <0.001 suggests a significant difference in favor of Letrozole

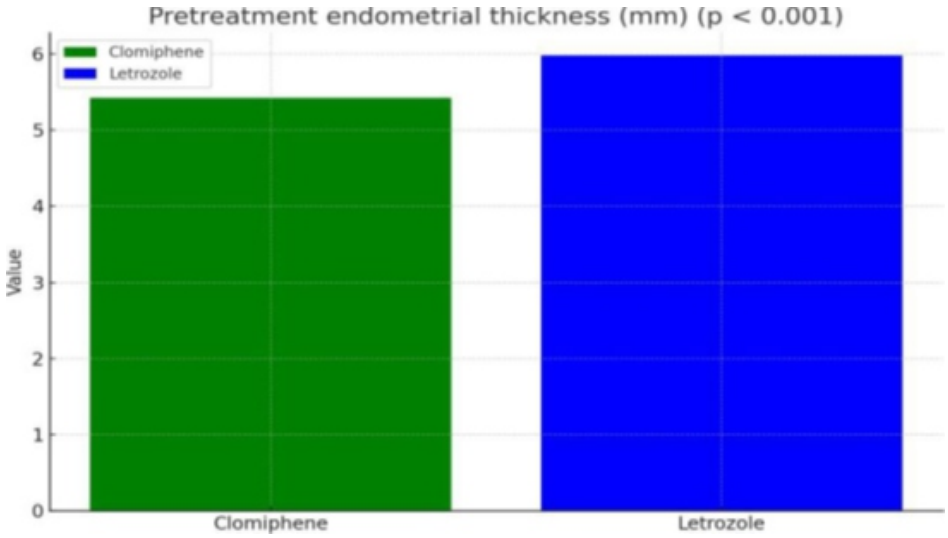

Figure 5: Bar diagram compares the pretreatment endometrial thickness measured in millimeters between the two groups. A highly significant difference is noted (p < 0.001)

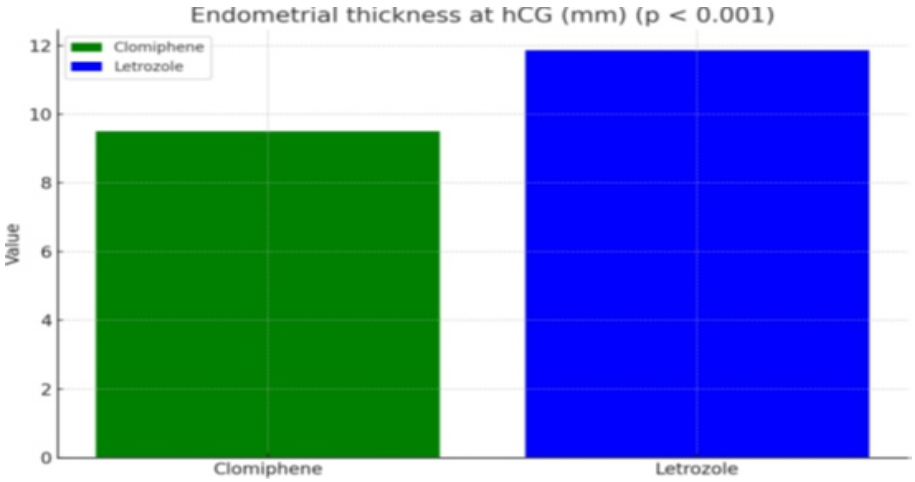

Figure 6: Bar diagram illustrates the endometrial thickness at the time of hCG administration, with Letrozole showing significantly thicker endometrium (p < 0.001)

