

CLINICAL AND ENDOCRINE EVALUATION OF HORMONAL THERAPY IN THE MANAGEMENT OF POLYCYSTIC OVARY SYNDROME (PCOS): A LONGITUDINAL OBSERVATIONAL STUDY

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Relevance

Polycystic Ovary Syndrome (PCOS) represents one of the most common endocrine disorders affecting women of reproductive age. With a global prevalence estimated at around 10–15%, PCOS manifests in a spectrum of clinical features including hyperandrogenism, oligo/anovulation, and polycystic ovarian morphology. Additionally, it is associated with significant metabolic complications, including insulin resistance, type 2 diabetes mellitus, dyslipidemia, and obesity. The heterogeneity of PCOS presentation and progression necessitates individualized treatment plans.

Hormonal therapy, primarily involving combined oral contraceptives (COCs) and anti-androgen agents, remains the cornerstone of symptom management in PCOS. While COCs effectively regulate menstrual cycles and reduce hyperandrogenic symptoms, the variability in individual responses to these therapies necessitates further clinical evaluation. This research provides a longitudinal analysis of the efficacy of hormonal therapy on clinical, endocrine, and metabolic parameters over an extended follow-up period, thereby contributing to optimizing therapeutic strategies for PCOS.

Aim

The primary aim of this research is to evaluate the effectiveness of hormonal therapy in managing clinical symptoms, endocrine dysfunction, and metabolic anomalies in women with PCOS over a 24-month follow-up period. Secondary objectives include assessing patient compliance, side-effect profiles, and the impact on quality of life.

Materials and Methods

Study Design: This is a prospective, longitudinal observational study conducted over 24 months at the Department of Endocrinology and Reproductive Medicine in a tertiary care academic

hospital. The research was approved by the institutional ethics committee, and informed consent was obtained from all participants.

Participants: A total of 300 women aged 18–35 years diagnosed with PCOS based on the Rotterdam criteria (presence of at least two of the following: oligo/anovulation, clinical or biochemical signs of hyperandrogenism, and polycystic ovaries on ultrasound) were enrolled.

Group Division: Participants were divided into three treatment groups:

- a. Group A (n=100): Received COCs containing ethinylestradiol (30 mcg) and cyproterone acetate (2 mg).
- b. Group B (n=100): Received metformin (1500 mg/day) and spironolactone (100 mg/day).
- c. Group C (n=100): Received lifestyle modification counseling, including dietary changes and structured physical activity.

Inclusion Criteria:

- Women aged 18–35 years
- Diagnosed with PCOS using Rotterdam criteria
- No history of hormonal treatment in the past 6 months

Exclusion Criteria:

1. Presence of other endocrine disorders (thyroid dysfunction, Cushing's syndrome, hyperprolactinemia)
2. Pregnancy or lactation
3. Contraindications to hormonal therapy
4. Data Collection: Baseline data collected included:
5. Anthropometric measures (height, weight, BMI, waist-to-hip ratio)
6. Menstrual history and pattern
7. Hirsutism score using the modified Ferriman-Gallwey scale
8. Acne severity grading
9. Serum hormone levels (LH, FSH, total testosterone, SHBG, DHEAS)
10. Fasting blood glucose, insulin, HOMA-IR
11. Pelvic ultrasound to assess ovarian morphology

Follow-up assessments were conducted every 6 months for 24 months, recording changes in clinical symptoms, biochemical markers, and adherence to therapy.

Statistical Analysis: Descriptive statistics were used for baseline characteristics. Repeated-measures ANOVA was applied to assess changes over time within and between groups. A p-value of <0.05 was considered statistically significant.

Analysis was performed using SPSS Version 26.0.

Results

Baseline Characteristics: All groups were comparable at baseline with respect to age, BMI, hirsutism score, hormone levels, and menstrual irregularities.

Menstrual Regulation: By 6 months, Group A showed normalization of menstrual cycles in 78% of participants. This increased to 90% by 12 months and was sustained at 92% at 24 months.

Group B showed delayed but significant improvement (60% by 12 months; 80% by 24 months). Group C had minimal improvement (20% at 24 months).

Hyperandrogenism: Group A showed significant reductions in serum testosterone (mean decrease of 1.5 ng/mL) and Ferriman-Gallwey scores (mean drop of 7 points) by 12 months. Group B showed a more gradual decrease. Group C showed negligible change.

Metabolic Parameters: Group B demonstrated the most significant improvement in insulin resistance and lipid profiles. HOMA-IR reduced from 4.2 to 2.1 ($p < 0.001$). Group A showed modest improvement, and Group C had minimal changes.

Ovarian Morphology: Ultrasound findings in Group A and B showed partial resolution of polycystic morphology by 24 months. No significant change was observed in Group C.

Quality of Life: WHOQOL-BREF questionnaire results showed improved psychological and social domains in Groups A and B. Group C reported negligible change.

Side Effects and Compliance: Group A experienced side effects including nausea (12%) and weight gain (10%). Group B had mild hypotension (5%) and menstrual spotting (8%).

Compliance was highest in Group A (88%) followed by Group B (80%) and Group C (65%).

Discussion

This study affirms the utility of hormonal therapy, especially combined oral contraceptives, in managing the reproductive and dermatological manifestations of PCOS. Group A showed substantial improvements in menstrual cycle regularity and hyperandrogenic symptoms, aligning with existing literature that supports the use of ethinylestradiol-cyproterone acetate combinations as first-line therapy.

Metformin and spironolactone (Group B) were effective in addressing metabolic dysfunction, notably insulin resistance. The delayed response observed in Group B underscores the need for longer therapeutic windows to observe metabolic benefits, in contrast to the rapid symptom relief seen with COCs.

Group C, which focused on lifestyle modification, confirmed the limited standalone effectiveness of non-pharmacological interventions. However, it should be noted that lifestyle changes remain an essential adjunct to pharmacologic therapy and may provide long-term cardiovascular benefits not captured within the study period.

The compliance and side-effect profile analysis further helps clinicians in tailoring treatment strategies. Despite modest side effects, the therapeutic benefits of hormonal therapy, particularly COCs, outweighed the risks in the majority of patients.

Limitations include the observational design, lack of randomization, and possible reporting bias in self-reported outcomes. Future studies may include randomized controlled trials comparing newer hormonal formulations and longer-term outcomes, especially concerning fertility.

Conclusion

Hormonal therapy remains a critical component in the management of PCOS. This longitudinal study demonstrated that COCs are effective in regulating menstrual cycles and reducing hyperandrogenic features. Anti-androgenic agents combined with insulin sensitizers offer superior metabolic control, supporting a symptom-directed treatment approach. Lifestyle modifications, while less effective as monotherapy, should be incorporated into comprehensive PCOS management plans. Personalized therapy based on dominant symptomatology, metabolic profile, and patient preference offers the best clinical outcomes.

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