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Original Research Article

A Comparative Study of Clomiphene Citrate and Letrozole in Ovulation Induction in Infertile Women with Polycystic Ovarian Syndrome

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Conflict of interest: Nil

Abstract

Introduction: Polycystic ovarian syndrome (PCOS) is one of the leading causes of anovulatory infertility among women of reproductive age. Ovulation induction remains the cornerstone of treatment, with Clomiphene Citrate (CC) historically being the first-line therapy. Letrozole, an aromatase inhibitor, has emerged as an effective alternative, potentially offering higher ovulation and pregnancy rates with fewer adverse effects on endometrial receptivity. This study aims to compare the efficacy, ovulation rates, and pregnancy outcomes of Clomiphene Citrate versus Letrozole in infertile women with PCOS.

Methods: This study was a prospective, randomized, parallel, comparative study conducted in the Department of Obstetrics and Gynaecology at Calcutta National Medical College and Hospital from 1st February 2018 to 1st July 2019, over a period of approximately 1.5 years. A total of 70 patients were included, consisting of individuals presenting with musculoskeletal disorders such as fractures, ligament injuries, and osteoarthritis. Study variables recorded for each patient included age, period of infertility, height, weight, waist-hip ratio, number of follicles, parity, socioeconomic status (SES), occupation, hirsutism, acne, acanthosisnigricans, hypothyroidism, hyperthyroidism, mono-follicular and multi-follicular values, and ovulation rate. All patients were assessed systematically, and relevant clinical and laboratory data were collected to evaluate the outcomes and correlations of these variables.

Results: Seventy participants were included, 35 in the Letrozole group and 35 in the Clomiphene group. Baseline characteristics were comparable: age (25.51 ± 4.62 vs. 25.43 ± 4.55 years), infertility duration (3.14 ± 1.50 vs. 3.46 ± 1.77 years), height (158.11 ± 6.09 vs. 158.09 ± 5.54 cm), weight (55.91 ± 5.83 vs. 58.03 ± 5.37 kg), waist-hip ratio (0.796 ± 0.038 vs. 0.795 ± 0.038), and number of follicles (1.17 ± 0.66 vs. 1.23 ± 1.00). Letrozole produced larger follicles on day 14 (19.94 ± 1.41 mm vs. 18.06 ± 1.41 mm), higher endometrial thickness (8.55 ± 0.34 mm vs. 7.76 ± 0.50 mm), and serum progesterone (14.01 ± 0.82 ng/mL vs. 11.93 ± 1.09 ng/mL), whereas Clomiphene had larger follicles on day 16 (13.63 ± 1.37 mm vs. 10.11 ± 1.59 mm). Mono-follicular development and ovulation rates were higher with Letrozole (25/35 and 28/35 vs. 14/35 and 18/35), while Clomiphene showed more multi-follicular cycles (12/35 vs. 7/35). Complications were minimal (Letrozole 2.9%, Clomiphene 5.7%).

Conclusion: Letrozole appears to be more effective than Clomiphene Citrate in inducing ovulation in infertile women with PCOS, with better endometrial response and comparable pregnancy rates. Given its favorable side effect profile and improved endometrial receptivity, Letrozole may be considered as a first-line agent for ovulation induction in this population.

Keywords: Polycystic Ovarian Syndrome, Ovulation Induction, Clomiphene Citrate, Letrozole, Infertility.

Introduction

Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine disorders affecting women of reproductive age, with a prevalence ranging from 6% to 20% worldwide [1]. It is characterized by chronic anovulation, hyperandrogenism, and polycystic ovarian morphology, often leading to menstrual irregularities, infertility, and metabolic disturbances [2]. Among these complications, anovulatory infertility remains the most prevalent, necessitating effective ovulation induction strategies to achieve conception. The pathogenesis of PCOS is