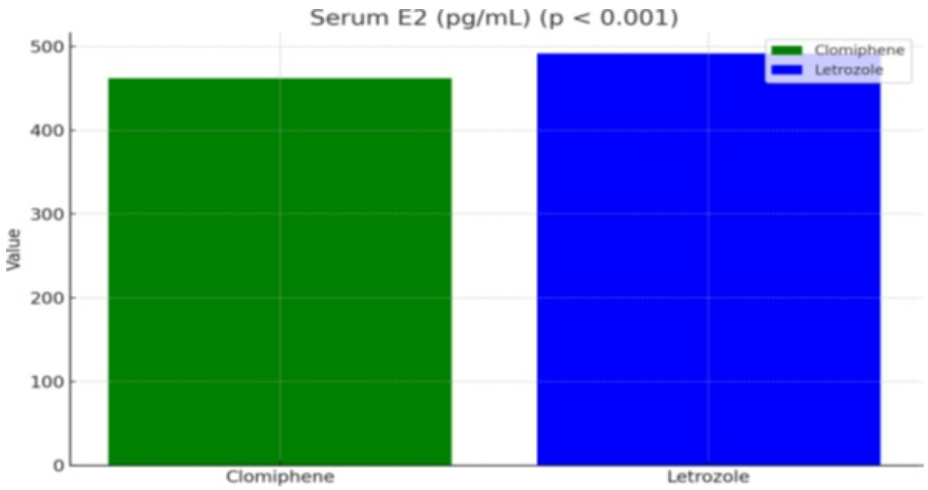

Figure 7: Bar diagram shows that letrozole associated with higher levels. The difference is statistically significant (p < 0.001)

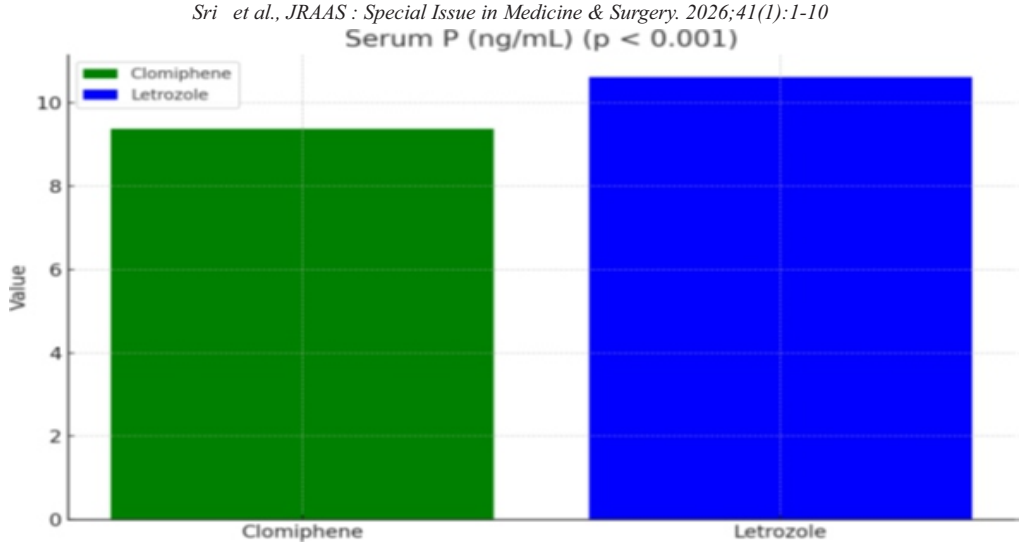

Figure 8: Bar diagram shows serum progesterone (P) levels in ng/mL. There is a significant difference between the groups, as indicated by a p-value < 0.001

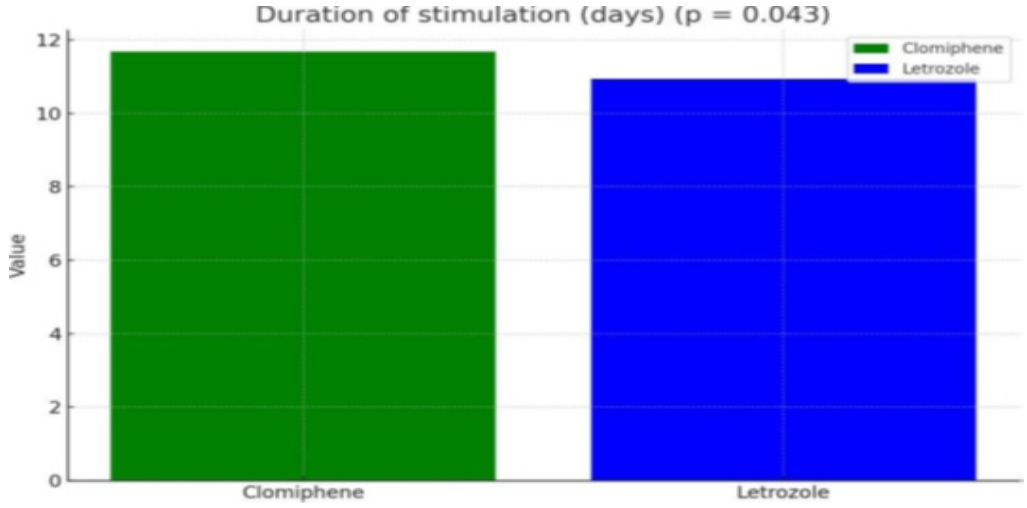

Figure 9: Bar diagram shows duration of stimulation required for each treatment protocol. The slight difference between groups is statistically significant with a p value of 0.043

