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Original Research Article

STUDY OF THE PROTOCOLS OF OVULATION INDUCTION IN THE PATIENTS OF POLYCYSTIC OVARIAN SYNDROME WITH INFERTILITY AND ITS OUTCOME AT A TERTIARY CARE CENTER

Bharti Maheshwari[1], Preeti Sharma[2], Anita Mathew[3]

[1]Professor and Head, Department of Obstetrics and Gynaecology, Muzaffarnagar medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India.
[2]Associate Professor, Department of Obstetrics and Gynaecology, Muzaffarnagar medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India.
[3]Post Graduate, Department of Obstetrics and Gynaecology, Muzaffarnagar medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India.

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Corresponding Author:
Dr. Anita Mathew,
Post Graduate, Department of Obstetrics and Gynaecology, Muzaffarnagar medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India..
Email: anitamathew382@gmail.com

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ABSTRACT

Background: Polycystic Ovarian Syndrome (PCOS) is a common cause of anovulatory infertility. Various ovulation induction protocols are available, but selecting the most effective one requires clinical evaluation based on individual response and safety. The objective of the study is to assess and compare the outcomes of three different ovulation induction protocols in women with PCOS-related infertility: Letrozole alone, Letrozole with Gonadotropins, and Chronic Low Dose Gonadotropin protocol.
Materials and Methods: This prospective study was conducted on 120 women diagnosed with PCOS and infertility. Participants were randomly divided into three equal groups. Group A received Letrozole alone, Group B received Letrozole plus a single dose of Gonadotropin, and Group C underwent a chronic low-dose Gonadotropin regimen. All patients were monitored for follicular development, endometrial thickness, ovulation, and hormone levels. Statistical analysis was performed to compare the outcomes across groups.
Results: Ovulation was achieved in 71.7% of patients. Group B had the highest ovulation rate (80%) and better follicular response and endometrial development. Group C showed higher rates of monofollicular growth but delayed ovulation. Group A had the lowest hormonal and endometrial responses. Differences in ovulation day, number of dominant follicles, and hormone levels were statistically significant among the groups.
Conclusion: The combination of Letrozole and Gonadotropins yielded better clinical outcomes in terms of ovulation and endometrial response. Individualized selection of induction protocols based on patient profile and response is recommended to optimize fertility outcomes in women with PCOS.
Keywords: Ovulation Induction, PCOS, Letrozole.

INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is one of the most prevalent endocrine disorders among women of reproductive age, affecting approximately 6–16% of this population globally, with an even higher prevalence—up to 20%—among infertile women.[1,2] Initially described by Stein and Leventhal in 1935 as sclerocystic ovaries, the condition is now recognized as a multifaceted syndrome characterized by chronic anovulation, clinical or biochemical hyperandrogenism, and polycystic ovarian morphology on ultrasound.[3] Diagnosis is typically established based on the Rotterdam criteria, which require the presence of at least two of the aforementioned features, following the exclusion of differential diagnoses such as Cushing's syndrome and late-onset congenital adrenal hyperplasia.[4] PCOS is associated with a spectrum of metabolic and reproductive comorbidities, including obesity, type 2

diabetes mellitus, cardiovascular disease, obstructive sleep apnea, endometrial hyperplasia, and mood disorders.[1,5]

The international consensus on PCOS, reaffirmed in the 2018 and 2023 guidelines, emphasizes a comprehensive and individualized approach to diagnosis and management. These guidelines endorse lifestyle modification as the first-line therapy, especially for overweight patients, and advocate for early detection of metabolic risks such as insulin resistance and dyslipidemia.[5,6] Letrozole has emerged as the preferred ovulation induction agent due to its superior ovulation and pregnancy rates, as well as its favorable safety profile when compared to clomiphene citrate.[6,7] The guidelines also underscore the significance of individualized protocols that consider phenotypic variations among PCOS patients to optimize clinical outcomes.[7]

