Original Article

# The Comparison of Impact Of Myo-Inositol In Combination With Metformin Versus Metformin Alone On Androgenic Features of PCOS Patients

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## Abstract

**Objective:** To compare the effects of a combination of myo-inositol and metformin versus metformin alone on hirsutism and acne in PCOS patients.

**Methods:** We randomised 114 adult women with polycystic ovary syndrome (PCOS) and hirsutism with acne to one of two treatments (double-blinded study) for 8 months (September 2022 to May 2023) at the outpatient department of gynaecology and obstetrics of Khyber Teaching Hospital, Peshawar: Group A (n = 57) received a combination of 500 mg of oral metformin three times per day and 4000 mg of myo-inositol once daily; Group B (n = 57) received 500 mg of oral metformin three times per day as single therapy. All hormonal, metabolic, and clinical indicators were assessed at the initial and 8-month points after the initiation of treatment.

**Results**: A significant difference was noted in terms of the mean change in the Farriman–Gallwey score in Group A (n=55), 3.59±0.81, versus Group B (n=54), 4.68±0.55 (p=0.00). Similarly, there was a notable improvement in mean change in Global acne score in Group A 1.51±0.50 when compared to Group B 2.38±0.67 (p =0.00), similarly there was significant differences between Group A 33.2±3.01 and Group B 41.5±32.99 in terms of mean serum Total testosterone levels p=0.00 and significant difference between Group A 95.56±5.71 and Group B 146.70±15.75 in terms of mean serum DHEA levels p=0.00.

**Conclusion**: Combining myo-inositol and metformin is more successful in treating hirsutism and acne in adult patients with PCOS than metformin alone in terms of balancing hormones and improving the metabolic profile.

**Keywords**: Polycystic ovarian syndrome, hirsutism, myo-inositol, metformin.

**Contributions:**
HEK AU AK - Conception, Design
HEK SKM MZ SG - Acquisition, Analysis, Interpretation
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## Introduction

The prevalent hormonal condition, Polycystic ovarian syndrome, targets 6 -20% of females of childbearing age.[1] According to the most widely used Rotterdam criteria, a woman must meet two of the three criteria listed below in order to be diagnosed with PCOS: oligo- or amenorrhoea, biochemical or clinical evidence of hyperandrogenism, and the typical ultrasonography features of the polycystic ovary. The second most used diagnostic classification in the US is the National Institutes of Health's (NIH) classification of PCOS as a consequence of both hyperandrogenism and ovulatory failure. Typically, Clinical hyperandrogenism manifests as hirsutism, acne, and alopecia.[2] Increased levels of serum androgen, such as androstenedione, DHEAS, free and total testosterone, and the free androgen index, are indicative of biochemical hyperandrogenism.[3] Many patients are diagnosed with PCOS when looking into symptoms like recurring acne, hirsutism, and oligo/amenorrhea in adolescents, but some women may not be aware of their disease until they seek out support for conception.[4] This condition puts a significant burden on health services in terms of reproductive treatments, managing obesity-related diseases, cutaneous, metabolic, cardiovascular, and associated psychological elements.

Insulin resistance (IR), which affects 50%–70% of the population, is the primary characteristic that distinguishes PCOs. It causes a hyperinsulinaemic compensatory reaction. Many scientists have also suggested a strong link between insulin levels and androgens, as insulin causes the production of androgens by thecal cells, and higher levels of androgens are associated with several problems, including skin abnormalities in PCOS.[5] The reported hyperinsulinaemia in PCOs is typically caused by decreased hepatic insulin clearance and increased basal insulin synthesis.[6]

Excessive terminal hair growth in women that follows a male pattern is referred to as "hirsutism." A common tactic is the modified semi-subjective Ferriman-Gallwey score, where hirsutism is indicated by a score of 4–8.[7] Two additional cutaneous markers of androgen excess are severe cystic acne and male pattern baldness. Because the Global Acne Grading Scale (0–4) evaluates the location (anatomic region) and type of acne lesions (comedones, papules, pustules, and nodules), it may provide more precise and comprehensive information about the severity of acne in hirsute individuals with PCOS.[8] Hirsutism and acne may negatively affect health because of their associations with anxiety and sadness. Promoting general well-being requires a comprehensive approach to patient care that addresses the psychological and physical aspects of acne.[9]

In the past, thiazolidinediones and metformin, two insulin-sensitising medications, have been employed to treat this syndrome. Both have been shown to reduce the ability of ovarian theca cells to produce androgens, prevent the liver from producing glucose, and increase the sensitivity of peripheral organs to insulin.

