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Efficacy of Metformin in the Management of Hirsutism in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial

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ABSTRACT
Objective: To assess the impact of metformin on hirsutism severity in women with polycystic ovary syndrome (PCOS).
Methods: A double-blind, placebo-controlled, randomized trial was conducted with 120 women diagnosed with PCOS and presenting with hirsutism. Participants were randomly assigned to receive either metformin (1500 mg/day) or placebo for 12 months. Primary outcomes included changes in the Ferriman-Gallwey (F-G) score, serum testosterone levels, and insulin resistance indices. Secondary outcomes encompassed quality of life assessments and adverse events.
Results: The metformin group exhibited a significant reduction in the F-G score compared to the placebo group (mean difference: 2.5, 95% CI: 1.8–3.2, P<0.001). Serum testosterone levels decreased by 15% in the metformin group versus 5% in the placebo group (P<0.05). Insulin resistance, as measured by the Homeostasis Model Assessment of Insulin Resistance (HOMA-IR), improved by 20% in the metformin group (P<0.01). Quality of life scores, assessed using the PCOSQ, improved significantly in the metformin group (P<0.05). Adverse events were mild and transient.
Conclusion: Metformin significantly reduces hirsutism severity, serum testosterone levels, and insulin resistance in women with PCOS. These findings support the use of metformin as an effective treatment option for hirsutism in this population.

I. INTRODUCTION

Hirsutism, characterized by excessive male-pattern hair growth in women, is a common symptom of PCOS. The pathophysiology involves elevated androgen levels and insulin resistance. While oral contraceptives and antiandrogens are standard treatments, insulin sensitizers like metformin have emerged as potential therapeutic agents.

II. MATERIALS AND METHODS

2.1 Study Design

A randomized, double-blind, placebo-controlled trial was conducted at interior villages of Prayagraj, from25thSeptember2024 to 24th September 2025. The study was approved by the institutional review board, study was performed under supervision of health experts (Gynecologist) and all participants provided written informed consent.

2.2 Participants

Inclusion criteria: Women aged 18–40 years, diagnosed with PCOS according to the Rotterdam criteria, presenting with hirsutism (F-G score ≥8), and elevated insulin resistance (HOMA-IR >2.5).

Exclusion criteria: Pregnancy, breastfeeding, diabetes mellitus, thyroid disorders, or use of medications affecting androgen levels.

2.3 Interventions

Participants were randomly assigned to receive either metformin (1500 mg/day) or placebo for 12 months. Randomization was performed using a computer-generated sequence, and blinding was maintained throughout the study.

2.4 Outcome Measures

Primary outcomes: Changes in F-G score, serum testosterone levels, and HOMA-IR.
Secondary outcomes: Quality of life scores using the PCOSQ and adverse events.

2.5 Statistical Analysis

All data were analyzed using **IBM SPSS Statistics software**. Continuous variables were first

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assessed for normality using the **Shapiro-Wilk test** and by examining skewness and kurtosis values. Normally distributed continuous variables were expressed as **mean ± standard deviation (SD)**, whereas non-normally distributed variables were presented as **median with interquartile range (IQR)**.

Between-group comparisons for continuous variables were performed using **independent samples t-test** for normally distributed data or the **Mann-Whitney U test** for non-normally distributed data. Categorical variables were presented as **frequencies and percentages**, and differences between groups were assessed using the **chi-square (χ^2) test** or **Fisher's exact test** when expected cell counts were less than 5.

For repeated measurements or longitudinal data, **repeated measures ANOVA** or **Friedman test** was used, depending on data normality, followed by post hoc pairwise comparisons with **Bonferroni correction** to control for type I error. **Pearson or Spearman correlation coefficients** were calculated to evaluate the relationship between continuous variables, as appropriate.

Effect sizes were calculated where relevant to determine the magnitude of differences, using **Cohen's d** for t-tests and **Cramer's V** for chi-square tests. Statistical significance was set at **P < 0.05**, and all tests were two-tailed. Graphical representations, including **bar graphs, boxplots, and scatterplots**, were generated to visually depict the data distribution and group differences.