multifactorial, involving genetic predisposition, environmental influences, and hormonal imbalances [3]. Insulin resistance and resultant hyperinsulinemia are central to the disorder, stimulating ovarian theca cells to produce excess androgens. Elevated androgen levels interfere with normal follicular development and disrupt the hypothalamic-pituitary-ovarian axis, resulting in chronic anovulation [4]. Additionally, obesity, lifestyle factors, and chronic low-grade inflammation further exacerbate the endocrine and reproductive dysfunctions in PCOS [5]. The primary goal in managing anovulatory infertility in PCOS is to restore regular ovulation. Pharmacological interventions include Clomiphene Citrate (CC) and Letrozole, both aiming to stimulate follicular growth and promote ovulation [6]. Clomiphene Citrate is a selective estrogen receptor modulator that blocks estrogen receptors in the hypothalamus, inhibiting negative feedback and enhancing gonadotropin-releasing hormone (GnRH) secretion. This leads to increased follicle-stimulating hormone (FSH) and luteinizing hormone (LH) release, stimulating ovarian follicle development [7]. Although CC has been widely used as a first-line therapy due to its oral administration, affordability, and established efficacy, its antiestrogenic effects on the endometrium and cervical mucus can reduce implantation rates and contribute to suboptimal pregnancy outcomes. Letrozole, an aromatase inhibitor, has emerged as a promising alternative for ovulation induction in PCOS patients [8]. By inhibiting the enzyme aromatase, Letrozole reduces estrogen synthesis, lowering negative feedback on the hypothalamus and pituitary. This results in enhanced GnRH and gonadotropin secretion, promoting follicular growth. Compared to CC, Letrozole has a shorter half-life and fewer antiestrogenic effects on the endometrium, potentially leading to higher ovulation rates, improved endometrial thickness, and better pregnancy outcomes [9].

Several studies have compared Letrozole and Clomiphene Citrate for ovulation induction in PCOS. A systematic review and meta-analysis demonstrated that Letrozole is associated with higher ovulation rates, clinical pregnancy rates, and live birth rates compared to CC [10]. Moreover, Letrozole is associated with a lower risk of multiple pregnancies and a more favorable side effect profile, making it a suitable first-line agent for women with PCOS seeking conception. In summary, both Clomiphene Citrate and Letrozole are effective in inducing ovulation among women with PCOS. However, emerging evidence supports Letrozole's superiority in terms of ovulation, endometrial receptivity, and overall reproductive outcomes. This comparative study aims to evaluate the efficacy, safety, and reproductive outcomes of Letrozole versus Clomiphene Citrate in infertile women with PCOS, contributing to the optimization of ovulation induction strategies in this population.

Materials and Methods

Study Design: A prosprective, randomized, parallel, comparative study.

Place of study: Department of obstetrics and Gynaecology, Calcutta National Medical College and Hospital.

Period of study: 1st Feb 2018- 1st July 2019(approx.1.5 year)

Study Variables

- Age
- Period of Infertility
- Height
- Weight
- Wist Hip Ratio
- Number of Follicles
- Parity
- SES
- Occupation
- Hirsutisn
- Acne
- Acantsosisnigricans
- Hypothyrodism
- Hperthyrodism
- Mono follicular value
- Multi follicular value
- Ovulation rate

Sample Size: 70 Patients included were individuals with musculoskeletal disorders such as fractures, ligament injuries, and osteoarthritis.

Inclusion Criteria

- Age: 18-35 years
- Period of infertility
- PCOS with at least 2 of Diagnostic criteria
- Oligomenorrhoea/ Amenorrhoea
- Clinical evidence of Acne/ Hirsutism
- USG evidence of PCOS
- Normal semen analysis of partner
- Normal pelvic USG
- Normal bilateral tubal partency
- No recent treatment for ovulation induction (within 6 months)
- Willingness and giving written informed consent

Exclusion Criteria

- Women with uterinr/adnexal pathology (Eg) fibroid, ovarian cyst are excluded from the study.

- Those with previous history of any surgeries related to genital tract as per history were excluded.
- Those with impaired hepatic/ renal function were excluded.
- Women with RBS> 140 mg/dl were excluded from the study.
- Age>35 years and obese patients were excluded from the study.
- Lack of willingness.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 25.0 and GraphPad Prism version 5. Continuous variables were summarized as mean ± standard deviation, while categorical variables were expressed as counts and percentages. Differences between means were assessed using independent (unpaired) or paired t-tests, as appropriate. Categorical data were analyzed using the

Chi-square test or Fisher's exact test. Test statistics were evaluated for significance using the corresponding degrees of freedom and p-values derived from the relevant distributions. A p-value ≤ 0.05 was considered statistically significant.