Patients with PCOS have been successfully treated with myo-inositol, a brand-new insulin-sensitizing substance. It reduces hyperinsulinaemia by post-receptor regulation of the insulin signal via membrane-associated GLUT4, a sodium-dependent inositol co-transporter. Relationships between inositol and other

compounds have been proposed, which may increase the therapeutic effect. Both myo-inositol and metformin lower insulin resistance through various mechanisms, thereby dramatically increasing insulin sensitivity in patients with PCOS.[10]
The main objective of this study is to improve the hormonal and metabolic profiles of patients with PCOS who are self-conscious about their facial appearance in order to alleviate their skin symptoms, namely hirsutism and acne, due to the synergistic effects of Myo-inositol and metformin when used in combination. This will significantly improve the quality of life and self-esteem of adult patients with PCOS.

## Materials And Methods

In the outpatient department of gynaecology and obstetrics of the Peshawar Teaching Hospital, a double-blinded, randomised controlled trial was conducted from September 2022 to May 2023 after approval by the Institute Ethics Committee. A total of 114 adult women with PCOS were screened and enrolled in the trial.
Women aged 20–38 years with polycystic ovary syndrome, a Global acne score ≥2.5, and a Modified Ferriman Gallwey score ≥4 were included in this study.
Patients with Cushing's syndrome, androgen-secreting tumours, uncontrolled hyperthyroidism or hypothyroidism, congenital hyperplasia of the adrenal glands (ambiguous genitalia), and those with uncontrolled hyperthyroidism or hypothyroidism were among the excluded groups. Consecutive (non-probability) sampling and a computer-generated randomisation table were used to divide the patients into two groups. The females' written informed permission was acquired following a comprehensive study description, objectives, and length.
After performing a thorough history and physical examination, including hip circumference (calculated as the distance between the two greater trochanters), waist circumference (measured horizontally to the umbilicus), waist-to-hip ratio, and body mass index (kg/m2), the patient's condition was determined. Secondary sexual features, the global acne scale, and the modified Ferriman-Gallwey hirsutism scale were noted.
Blood sampling for baseline biochemistry measurements, including a fasting blood sample, was taken to test for lipids, insulin, and glucose. The beta-cell function and insulin resistance were evaluated using the homeostatic model assessment (HOMA) approach. Hormonal assays included serum Free & Total Testosterone, SHBG, and DHEA, which were analyzed by Cobas c 702 using (EIA) enzyme immune assay kits for hormone testing. Every parameter was completed on days two to five of the menstrual cycle. (Table I)
All participants were randomly divided into two groups and received the prescribed care. Group A (57 subjects) obtained Myo-inositol 4000 mg/day, preferably at the same time each day (morning), and metformin 500 mg/day (TDS) (morning, evening, night). Group B (57 subjects) received metformin 500 mg/day TDS (morning, evening, and night) in envelopes. The treatment lasted for eight months.
After eight months of therapy, a follow-up was conducted, during which the Modified Ferriman Gallwey score and the Global Acne Scale were recorded. All laboratory investigations were repeated. All study participants had ongoing direct engagement with the researchers to resolve this issue throughout the 8-month trial period. Every month, a text message was sent to monitor any adverse effects and their compliance with their medication. They were encouraged to contact the researchers via WhatsApp during the experiment to keep them updated on their progress and to ask any questions they might have regarding PCOS or their medications. Regular contact most likely improved adherence and might have also affected the effectiveness of both therapies and how things went throughout the washout period. Two subjects from Group A and three subjects from Group B were withdrawn from the study as they were non-compliant and found the treatment ineffective.
Data were collected using a structured form. Version 23 of SPSS was utilised to examine the information. Initially, descriptive data analysis was conducted and reported in the form of tables and charts.
Normality of data was assessed to check the normal distribution of outcome variables. To determine the Mean and SD between the two groups, a Student's t-test was performed. P <0.05 was adopted as the significance level.

