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Original Article

Impact of Lifestyle and Pharmacological Interventions on Fertility in PCOS: Patient Perspectives and Clinical Outcomes

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ABSTRACT

Background: Polycystic ovary syndrome is a leading cause of anovulatory infertility and is frequently associated with insulin resistance, obesity, menstrual dysfunction, and psychosocial burden. Integrated treatment strategies may improve reproductive outcomes by targeting both metabolic and ovulatory mechanisms. Objective: To evaluate the impact of lifestyle modification alone versus combined lifestyle and pharmacological therapy on ovulation, menstrual regularity, pregnancy, BMI, and patient experiences among women with insulin-resistant PCOS. Methods: A prospective mixed-methods observational study was conducted over four months in the Islamabad-Rawalpindi region. Seventy-two women aged 18–35 years with PCOS, insulin resistance, and subfertility were enrolled, and 68 completed follow-up. Quantitative outcomes included ovulation confirmed by mid-luteal progesterone, menstrual regularity, pregnancy confirmed by serum beta-hCG, BMI change, and progesterone levels. Qualitative interviews explored adherence and treatment experiences. Results: Ovulation increased from 18.1% to 57.4%, menstrual regularity from 22.1% to 61.8%, and pregnancy occurred in 20.6% of participants. Combined therapy produced higher ovulation than lifestyle modification alone (68.2% vs 46.7%) and greater BMI reduction (1.6 ± 0.8 vs 0.9 ± 0.6 kg/m²). BMI reduction correlated positively with ovulatory improvement. Conclusion: Combined lifestyle and pharmacological therapy improved short-term reproductive and metabolic outcomes in insulin-resistant PCOS. Keywords: Body Mass Index; Infertility; Insulin Resistance; Ovulation Induction; Polycystic Ovary Syndrome; Pregnancy Rate; Reproductive Health.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is among the most common endocrine disorders affecting women of reproductive age and remains a major contributor to anovulatory infertility. Its clinical phenotype is heterogeneous, commonly involving menstrual irregularity, hyperandrogenism, polycystic ovarian morphology, and metabolic abnormalities, particularly insulin resistance. Insulin resistance plays a central role in the pathophysiology of PCOS by aggravating hyperinsulinemia, ovarian androgen excess, impaired follicular maturation, and ovulatory dysfunction, thereby linking metabolic disturbance directly with reproductive impairment (1, 2). The burden of PCOS-related infertility is therefore not limited to failure of conception but extends to long-term metabolic risk, psychological distress, and

reduced quality of life, especially in sociocultural settings where infertility places disproportionate emotional and social pressure on women (3–5).

Pharmacological ovulation induction and insulin-sensitizing therapy remain important components of fertility management in PCOS. Metformin has been widely used to target insulin resistance, while ovulation induction agents such as clomiphene citrate are frequently used to restore ovulatory cycles in women seeking conception (6, 7). However, pharmacological therapy alone may not fully address the metabolic drivers of PCOS, particularly excess adiposity and impaired insulin sensitivity. Lifestyle modification through dietary regulation, structured physical activity, and weight reduction has therefore become a foundational strategy, as even modest weight loss may improve insulin sensitivity, menstrual cyclicity, and ovulatory function (8, 9). Despite its clinical importance, lifestyle modification is often difficult to sustain because adherence is shaped by motivation, counseling quality, environmental constraints, time limitations, and family or social support.

Although existing evidence supports both lifestyle and pharmacological approaches, important gaps remain in understanding their combined effectiveness in routine outpatient practice. Many available studies emphasize controlled clinical endpoints but provide limited insight into patient adherence, treatment acceptability, and contextual barriers that influence real-world outcomes. This gap is particularly relevant in resource-constrained South Asian settings, where access to structured fertility care, continuity of counseling, and sociocultural expectations may substantially affect treatment response (10–12). A patient-centered mixed-methods approach is therefore needed to evaluate not only whether combined intervention improves clinical fertility outcomes, but also how women experience and adhere to such treatment in routine care.