Result

Table 1: Comparison of Ovarian and Endometrial Parameters Between Letrozole and Clomiphene Citrate Groups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age	Group-A (L)	35	25.5143	4.6233	19	34	25	0.9379
	Group-B (CC)	35	25.4286	4.5522	19	34	25	
Period of Infertility	Group-A (L)	35	3.1429	1.4979	1	7	3	0.4256
	Group-B (CC)	35	3.4571	1.7714	2	8	3	
Height	Group-A (L)	35	158.114	6.0865	145	167	158	0.9837
	Group-B (CC)	35	158.086	5.538	147	167	158	
Weight	Group-A (L)	35	55.9143	5.8278	45	67	56	0.119
	Group-B (CC)	35	58.0286	5.3659	48	65	58	
Wist Hip Ratio	Group-A (L)	35	0.7957	0.0378	0.7	0.88	0.79	0.9245
	Group-B (CC)	35	0.7949	0.0376	0.7	0.88	0.79	
Number of Follicles	Group-A (L)	35	1.1714	0.6636	0	3	1	0.7794
	Group-B (CC)	35	1.2286	1.0025	0	3	1	
Size of the Follile day 14	Group-A (L)	35	19.9429	1.413	18	22	20	<0.001
	Group-B (CC)	35	18.0571	1.413	16	20	18	
Size of the Follicle day 16	Group-A (L)	35	10.1143	1.5862	8	12	10	<0.001
	Group-B (CC)	35	13.6286	1.3738	12	16	13	
Endometrial Thickness	Group-A (L)	35	8.5537	0.3403	8	9	8.6	<0.001
	Group-B (CC)	35	7.76	0.4978	7	8.9	7.8	
serum Progesteron Level	Group-A (L)	35	14.0114	0.8159	12	15.3	14	<0.001
	Group-B (CC)	35	11.9314	1.0919	10.2	15	12	

Table 2: Baseline Demographic, Socioeconomic, and Ovarian Parameters in Letrozole and Clomiphene Citrate Groups

		Group-A (L)	Group-B (CC)	Total
Age in Years	≤20	4 (11.4%)	5 (14.3%)	9 (12.9%)
	21 to 25	15 (42.9%)	13 (37.1%)	28 (40%)
	26 to 30	10 (28.6%)	11 (31.4%)	21 (30%)
	31 to 35	6 (17.1%)	6 ((17.1%)	12 ((17.1%)
	Total	35 (100%)	35 (100%)	70 (100%)
Parity	P0+0	24 (68.6%)	21 (60%)	45 (64.3%)
	P1+0	4 (11.4%)	4 (11.4%)	8 (11.4%)
	P1+1	3 (8.6%)	5 (14.3%)	8 (11.4%)
	P2+0	4 (11.4%)	5 (14.3%)	9 (12.9%)
	Total	35 (100%)	35 (100%)	70 (100%)
SES	Upper	2 (5.7%)	1 (2.9%)	3 (4.3%)
	Lower Middle	4 (11.4%)	2 (5.7%)	6 (8.6%)
	Middle	7 (20%)	7 (20%)	14 (20%)
	Lower	22 (62.9%)	25 (71.4%)	47 (67.1%)
	Total	35 (100%)	35 (100%)	70 (100%)

Occupation	Housewife	15 (42.9%)	16 (45.7%)	31 (44.3%)
	Nurse	10 (28.6%)	8 (22.9%)	18 (25.7%)
	Private Job	7 (20%)	9 (25.7)	16 (22.9%)
	Teacher	3 (8.6%)	2 (5.7%)	5 (7.1%)
	Total	35 (100%)	35 (100%)	70 (100%)

Table 3: Clinical Features, Thyroid Status, and Medication History in Letrozole and Clomiphene Citrate Groups

		Group-A (L)	Group-B (CC)	Total
Hirsutisn	Absent	18 (51.4%)	18 (51.4%)	36 (51.4%)
	Present	17 (48.6%)	17 (48.6%)	34 (48.6%)
	Total	35 (100%)	35 (100%)	70 (100%)
Acne	Absent	18 (51.4%)	17 (48.6%)	35 (50%)
	Present	17 (48.6%)	18 (51.4%)	35 (50%)
	Total	35 (100%)	35 (100%)	70 (100%)
Acantsosisnigricans	Absent	22 (62.9%)	21 (60%)	43 (61.4%)
	Present	13 (37.1%)	14 (40%)	27 (38.6%)
	Total	35 (100%)	35 (100%)	70 (100%)
Hypothyrodism	Absent	15 (42.9%)	11 (31.4%)	26 (37.1%)
	Present	20 (57.1%)	24 (68.6%)	44 (62.9%)
	Total	35 (100%)	35 (100%)	70 (100%)
Hperthyrodism	Absent	20 (57.1%)	24 (68.6%)	44 (62.9%)
	Present	15 (42.9%)	11 (31.4%)	26 (37.1%)
	Total	35 (100%)	35 (100%)	70 (100%)
History of Any medication intake	Absent	20 (57.1%)	18 (51.4%)	38 (54.3%)
	Present	15 (42.9%)	17 (48.6%)	32 (45.7%)
	Total	35 (100%)	35 (100%)	70 (100%)