## Results

After 8 months of therapy, there was significant progress and difference in terms of the mean change in Farriman–Gallwey scores in Group A (n=55), 3.59±0.81 versus Group B (n=54) 4.68±0.55 (p= 0.00). Similarly, there was a notable improvement in mean change in Global acne score in Group A 1.51±0.50 when compared to Group B 2.38±0.67 (p =0.00), similarly there was significant differences between Group A 33.2±3.01 and Group B 41.5±32.99 in terms of mean serum Total testosterone levels p=0.00 and significant difference between Group A 95.56±5.71 and Group B 146.70±15.75 in terms of mean serum DHEA levels p=0.00 as shown in the Table. II and Table. III. However, five subjects found the therapies ineffective and withdrew.

**Table 1: Baseline differences in the two groups' demographics, clinical characteristics, hormonal, and metabolic profiles before treatment**

| Features | Group A (55 subjects) | Group B (54 subjects) | p-Value* |
|---|---|---|---|
| **Subjects Clinical Characteristics** | | | |
| **Individual Age** | 28.94 ± 3.77 | 28.61 ± 3.64 | (0.64) |
| **Body Mass Index (kg/m²)** | 28.58 ± 2.52 | 28.65 ± 2.35 | (0.88) |
| **Duration of menstrual cycle** | 2.36 ± 0.86 | 2.57 ± 0.59 | (0.14) |
| **Global scale of acne** | 2.81 ± 1.09 | 2.66 ± 1.14 | (0.59) |
| **Scale of Ferriman Gallwey** | 5.30 ± 1.31 | 5.25 ± 1.33 | (0.84) |
| **Metabolic Characteristics** | | | |
| **Blood sugar fasting (mg/dl)** | 99.2 ± 11.1 | 100.7 ± 11.2 | (0.48) |
| **Insulin fasting (ulL/dl)** | 101.3 ± 13.8 | 101.3 ± 13.3 | (0.97) |
| **Serum Total Cholesterol** | 176 ± 25 | 175 ± 21 | (0.86) |
| **Hormonal Characteristics** | | | |
| **Total Testosterone (ng/dl) levels** | 47.4 ± 2.7 | 47.09 ± 3.25 | (0.58) |
| **Serum DHEA (µg/dl) levels** | 199.30 ± 9.8 | 199.9 ± 12.3 | (0.67) |

*p<.05 is statistically significant*

**Table 2: mFG and Acne score at baseline.**

| Clinical Characteristics (Before therapy) | Group A (N=55) | Group B (N=54) | p-Value |
|---|---|---|---|
| **mFG score** | 5.30 ± 1.31 | 5.25 ± 1.33 | (0.84) |
| **Score of Global Acne** | 2.81 ± 1.09 | 2.66 ± 1.14 | (0.48) |
| **Serum Total testosterone (ng/dl) levels** | 47.4 ± 2.7 | 47.09 ± 3.25 | (0.58) |
| **Serum DHEA (µg/dl) levels** | 199.30 ± 9.8 | 199.9 ± 12.3 | (0.67) |

*p <.05 is statistically significant*

**Table 3: mFG and Acne score after 8 months**

| Clinical Characteristics (After therapy) | Group A (N=55) | Group B (N=54) | p-Value |
|---|---|---|---|
| **mFG score** | 3.59 ± 0.81 | 4.68 ± 0.55 | (0.00) |
| **Score of Global Acne** | 1.51 ± 0.50 | 2.38 ± 0.67 | (0.00) |
| **Serum Total testosterone (ng/dl)** | 33.2 ± 3.01 | 41.5 ± 32.99 | (0.00) |
| **Serum DHEA (µg/dl) levels** | 95.56 ± 5.71 | 146.70 ± 15.75 | (0.00) |