Using a PICO framework, the present study focused on women aged 18–35 years with insulin-resistant PCOS and subfertility, comparing lifestyle modification alone with combined lifestyle and pharmacological therapy, and evaluating ovulation, menstrual regularity, pregnancy, body mass index reduction, and patient-reported treatment experiences. The study was based on the hypothesis that combined lifestyle and pharmacological intervention would produce greater improvement in ovulatory function and early pregnancy outcomes than lifestyle modification alone, and that structured counseling would improve adherence and perceived treatment benefit among women with insulin-resistant PCOS (13).

MATERIALS AND METHODS

This prospective mixed-methods observational study was conducted over four months in outpatient gynecology and endocrinology settings in the Islamabad-Rawalpindi region. The design was selected to evaluate clinical outcomes under routine practice conditions while also incorporating patient perspectives regarding treatment adherence, perceived benefit, and barriers to lifestyle modification. The quantitative component assessed reproductive and metabolic outcomes from baseline to study completion, whereas the qualitative component explored treatment experiences through semi-structured interviews conducted at the end of follow-up.

Women aged 18–35 years were eligible if they had a confirmed diagnosis of PCOS based on Rotterdam criteria, evidence of insulin resistance assessed using the Homeostatic Model Assessment for Insulin Resistance, and a history of subfertility for at least one year. Women were excluded if they had infertility attributable to non-PCOS causes, including tubal blockage or male factor infertility, chronic systemic disorders such as diabetes mellitus or thyroid disease, current use of assisted reproductive technologies, or incomplete baseline clinical assessment. Participants were recruited consecutively from outpatient clinics after clinical eligibility was confirmed. Written informed consent was obtained before enrolment, and participants were informed about the study objectives, follow-up requirements, confidentiality of clinical and interview data, and their right to withdraw without affecting ongoing care.

A total of 72 women were enrolled at baseline. Sample size was determined pragmatically using comparable short-term fertility studies in PCOS populations, where cohorts of approximately 60–80 participants have been considered feasible for detecting clinically meaningful changes in ovulation and menstrual outcomes in routine care settings. Participants continued management according to standard clinical decision-making rather than random allocation. Based on the treating clinician's plan, participants received either lifestyle modification alone or combined lifestyle and pharmacological therapy. Lifestyle modification included dietary counseling, advice on caloric control and balanced macronutrient intake, and structured physical activity recommendations. Pharmacological management primarily included metformin for insulin resistance and ovulation induction agents such as clomiphene citrate where clinically indicated.

The primary outcome was ovulation achieved by the end of the four-month follow-up, confirmed using mid-luteal serum progesterone measurement. Secondary outcomes included menstrual regularity, confirmed pregnancy, change in body mass index, change in mid-luteal progesterone level, and patient-reported adherence and treatment acceptability. Pregnancy was confirmed using serum beta-human chorionic gonadotropin testing. Menstrual regularity was defined as restoration of predictable menstrual cycles during follow-up. Anthropometric assessment included body mass index and waist-to-hip ratio, recorded at baseline and during follow-up visits. Clinical and laboratory data were collected at baseline and monthly follow-up visits using standardized data collection forms to ensure consistency across participants.

To reduce measurement bias, ovulation and pregnancy outcomes were assessed using objective laboratory criteria rather than self-report alone. Consecutive recruitment was used to reduce selection bias, and baseline demographic and clinical variables were recorded to allow comparison between intervention groups. Because treatment allocation was based on clinical practice rather than randomization, confounding by baseline age, body mass index, severity of insulin resistance, and infertility duration was considered during analysis. Missing outcome data from participants lost to follow-up were handled using complete-case analysis for primary reporting, with denominators clearly stated for baseline and follow-up analyses.

Qualitative data were collected through semi-structured interviews after completion of the intervention period. The interview guide explored experiences with lifestyle modification, medication use, counseling, perceived psychological burden, adherence facilitators, and barriers such as dietary compliance, time constraints, and family support. Interviews were transcribed verbatim and analyzed using thematic analysis. Initial codes were generated from repeated reading of transcripts, then grouped into categories and broader themes. Coding consistency was strengthened through review of recurring patterns, comparison of coded segments, and confirmation that themes reflected participant experiences relevant to adherence, satisfaction, and perceived treatment benefit.