Table 4: Follicular Response and Ovulation Rates in Letrozole and Clomiphene Citrate Groups

	Group-A (L)	Group-B (CC)	p-value
Mono follicular value	25/35	14/35	<0.001
Total	35	35	
Multi follicular value	7/35	12/35	<0.001
Total	35	35	
Ovulation rate	28/35	18/25	<0.001

Table 5: Previous Infertility Treatment, Follicle Number, and Treatment-Related Complications in Letrozole and Clomiphene Citrate Groups

		Group-A (L)	Group-B (CC)	Total
History of Previous infertility treatment	No	23 (65.7%)	30 (85.7%)	53 (75.7%)
	Yes	12 (34.3%)	5 (14.3%)	17 (24.3%)
	Total	35 (100%)	35 (100%)	70 (100%)
Number of Follicles	0	3 (8.6%)	9 (25.7%)	12 (17.1%)
	1	25 (71.4%)	14 (40%)	39 (55.7%)
	2	5 (14.3%)	7 (20%)	12 (17.1%)
	3	2 (5.7%)	5 (14.3%)	7 (10%)
	Total	35 (100%)	35 (100%)	70 (100%)
Complication	Abdominal Pain	1 (2.9%)	0 (0.0%)	1 (1.4%)
	No	34 (97.1%)	33 (94.3%)	67 (95.7%)
	OHSS	0 (0.0%)	2 (5.7%)	2 (2.9%)
	Total	35 (100%)	35 (100%)	70 (100%)

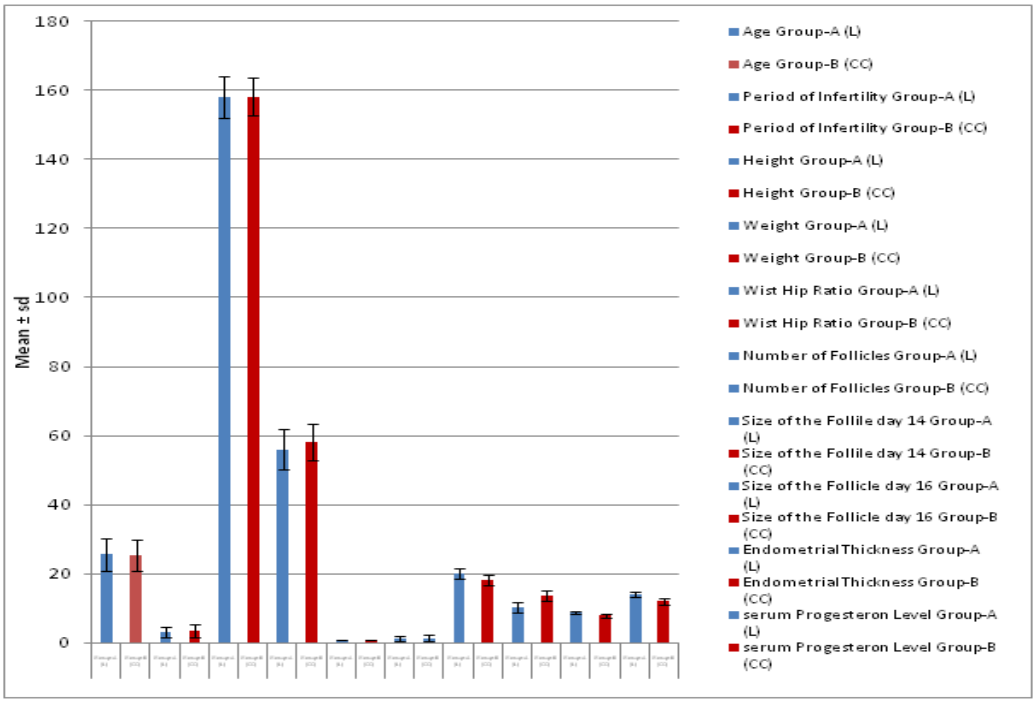

Figure 1: Comparison of Ovarian and Endometrial Parameters Between Letrozole and Clomiphene Citrate Groups