*p <.05 is statistically significant*

## Discussion

Biochemical hyperandrogenism is confirmed by the documentation of elevated serum androgen concentrations.[11] The relationship between circulating androgen concentrations, local androgen concentrations, and the sensitivity of the pilosebaceous unit/hair follicle to androgens determines the extent of the clinical signs of hyperandrogenism. Medications used to treat hirsutism may take several months to show a clinical response, and it may take up to a year to realize the complete benefits.[12] Myo-inositol and metformin, two insulin-sensitising medications, have been shown in numerous studies to significantly lower hyperandrogenism.[13] Managing hirsutism and acne in this way. Instead of using metformin as a monotherapy to treat PCOS symptoms, both of these insulin sensitisers can be taken in combination to alleviate hyperandrogenism through distinct mechanisms of action. In case of hirsutism, the current trial demonstrated a significant improvement in mFG scores due to a significant decrease in serum DHEA as well as total testosterone level in the group undergoing myo-inositol and metformin combination therapy as compared to metformin alone. Similar results were found in a study by Shazly, S. et al.,[14,] the group receiving combination therapy of metformin and inositol had a significant decrease in mFG scores (p=0.001) due to a significant decline in DHEA levels (p=0.001) as compared to the groups receiving metformin and/or inositol alone. Francinny Alves Kelly et al., [10] also found a significant decrease in hirsutism. Similarly, Genazzani et al. found a noticeable improvement in the Ferriman-Gallwey score. The mean mFG score of hirsutism also decreased significantly in Angik et al.'s study, which examined both groups after six months; however, the difference was not significant (p=0.813). Similarly, in a research by Agrawal et al.,[15] there was more improvement in a group receiving combination therapy of myo-inositol as well as metformin, as compared to a group receiving metformin alone, in case of mean mFG score (p=0.71), but the difference was not significant, suggesting that a longer time frame may have been needed to see the better outcomes. Similarly, in a study done by Ceyda Karadag et al.,[16,] although there was no discernible difference between the groups, all of the groups receiving metformin or myo-inositol alone or in combination saw a decline in modified Ferriman Gallwey scores. Nagaria et al. [17] found modest improvement in facial hair (10/34 or 29%). Fruzzetti et al. ([18] examined the effects of metformin and MI, and a minor improvement in hirsutism was noted in both groups. In a study by Sangeereni et al., [19] significant differences were seen with metformin in the case of hirsutism as compared to myo-inositol, but Sadia Wazir found myo-inositol superior to metformin in terms of mFG scores, but still did not find any significant difference between the two groups receiving metformin and Myo-inositol.[20] However, in a study by Nguyen Sa Viet et al. Metformin showed more improvement in hirsutism as compared to inositol [21]

Bahadur et al. ([22] did not find notable progress in the mean Hirsutism score (p=0.174) in the group receiving combined therapy with metformin and Myo-inositol. In cases of acne, the present study showed significant improvement in Group A using a combination of Myo-inositol and metformin, as compared to Group B using metformin alone (p=0.001). Similar results were achieved by Thakur et al. 23,[23] in which the global acne score (mFG score) significantly improved when Myo-inositol and metformin were administered in combination therapy, as opposed to groups utilising either Myo-inositol or metformin alone. Similarly, in a study on acne in patients with PCOS, Bahadur et al.,[22] also found substantial improvement in the mean acne score in the group receiving combined Myo-inositol and metformin therapy when compared to the group receiving metformin alone (p 0.004). In patients with PCOS utilising Myo-inositol plus metformin, Nagaria et al.,[17] noted the greatest improvement in acne (4/6) or 66.6%. Both Zacche et al. and Ranwa et al. also noted an improvement in acne following a 6-month course of Myoinositol administration due to a significant decrease in free and total testosterone levels. In a study by Agrawal et al.,[15] the mean acne score (p=0.09) improved more in the combination treatment group than in the metformin-only group; however, the difference did not reach statistical significance.

According to Francinny Alves Kelly et al.,[10,] there was no discernible difference in the acne score between the groups receiving Myo-inositol and Metformin combo treatment and those taking Metformin only. Fruzzetti et al.,[18] in which the authors examined the effects of Metformin and MI. The mean acne score did not, however, alter statistically significantly between the baseline and six-month evaluations.

## Conclusions

Our study provides evidence that myo-inositol and metformin combination therapy has higher efficacy in treating PCOS symptoms. Because of its synergistic benefits, this combination may be employed as the primary therapy method for patients with PCOS and hyperandrogenism, such as hirsutism and/or acne. However, more research utilising large sample sizes in randomised controlled trials is needed to determine whether the two medications should be used together or separately.

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