DISCUSSION

Polycystic Ovarian Syndrome (PCOS) is a common endocrine disorder in women of reproductive age, characterized by chronic anovulation, hyperandrogenism, and polycystic ovarian morphology, often resulting in infertility and necessitating ovulation induction as a key therapeutic strategy [23]. Among available options, Letrozole and Clomiphene Citrate remain the most widely used agents for inducing ovulation in anovulatory women with PCOS. Clomiphene Citrate, traditionally the first-line therapy, acts by blocking hypothalamic estrogen receptors, thereby increasing gonadotropin secretion and stimulating ovarian activity [24]. However, its limitations include relatively lower pregnancy rates, risk of multiple gestations, ovarian hyperstimulation, and resistance in a subset of patients. In contrast, Letrozole, an aromatase inhibitor, reduces estrogen synthesis, leading to enhanced follicle-stimulating hormone secretion and improved follicular development. Accumulating evidence suggests that Letrozole may offer superior outcomes, including higher ovulation and pregnancy rates, fewer adverse effects, and reduced risk of multiple pregnancies, making it an increasingly preferred alternative.

Several comparative studies support the superiority of Letrozole over Clomiphene Citrate in inducing ovulation and achieving pregnancy [25]. Higher cumulative ovulation and live birth rates, along with fewer complications such as ovarian hyperstimulation syndrome and multiple gestations, have been consistently reported with Letrozole. In the present study, baseline patient characteristics, including age, parity, oligo/anovulation, and hyperandrogenism were comparable between the two groups, indicating homogeneity of the study population [26,27]. However, a statistically significant difference was observed in luteinizing hormone (LH) levels, which were higher in the Clomiphene Citrate group, suggesting possible differences in ovarian response. These findings are consistent with previous studies by Banerjee Ray P et al. (2012), Tsiami AP et al. (2021), & Bansal, S et al. (2021), which demonstrated higher ovulation rates and improved endometrial development with Letrozole [28]. Although serum estradiol levels were higher in the Clomiphene Citrate group, this did not translate into better clinical outcomes. A greater proportion of women in the Letrozole group achieved ovulation (62.5% vs. 37.5%), with higher pregnancy rates, further supporting its superior efficacy [29].

Our findings regarding comparable baseline characteristics align with studies such as Khodary MM et al. (2022), which reported no significant differences in treatment outcomes between the two agents [30]. However, other studies, including Al-Shoraky Mohamed S et al. (2020), have demonstrated significantly higher ovulation rates, improved endometrial thickness, and better pregnancy outcomes with Letrozole, reinforcing its potential as a more effective first-line therapy [31]. In terms of hyperandrogenism, no significant difference was observed between the two groups, consistent with existing literature, although a statistically significant difference in height was noted, an observation not commonly reported in similar studies [32]. Previous studies by Roy KK et al. (2012) & Behnoud N et al. (2019) also highlighted improved endometrial thickness and higher pregnancy rates with Letrozole, despite comparable ovulation rates, further supporting its advantages [33]. Analysis of anthropometric parameters revealed a significantly higher mean weight in the Clomiphene Citrate group, whereas body mass index (BMI) was comparable between groups, indicating that weight differences did not significantly influence overall body composition [34]. These findings are supported by studies such as Zakaria AE et al. (2018) and Atay V et al. (2006), which reported higher ovulation and pregnancy rates with Letrozole, along with better endometrial outcomes despite fewer mature follicles [35]. Hormonal evaluation demonstrated no significant difference in follicle-stimulating hormone (FSH) levels between the groups, whereas LH levels were significantly higher in the Clomiphene Citrate group, a factor that may influence treatment response and side effect profile [36]. Similar observations were reported by Ibrahim MI et al. (2012), who noted higher pregnancy rates and improved endometrial receptivity with Letrozole despite higher follicle numbers in the Clomiphene Citrate group. El Shafey KH et al. (2022) also reported improved fertility outcomes with Letrozole without significant differences in demographic parameters, further validating these findings [37,38].