Quantitative data were analyzed using SPSS version 26. Continuous variables were summarized as mean and standard deviation, while categorical variables were presented as frequencies and percentages. Normality was assessed using the Shapiro-Wilk test. Paired comparisons were used to evaluate within-participant changes from baseline to follow-up, while independent t-tests or one-way analysis of variance were applied for between-group comparisons of continuous variables according to distributional assumptions. Chi-square tests were used for categorical outcomes, including ovulation and pregnancy rates. Pearson correlation analysis was performed to assess the association between body mass index reduction and ovulatory improvement. Where applicable, adjusted analyses were planned to account for clinically relevant confounders, including age, baseline body mass index, infertility duration, and baseline insulin resistance. A p-value below 0.05 was considered statistically significant.

Ethical approval was obtained from the relevant institutional review process before data collection. Participant confidentiality was maintained by anonymizing records and restricting access to study data. Data integrity was supported through standardized forms, consistent follow-up timing, verification of

laboratory-based outcomes, and cross-checking of entered data before analysis. This approach was intended to ensure reproducibility while preserving the pragmatic nature of evaluating integrated PCOS fertility care in routine outpatient practice.

RESULTS

A total of 78 eligible women were approached, of whom 72 consented and were enrolled, giving a response rate of 92.3%. Four participants were lost to follow-up, and the final complete-case analysis included 68 participants. Baseline characteristics showed that most participants were aged 25–30 years, with a mean age of 27.4 ± 4.2 years. Overweight and obesity were common, affecting 50 participants collectively, and the mean baseline BMI was 29.1 ± 3.8 kg/m². Baseline insulin resistance was moderate, with a mean HOMA-IR of 3.2 ± 0.9, while menstrual irregularity was present in 56 participants at enrolment.

Table 1. Baseline Demographic and Clinical Characteristics of Participants

Variable	Category	n (%) / Mean ± SD
Age	18–24 years	18 (25.0%)
	25–30 years	40 (55.6%)
	31–35 years	14 (19.4%)
Mean age	—	27.4 ± 4.2
BMI	Normal	22 (30.6%)
	Overweight	28 (38.9%)
	Obese	22 (30.5%)
Mean BMI	—	29.1 ± 3.8 kg/m²
Duration of infertility	—	2.8 ± 1.1 years
HOMA-IR	—	3.2 ± 0.9
Menstrual irregularity	Yes	56 (77.8%)
	No	16 (22.2%)

At the end of follow-up, ovulation increased from 18.1% at baseline to 57.4%, representing an absolute improvement of 39.3 percentage points. Menstrual regularity improved from 22.1% to 61.8%, with an absolute gain of 39.7 percentage points. Mean BMI decreased from 29.1 ± 3.8 kg/m² to 27.8 ± 3.5 kg/m², while mid-luteal progesterone increased from 5.6 ± 2.1 ng/mL to 9.8 ± 3.4 ng/mL. Pregnancy was confirmed in 14 of 68 participants, giving an overall pregnancy rate of 20.6%.

Table 2. Changes in Clinical Outcomes Over the Study Duration

Outcome	Baseline	End of Study	Absolute Change	p-value
Ovulation rate	18.1%	57.4%	+39.3 percentage points	<0.001
Regular menstrual cycles	22.1%	61.8%	+39.7 percentage points	0.002
BMI	29.1 ± 3.8 kg/m²	27.8 ± 3.5 kg/m²	−1.3 kg/m²	0.003
Mid-luteal progesterone	5.6 ± 2.1 ng/mL	9.8 ± 3.4 ng/mL	+4.2 ng/mL	<0.001
Confirmed pregnancy	—	14/68 (20.6%)	—	—

BMI reduction showed a statistically significant positive association with ovulatory improvement, indicating that greater reduction in BMI was related to better ovulatory response. The correlation was moderate in strength and clinically relevant.