Infertility, defined as the inability to conceive after 12 months of regular unprotected intercourse, affects nearly one in six couples globally, with ovulatory dysfunction—most notably due to PCOS—contributing to about 25–30% of cases. Among anovulatory women, PCOS is identified in approximately 70%.[8] Various ovulation induction protocols are utilized to restore fertility in these patients, including the use of oral agents like letrozole, injectable gonadotropins, and combination therapies. While letrozole acts by inhibiting aromatase and promoting a natural rise in follicle-stimulating hormone (FSH), gonadotropins directly stimulate the ovaries, with the chronic low-dose regimen providing a safer alternative that minimizes the risk of ovarian hyperstimulation syndrome (OHSS).[9,10]

Despite the availability of multiple ovulation induction protocols, the optimal regimen for women with PCOS-related infertility remains a subject of ongoing research. The present study aims to compare the effectiveness and safety of three commonly used strategies—letrozole alone, letrozole combined with gonadotropins, and the chronic low-dose gonadotropin protocol. By evaluating ovulation rates, adverse effects, and pregnancy outcomes, this research seeks to provide evidence-based guidance for clinicians and improve fertility care in women with PCOS. Given the limited comparative studies in this domain, the findings of this study may significantly contribute to refining treatment protocols and enhancing reproductive outcomes in affected women.

MATERIALS AND METHODS

This hospital-based prospective study was conducted in the Department of Obstetrics and Gynaecology at Muzaffarnagar Medical College and Hospital over a period of 18 months. Ethical approval was obtained from the Institutional Ethics Committee (IEC No: MMC/IEC/2023/254). The study included 120 women aged 20 to 40 years who were diagnosed with polycystic ovarian syndrome (PCOS) based on the Rotterdam 2003 criteria and had infertility. Patients with a BMI of up to 40 kg/m² were included. Informed written consent was obtained from all participants prior to enrolment.

Patients were excluded if they had tubal factors of infertility, male factor infertility, thyroid or prolactin disorders, congenital adrenal hyperplasia, ovarian or adrenal tumors, premature ovarian failure, uterine anomalies, active genital tuberculosis, liver or renal dysfunction, or any condition that could interfere with the study outcomes. A detailed clinical history was taken, and all participants underwent a general, systemic, and gynecological examination. Baseline investigations included hormonal assays (AMH, FSH, LH, insulin, testosterone, estradiol, progesterone, prolactin, and TSH), pelvic ultrasound, and other infertility work-up tests.

All eligible patients were first advised lifestyle modifications and were given metformin 500 mg twice daily for three months. Those with irregular menstrual cycles were treated with oral contraceptive pills for three cycles to regularize menstruation before starting ovulation induction protocols. A baseline ultrasound and serum estradiol level were obtained on Day 2 of the menstrual cycle to rule out any cysts or dominant follicles.

The patients were divided into three groups of 40 each based on the ovulation induction protocol. Group A received Letrozole 2.5 mg twice daily for five days starting from Day 3 of the menstrual cycle. Group B received the same Letrozole regimen along with a single intramuscular dose of recombinant FSH 150 IU on Day 7. Group C followed a chronic low-dose gonadotropin protocol starting with recombinant FSH 37.5 IU from Day 5, adjusted weekly based on follicular development as assessed by ultrasound. If no mature follicle developed by Day 28, the cycle was cancelled.

All patients were monitored by transvaginal ultrasound from Day 8 onwards to assess follicular growth, endometrial thickness, and ovulation signs. When a dominant follicle reached approximately 18 mm in size, HCG 10,000 IU intramuscularly was administered as a trigger. Ovulation was confirmed 48–72 hours later using transvaginal ultrasound for follicular rupture and presence of free fluid in the pouch of Douglas. Additionally, serum progesterone levels were measured one week after HCG administration to confirm ovulation (>3 ng/mL).