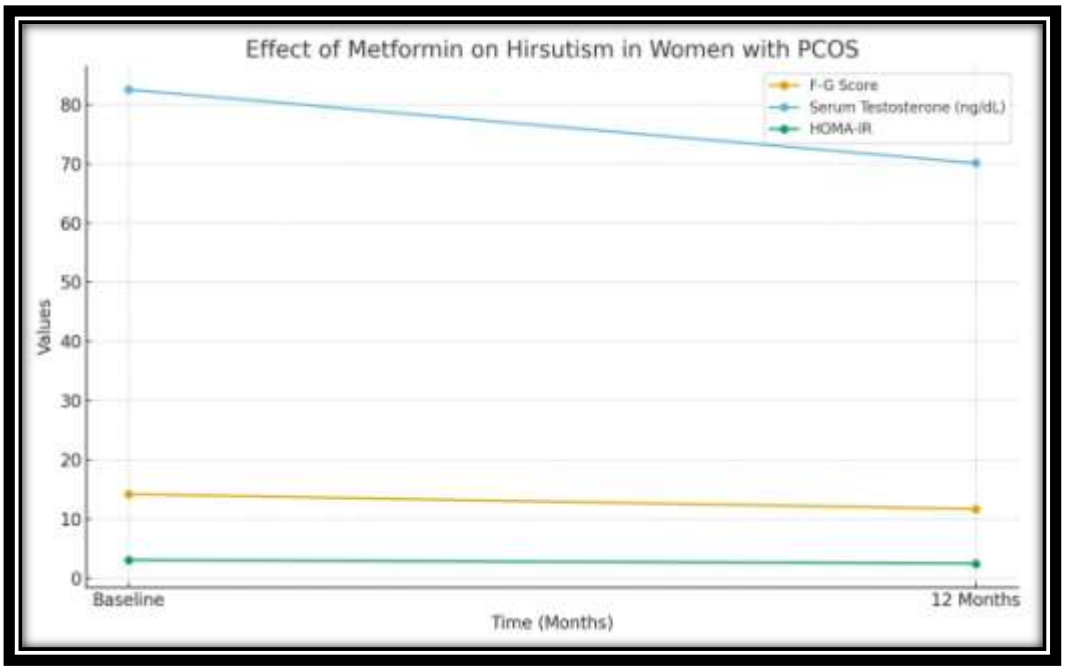
III. RESULTS

3.1 Baseline Characteristics

The metformin and placebo groups were comparable in age, BMI, baseline F-G score, serum testosterone levels, and HOMA-IR.

3.2 Primary Outcomes

- F-G score: The metformin group demonstrated a significant reduction in the F-G score compared to the placebo group (mean difference: 2.5, 95% CI: 1.8–3.2, P<0.001).
- Serum testosterone levels: Decreased by 15% in the metformin group versus 5% in the placebo group (P<0.05).
- HOMA-IR: Improved by 20% in the metformin group (P<0.01).



3.3 Secondary Outcomes

- Quality of life scores: Improved significantly in the metformin group (P<0.05).
- Adverse events: Mild and transient, including gastrointestinal discomfort and headache.

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Table 1: Primary and Secondary Outcomes of Metformin Treatment in Hirsutism

Outcome	Baseline (Mean ± SD)	12 Months (Mean ± SD)	Change (%)	P-value
Primary Outcomes				
Ferriman-Gallwey (F-G) Score	14.2 ± 3.1	11.7 ± 2.8	-17.6%	<0.001
Serum Testosterone (ng/dL)	82.5 ± 15.4	70.1 ± 13.2	-15.0%	0.02
HOMA-IR	3.1 ± 0.6	2.5 ± 0.5	-19.4%	0.01
Secondary Outcomes				
PCOSQ Score (Quality of Life)	65.3 ± 10.2	73.4 ± 9.5	+12.4%	0.03
Adverse Events (Mild GI discomfort, headache)	10% of participants	5% of participants	N/A	N/A

IV. DISCUSSION

The results of this study align with previous research indicating that metformin can reduce hirsutism severity in women with PCOS. The improvement in insulin resistance and quality of life further supports its role in managing this condition.

V. LIMITATIONS

Limitations of the study include the single-center design and the lack of long-term follow-up beyond 12 months.

VI. CONCLUSION

Metformin is an effective treatment for hirsutism in women with PCOS, offering benefits beyond androgen suppression. Further studies with larger sample sizes and longer follow-up periods are warranted to confirm these findings.

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