Table 3. Correlation Between BMI Reduction and Ovulatory Improvement

Variables	Pearson r	p-value
BMI reduction and ovulatory improvement	0.42	0.001

Participants receiving combined lifestyle and pharmacological therapy showed better reproductive and metabolic outcomes than those receiving lifestyle intervention alone. Ovulation was achieved in 68.2% of the combined-therapy group compared with 46.7% in the lifestyle-only group, corresponding to a risk ratio of approximately 1.47. Pregnancy was also higher in the combined-therapy group, at 26.3% compared with 13.3%. Mean BMI reduction was greater with combined therapy, with a between-group mean difference of 0.70 kg/m².

Table 4. Comparative Outcomes by Intervention Type

Outcome	Lifestyle Only (n=30)	Combined Therapy (n=38)	Effect Estimate	p-value
Ovulation achieved	14/30 (46.7%)	26/38 (68.2%)	RR 1.47; RD +21.8 percentage points	0.041
Pregnancy achieved	4/30 (13.3%)	10/38 (26.3%)	RR 1.97; RD +13.0 percentage points	0.048
BMI reduction	0.9 ± 0.6 kg/m²	1.6 ± 0.8 kg/m²	Mean difference +0.70 kg/m²	0.020

The clinical response profile demonstrated that the largest absolute improvements occurred in menstrual regularity and ovulation, with gains of 39.7 and 39.3 percentage points, respectively. Pregnancy occurred in 20.6% of participants during the four-month follow-up, suggesting that restoration of ovulatory and menstrual function translated into early fertility benefit, although longer follow-up would be required to evaluate sustained conception and live birth outcomes.

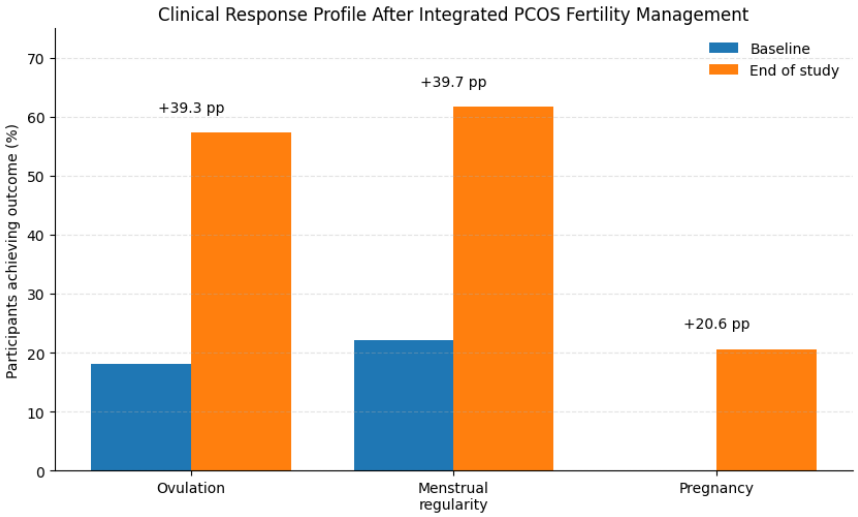

Figure 1 Clinical Response Profile After Integrated PCOS Fertility Management

The figure shows marked clinical improvement after integrated PCOS fertility management, with ovulation increasing by 39.3 percentage points, menstrual regularity by 39.7 percentage points, and pregnancy achieved in 20.6% of participants by the end of the study.

DISCUSSION

The present study demonstrated that integrated lifestyle and pharmacological management was associated with clinically meaningful improvement in reproductive outcomes among women with insulin-resistant PCOS. Ovulation increased from 18.1% at baseline to 57.4% after four months, while menstrual regularity improved from 22.1% to 61.8%, indicating restoration of ovarian cyclicity in a substantial proportion of participants. Pregnancy was achieved in 20.6% of women during the short follow-up period, which is clinically relevant in a population with at least one year of subfertility and no use of assisted reproductive techniques. The superior outcomes observed in the combined-intervention group, including higher ovulation rate, higher pregnancy rate, and greater BMI reduction, support the hypothesis that addressing both metabolic dysfunction and ovulatory impairment provides greater benefit than lifestyle modification alone (14, 15).