Data were collected using a structured proforma, including demographic and clinical variables. Statistical analysis was carried out using SPSS software. Descriptive statistics were used for baseline characteristics, and associations between variables were assessed using appropriate inferential tests. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 120 patients diagnosed with PCOS and undergoing ovulation induction were enrolled in the study and equally divided into three groups based on

the induction protocol used: Group A (Letrozole alone), Group B (Letrozole + Gonadotropins), and Group C (Chronic Low Dose Protocol). The mean age of participants was 30.73 ± 3.12 years, with the majority belonging to the 26–35 year age group. Most participants were housewives (54.2%), resided in urban areas (55.8%), and fell within the upper middle or middle socioeconomic class. The majority of patients (65.8%) were overweight, and 11.7% were obese. Comorbidities such as hyperlipidemia (14.2%), diabetes (5.8%), and hypertension (3.3%) were noted in a subset of patients, while 76.7% had no associated comorbidity [Table 1].

Table 1: Sociodemographic Profile of Participants (N=120)

Variable		Group A (n=40)	Group B (n=40)	Group C (n=40)	Total (%)
Age (years)	20–25	4	2	2	8 (6.7%)
	26–30	13	22	15	50 (41.7%)
	31–35	14	16	15	45 (37.5%)
	36–40	9	0	8	17 (14.1%)
Occupation	Housewife	23	18	24	65 (54.2%)
	Working	17	22	16	55 (45.8%)
Residence	Urban	22	25	20	67 (55.8%)
	Rural	18	15	20	53 (44.2%)
Socioeconomic Status	Upper Class	4	3	3	10 (8.3%)
	Upper Middle Class	10	14	13	37 (30.8%)
	Middle Class	14	11	10	35 (29.2%)
	Lower Middle Class	10	9	9	28 (23.3%)
	Lower Class	2	3	5	10 (8.3%)
BMI (kg/m²)	18.5 – 24.9 (Normal)	9	10	8	27 (22.5%)
	25.0 – 29.9 (Overweight)	28	25	26	79 (65.8%)
	≥ 30 (Obese)	3	5	6	14 (11.7%)
Comorbidities	Hyperlipidemia	6	4	7	17 (14.2%)
	T2DM	3	2	2	7 (5.8%)
	Hypertension	1	2	1	4 (3.3%)
	None	30	32	30	92 (76.7%)

Primary infertility was more prevalent than secondary infertility, observed in 60% of patients. The duration of infertility ranged from 2 to over 10 years, with the highest proportion (40%) falling in the 6–10 year category, followed by 26.7% with infertility persisting for more than a decade [Table 2].

Table 2: Infertility Profile of Study Participants (N=120)

Variable		Group A (n=40)	Group B (n=40)	Group C (n=40)	Total (%)
Type of Infertility	Primary	25	25	22	72 (60.0%)
	Secondary	15	15	18	48 (40.0%)
Duration of Infertility	2–5 years	12	15	13	40 (33.3%)
	6–10 years	19	14	15	48 (40.0%)
	>10 years	9	11	12	32 (26.7%)

Follicular development patterns varied significantly among the groups. Monofollicular growth was most common in Group C (90%) and Group A (85%), whereas Group B showed a lower rate (55%), but had a higher incidence of multifollicular development. The average number of dominant follicles was highest in Group B (1.7 ± 1.0), significantly more than in Group A (1.1 ± 0.3) and Group C (1.1 ± 0.4). Endometrial thickness on the trigger day was also significantly greater in Group B (11.1 ± 1.1 mm) and Group C (10.9 ± 0.4 mm) compared to Group A (8.9 ± 0.4 mm) [Table 3].