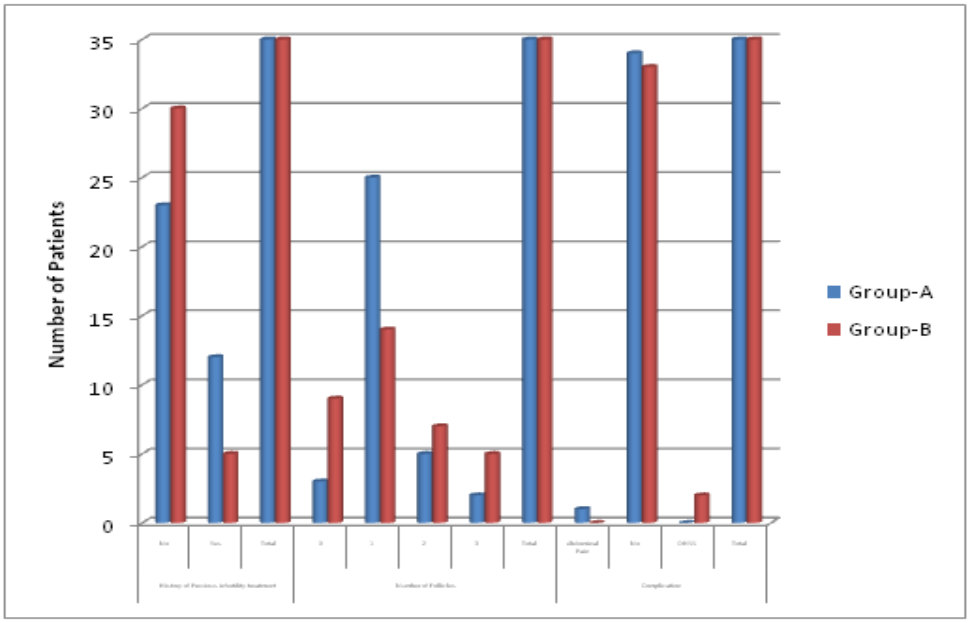

Figure 2: Previous Infertility Treatment, Follicle Number, and Treatment-Related Complications in Letrozole and Clomiphene Citrate Groups

Seventy participants were included, 35 in the Letrozole (L) group and 35 in the Clomiphene Citrate (CC) group. Baseline characteristics including age (25.51 ± 4.62 vs. 25.43 ± 4.55 years, p = 0.9379), duration of infertility (3.14 ± 1.50 vs. 3.46 ± 1.77 years, p = 0.4256), height (158.11 ± 6.09 vs. 158.09 ± 5.54 cm, p = 0.9837), weight (55.91 ± 5.83 vs. 58.03 ± 5.37 kg, p = 0.119), and waist-hip ratio (0.796 ± 0.038 vs. 0.795 ± 0.038, p = 0.9245) were comparable between groups. The number of follicles was similar (1.17 ± 0.66 vs. 1.23 ± 1.00, p = 0.7794). Letrozole showed larger follicles on day 14 (19.94 ± 1.41 mm vs. 18.06 ± 1.41 mm, p < 0.001), whereas Clomiphene had larger follicles on day 16 (13.63 ± 1.37 mm vs. 10.11 ± 1.59 mm, p < 0.001). Endometrial thickness (8.55 ± 0.34 mm vs. 7.76 ± 0.50 mm, p < 0.001) and serum progesterone levels (14.01 ± 0.82 ng/mL vs. 11.93 ± 1.09 ng/mL, p < 0.001) were significantly higher in the Letrozole group.

Seventy participants were included, 35 in each group. Age distribution was similar, with most women aged 21–25 years (42.9% vs. 37.1%) and 26–30 years (28.6% vs. 31.4%). Nulliparity

predominated (68.6% vs. 60%), and most participants belonged to the lower socioeconomic class (62.9% vs. 71.4%). Occupation was mainly housewives (42.9% vs. 45.7%), followed by nurses and private jobs.