These findings are biologically plausible because insulin resistance contributes to hyperinsulinemia, androgen excess, impaired follicular development, and anovulation in PCOS. Metformin and ovulation induction agents may improve endocrine and ovulatory function, while lifestyle modification can improve insulin sensitivity, body composition, and menstrual cyclicity. The observed correlation between BMI reduction and ovulatory improvement further supports the metabolic basis of reproductive recovery in PCOS. Although the mean BMI reduction was modest, the association with ovulation suggests that even short-term weight-related improvement may produce measurable reproductive benefit, consistent with evidence emphasizing metabolic optimization as a central target in PCOS fertility care (16, 17).

The pregnancy rate of 20.6% should be interpreted cautiously but remains clinically important given the short duration of follow-up. The combined-therapy group showed almost twice the pregnancy rate of the lifestyle-only group, suggesting that pharmacological support may accelerate reproductive response when combined with structured lifestyle intervention. However, pregnancy is influenced by multiple factors beyond ovulation, including duration of infertility, tubal status, semen parameters, treatment adherence, and timing of intercourse. Therefore, the pregnancy findings should be viewed as early fertility outcomes rather than definitive evidence of long-term reproductive success or live birth benefit (18).

The qualitative findings strengthened the interpretation of the quantitative results by showing that structured counseling improved adherence, satisfaction, and perceived treatment benefit. This patient-centered dimension is important because lifestyle modification is often difficult to sustain, especially when women face dietary restrictions, time constraints, psychological stress, or limited family support. These barriers may explain why lifestyle-only treatment produced lower reproductive gains than combined therapy. Integrating counseling, follow-up support, and individualized treatment goals may therefore improve both clinical outcomes and patient engagement in routine PCOS care (19).

This study had several strengths. Its prospective mixed-methods design allowed simultaneous evaluation of clinical outcomes and patient experiences, improving the practical relevance of the findings. Objective outcome assessment using mid-luteal progesterone and serum beta-hCG strengthened reproductive outcome measurement, while monthly follow-up reduced recall bias. The inclusion of a real-world outpatient population also improved applicability to routine clinical practice, particularly in South Asian settings where PCOS, obesity, insulin resistance, and infertility-related psychosocial burden frequently coexist (20).

Several limitations should be considered. The study was observational and non-randomized, so treatment allocation may have been influenced by baseline clinical differences, patient preference, physician judgment, or severity of symptoms. Although baseline characteristics were documented, residual confounding cannot be excluded. The sample size was modest, and the four-month follow-up was too short to evaluate sustained ovulation, miscarriage, live birth, long-term metabolic control, or treatment discontinuation. Lifestyle adherence was partly self-reported, which may have introduced reporting bias. The study also did not objectively quantify dietary intake or physical activity, limiting interpretation of the independent contribution of lifestyle modification (21, 22).

Future research should use larger randomized controlled designs with longer follow-up and live birth as a key endpoint. Adjusted analyses should account for baseline BMI, age, infertility duration, HOMA-IR, and PCOS phenotype. Objective adherence measures, including dietary logs, activity tracking, and medication compliance assessment, would improve reproducibility. Culturally tailored counseling and psychosocial support should also be evaluated as intervention components, as adherence barriers are likely to influence treatment success in routine care settings (23).

CONCLUSION

Combined lifestyle and pharmacological intervention produced significant short-term improvements in ovulation, menstrual regularity, BMI, and early pregnancy outcomes among women with insulin-resistant PCOS. The findings suggest that reproductive improvement in PCOS is closely linked to metabolic optimization, with BMI reduction showing a moderate positive association with ovulatory recovery. Although the observational design and short follow-up limit causal inference and long-term interpretation, the results support integrating structured lifestyle counseling with insulin-sensitizing and ovulation-induction therapy as a practical, patient-centered approach for fertility management in routine outpatient care.

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