Table 3: Follicular Growth and Endometrial Response (N=120)

Parameter		Group A	Group B	Group C
No. of Dominant Follicles	1 Follicle	34 (85%)	22 (55%)	36 (90%)
	2 Follicles	5 (12.5%)	9 (22.5%)	3 (7.5%)
	3 Follicles	1 (2.5%)	5 (12.5%)	1 (2.5%)
	4 Follicles	0	4 (10%)	0
Mean ± SD (Follicles)		1.1 ± 0.3	1.7 ± 1.0	1.1 ± 0.4
Endometrial Thickness (mm)	< 9 mm	11 (45.8%)	0	0
	9–11 mm	13 (54.2%)	14 (43.7%)	18 (60%)
	≥11 mm	0	18 (56.3%)	12 (40%)
Mean ± SD (ET in mm)		8.9 ± 0.4	11.1 ± 1.1	10.9 ± 0.4

Ovulation was achieved in 86 out of 120 patients (71.7%). Group B showed the highest ovulation rate (80%), followed by Group C (75%) and Group A (60%). Although numerically different, these variations were not statistically significant ($p = 0.118$), indicating comparable ovulation success across the three protocols [Figure 1].

The timing of ovulation post-induction showed marked differences among the groups. Group B experienced the earliest ovulation with a mean day of

15.3 ± 1.5, followed by Group A at 16.7 ± 2.2. Group C had the latest ovulation (20.3 ± 2.9), reflecting protocol-related delay. These differences were statistically significant, emphasizing the impact of protocol on timing of ovulatory response [Table 4].

When evaluating composite outcomes of induction, significant differences were observed in multiple parameters. While ovulation rates did not vary significantly (p = 0.118), Group C had the highest monofollicular development (90%), and Group B showed a significantly greater number of dominant follicles (1.7 ± 1.0). Endometrial thickness and serum estradiol levels on the trigger day were both significantly higher in Group B (11.1 ± 1.1 mm and 1012.5 ± 57.5 pg/ml, respectively). Additionally, serum progesterone levels measured one week post-ovulation were highest in Group B (5.7 ± 2.1 ng/ml), compared to Group C (4.8 ± 1.5 ng/ml) and Group A (4.2 ± 1.5 ng/ml). These outcomes underscore the superior endometrial and hormonal responses in Group B [Table 5].

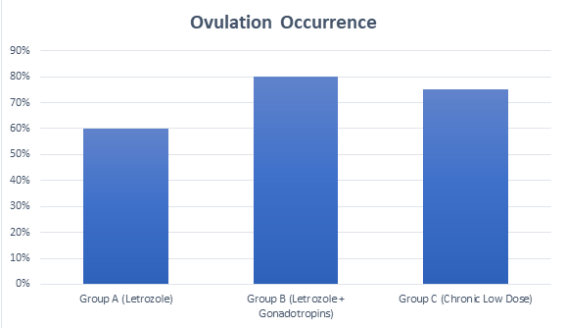

Figure 1: Bar chart showing ovulation occurrence among PCOS patients undergoing induction by different protocols

Table 4: Mean Day of Ovulation After Induction (Ovulatory Patients Only)

Group	Mean ± SD (Days)	Range (Days)
Group A	16.7 ± 2.2	14 – 21
Group B	15.3 ± 1.5	14 – 18
Group C	20.3 ± 2.9	16 – 26

Table 5: Comparison of Key Outcomes Across Ovulation Induction Protocols

Outcome Parameter	Group A (n=40)	Group B (n=40)	Group C (n=40)	p-value
1. Ovulation rate (%)	24 (60%)	32 (80%)	30 (75%)	0.118
2. Monofollicular growth (%)	34 (85%)	22 (55%)	36 (90%)	<0.001
3. Mean day of ovulation (days)	16.7 ± 2.2	15.3 ± 1.5	20.3 ± 2.9	<0.001
4. Mean no. of dominant follicles (DF)	1.1 ± 0.3	1.7 ± 1.0	1.1 ± 0.4	<0.001
5. Endometrial thickness (mm) on trigger day	8.9 ± 0.4	11.1 ± 1.1	10.9 ± 0.4	<0.001
6. Serum Estradiol (pg/ml) on day of trigger	940.1 ± 100.1	1012.5 ± 57.5	975.8 ± 90.1	<0.001
7. Serum Progesterone (ng/ml) 7 days post-ovulation	4.2 ± 1.5	5.7 ± 2.1	4.8 ± 1.5	<0.01