In terms of treatment outcomes, the total number of follicles was higher in the Clomiphene Citrate group; however, the Letrozole group showed significantly more mature follicles (>14 mm and >18 mm), indicating better follicular quality [39]. Additionally, both pretreatment and post–human chorionic gonadotropin endometrial thickness were significantly greater in the Letrozole group, reflecting improved endometrial receptivity. Serum estradiol and progesterone levels were also higher with Letrozole, and the duration of stimulation was shorter, suggesting enhanced treatment efficiency. These findings are consistent with those reported by Amer SA et al. (2017), who observed similar baseline characteristics but higher clinical pregnancy rates and improved endometrial parameters with Letrozole [40]. Overall, the present study demonstrates that Letrozole offers superior outcomes in terms of follicular maturation, endometrial thickness, and hormonal profile, which may translate into improved ovulation and pregnancy rates. Collectively, these findings highlight the evolving preference for Letrozole as a first-line agent for ovulation induction in women with PCOS.

Its higher efficacy improved endometrial receptivity, lower complication rates, and shorter duration of treatment provide a clear advantage over Clomiphene Citrate. The consistency of these results with multiple previous studies strengthens the evidence supporting Letrozole as a more effective therapeutic option in the management of PCOS-related infertility [41].

CONCLUSION

This study highlights that polycystic ovary syndrome-related infertility remains a significant clinical challenge requiring effective ovulation induction strategies. This study demonstrates that Letrozole offers clear advantages over Clomiphene Citrate, including the development of larger and more mature follicles, improved endometrial thickness, more favorable hormonal profiles, and a shorter duration of stimulation. These findings indicate better follicular maturation and endometrial receptivity, which are critical for successful conception, thereby supporting Letrozole as a preferable first-line agent for ovulation induction in women with PCOS. Clinically, its use may enhance treatment efficiency and reproductive outcomes while improving patient convenience. However, the study is limited by the lack of direct evaluation of pregnancy rates and a relatively modest sample size. Future research should focus on long-term reproductive outcomes, including pregnancy and live birth rates, and explore its effectiveness across different PCOS subgroups. Overall, Letrozole emerges as a more effective and promising therapeutic option, warranting broader adoption in clinical practice to optimize fertility outcomes in PCOS patients..

LIMITATIONS & FUTURE PERSPECTIVES

The study's limitations include a single-centre setting, a relatively small sample size, and a short study duration, which may limit the broader applicability of the results. Future studies should incorporate multicentre designs with larger populations to enhance validity, assess long-term outcomes, and investigate advanced diagnostic & management approaches. Such efforts will improve overall patient care and help minimize complications.

CLINICAL SIGNIFICANCE

The clinical significance of this study lies in its potential to bridge the gap between research findings and practical healthcare applications. It emphasizes the importance of translating scientific observations into meaningful improvements in patient care, diagnosis, and treatment outcomes. By highlighting real world relevance, the study contributes to evidence based medical practice and supports informed clinical decision making. Ultimately, the findings aim to enhance patient quality of life, optimize therapeutic strategies, and promote better disease management in clinical settings.

ABBREVIATIONS

PCOS: Polycystic Ovary Syndrome
LH: Luteinizing Hormone
FSH: Follicle-Stimulating Hormone
hCG: Human Chorionic Gonadotropin

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AUTHOR CONTRIBUTIONS

All authors significantly contributed to the study conception and design, data acquisition, or data analysis and interpretation. They participated in drafting the manuscript or critically revising it for important intellectual content, consented to its submission to the current journal, provided final approval for the version to be published, and accepted responsibility for all aspects of the work. Additionally, all authors meet the authorship criteria outlined by the International Committee of Medical Journal Editors (ICMJE) guidelines.

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CONFLICT OF INTEREST

Authors declared that there is no conflict of interest.

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ETHICAL APPROVAL & CONSENT TO PARTICIPATE

All necessary consent & approval was obtained by authors.

CONSENT FOR PUBLICATION

All necessary consent for publication was obtained by authors.

DATA AVAILABILITY

All data generated and analyzed are included within this research article. The datasets utilized and/or analyzed in this study can be obtained from the corresponding author upon a reasonable request.

USE OF ARTIFICIAL INTELLIGENCE (AI) & LARGE LANGUAGE MODEL (LLM)

The authors confirm that no AI & LLM tools were used in thewriting or editing of the manuscript, and no images were altered or manipulated using AI & LLM.

AUTHOR'S NOTE

This article serves as an important educational tool for the scientific community, offering insights that may inspire future research diretions. However, they should not be relied upon independently when making treatment decisions or developing public health policies.

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