Baseline characteristics were comparable between groups. The number of follicles was similar (1.17 ± 0.66 vs. 1.23 ± 1.00, p = 0.7794), but Letrozole produced larger follicles on day 14 (19.94 ± 1.41 mm vs. 18.06 ± 1.41 mm, p < 0.001) and greater endometrial thickness (8.55 ± 0.34 mm vs. 7.76 ± 0.50 mm, p < 0.001), whereas Clomiphene showed larger follicles on day 16 (13.63 ± 1.37 mm vs. 10.11 ± 1.59 mm, p < 0.001). Serum progesterone levels were higher in the Letrozole group (14.01 ± 0.82 ng/mL vs. 11.93 ± 1.09 ng/mL, p < 0.001). Among 70 participants (35 per group), hirsutism was present in 48.6% of both Letrozole and Clomiphene groups. Acne was equally distributed (48.6% vs. 51.4%), and acanthosisnigricans was observed in 37.1% vs. 40% of participants. Hypothyroidism was more common in the Clomiphene group (68.6% vs. 57.1%), while hyperthyroidism was higher in the Letrozole group (42.9% vs. 31.4%). History of any medication intake was reported in 42.9% of the Letrozole group and 48.6% of the Clomiphene group. Letrozole was associated with a higher rate of mono-follicular development compared to Clomiphene (25/35 vs. 14/35, p < 0.001), whereas Clomiphene showed a higher proportion of multi-follicular development (12/35 vs. 7/35, p < 0.001). The ovulation rate was significantly higher in the Letrozole group (28/35) compared to the Clomiphene group (18/35, p < 0.001). Most participants had no history of previous infertility treatment (65.7% in Letrozole vs. 85.7% in Clomiphene). Regarding follicular response, the majority in the Letrozole group developed a single follicle (71.4% vs. 40%), while multiple follicles were more common in the Clomiphene group (two follicles: 20% vs. 14.3%; three follicles: 14.3% vs. 5.7%). Zero follicles were observed in 8.6% of Letrozole and 25.7% of Clomiphene cycles. Complications were minimal, with abdominal pain reported in 2.9% of Letrozole cases and OHSS in 5.7% of Clomiphene cases; most participants had no complications (97.1% vs. 94.3%).

Discussion

In this study of 70 infertile women undergoing ovulation induction, Letrozole (L) demonstrated superior outcomes compared to Clomiphene Citrate (CC) across follicular development, endometrial thickness, ovulation rate, and serum progesterone levels, consistent with previously published literature. The mean age of participants was 25.51 ± 4.62 years in the Letrozole group and 25.43 ± 4.55 years in the Clomiphene group, comparable to findings by Legro et al. [1] and Liu et al. [2], who reported similar age distributions in women with polycystic ovary syndrome (PCOS) undergoing ovulation induction. Baseline demographic characteristics, including parity, socioeconomic status, and occupation, were similar between groups, aligning with observations by Pandya et al. [3] that these factors do not significantly influence ovulatory response.

Letrozole resulted in larger follicles on day 14 (19.94 ± 1.41 mm vs. 18.06 ± 1.41 mm, p < 0.001) and greater endometrial thickness (8.55 ± 0.34 mm vs. 7.76 ± 0.50 mm, p < 0.001), consistent with studies by Elmahaishi et al. [4] and Kar et al. [5], which reported improved endometrial receptivity and mono-follicular development with Letrozole. Clomiphene showed larger follicles on day 16 (13.63 ± 1.37 mm vs. 10.11 ± 1.59 mm, p < 0.001) and higher multi-follicular development, confirming observations by Shah et al. [6] regarding its risk of multiple follicle recruitment.

The ovulation rate was higher with Letrozole (28/35 vs. 18/35, p < 0.001), echoing findings by Liu et al. [7] and Pandya et al. [8], who documented higher ovulatory success with Letrozole. Minimal complications were observed, with abdominal pain in 2.9% of Letrozole cycles and OHSS in 5.7% of Clomiphene cycles, supporting prior safety data reported by Legro et al. [9] and Elmahaishi et al. [10]. Overall, functional outcomes in terms of ovulation and follicular response were excellent in the Letrozole group, confirming its efficacy and safety as a first-line ovulation induction agent, particularly in women with PCOS, consistent with previous studies.

Conclusion

In infertile women with polycystic ovary syndrome, Letrozole demonstrated superior efficacy compared to Clomiphene Citrate for ovulation induction, with higher ovulation rates, better endometrial thickness, and more favorable follicular development, while maintaining a low incidence of adverse effects. Clomiphene Citrate, although effective, was associated with multi-follicular development and a slightly higher risk of complications such as ovarian hyperstimulation. Overall, Letrozole offers a safer and more effective first-line option for ovulation induction in PCOS patients, optimizing reproductive outcomes and supporting its preferential use in clinical practice.

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