DISCUSSION

This study aimed to evaluate and compare the efficacy of three ovulation induction protocols—Letrozole alone, Letrozole + Gonadotropins, and the Chronic Low Dose protocol—in infertile women with polycystic ovarian syndrome (PCOS). The findings provide valuable insight into demographic, clinical, and ovulatory characteristics associated with different treatment regimens. Most patients (79.2%) were between 26–35 years, which aligns with the reproductive age group typically affected by PCOS, as noted in prior research by Teede et al. and Mulders et al.[11,12] This age distribution reflects the clinical reality that ovulation induction is predominantly sought by women in their reproductive prime. The majority of women were urban residents (66.7%), consistent with studies from India showing higher PCOS prevalence in urban populations due to sedentary lifestyles and dietary habits.[13,14]

A high prevalence of overweight and obesity (69.2%) was noted among the participants, reinforcing the established link between PCOS and metabolic dysregulation. This is in agreement with findings from Lim et al., who demonstrated that obesity aggravates both the reproductive and metabolic profiles of PCOS,[15] and Cesta et al., who observed diminished pregnancy and live birth rates in obese PCOS women undergoing IVF [16]. Additionally, primary infertility was more common (72.5%), which is expected given that PCOS often causes anovulatory infertility. Studies by Balen et al. support this, emphasizing the broader implications of PCOS on reproductive health and offspring outcomes.[17]

When analyzing the duration of infertility, it was observed that a significant portion of women (40%) had infertility lasting 6–10 years, with Group III showing a greater proportion with >10 years of infertility. Boivin et al. and Rooney et al. have similarly shown that longer infertility duration negatively impacts the success of ovulation induction and is associated with lower ovarian reserve.[18,19]

Regarding associated systemic conditions, our findings—14.2% hyperlipidemia, 5.8% Type 2 Diabetes Mellitus, and 3.3% hypertension—are in line with previous research by Azziz et al. and Randeva HS et al., who emphasized the increased risk of metabolic syndrome, insulin resistance, and cardiovascular disease in PCOS women.[20,21]

Group B (Letrozole + Gonadotropins) was superior in inducing multiple follicular growth (45%), with the highest mean follicle number (1.7 ± 1.0) and endometrial thickness (11.1 ± 1.1 mm), suggesting better ovulatory potential and endometrial

receptivity. These findings are consistent with studies by Legro et al. and Franik et al., which highlighted improved follicular recruitment and ovulation success using combination therapy.[22,23]

Estradiol and serum progesterone levels were also highest in Group B, indicating enhanced follicular function and luteal support. Mitwally & Casper and Kasius et al. confirmed that improved hormonal profiles and endometrial thickness positively influence implantation and pregnancy outcomes, though excessive estradiol levels may require OHSS risk monitoring.[24,25] Group C (Chronic Low Dose) showed moderate hormonal response but had significantly delayed ovulation (mean: 20.3 ± 2.9 days), which may affect cycle planning and patient adherence.

This study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Follow-up was limited to ovulation outcomes, and pregnancy or live birth rates were not assessed. Hormonal and biochemical assessments were performed only at selected time points, which may not capture the full endocrine dynamics of each protocol. Long-term safety, cost-effectiveness, and patient-reported outcomes were also not evaluated.

CONCLUSION

This study concludes that among the three ovulation induction protocols evaluated in PCOS patients—Letrozole alone, Letrozole with Gonadotropins, and the Chronic Low Dose protocol—the combination of Letrozole and Gonadotropins demonstrated superior outcomes in terms of follicular development, endometrial thickness, hormonal response, and ovulation rate. While Letrozole alone remains a preferred first-line option due to its safety, cost-effectiveness, and ease of use, the enhanced efficacy observed with the combination regimen underscores its potential utility in selected patients who do not respond to monotherapy. The chronic low-dose protocol showed comparable ovulation rates with minimal side effects but was limited by delayed ovulation and longer cycle duration. These findings emphasize the need for individualized treatment approaches to optimize fertility outcomes in women with PCOS.

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