

Comparison of Metformin and Myoinositol In Improving Insulin Sensitivity of Women with Polycystic Ovarian Syndrome

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ABSTRACT

Objective: To determine the outcome of Metformin versus Myoinositol in women with polycystic ovarian syndrome."

Study Design: Quasi-experimental study

Place and Duration of Study: Department of Obstetrics & Gynecology, Avicenna Medical Hospital Lahore for 06 months (Oct-2022 to March-2023).

Methodology: One hundred patients were enrolled and divided in two Groups. In Group A, females were given Myo-inositol. In Group B, females were given Metformin. After 24 weeks, blood sample was taken for assessment of HOMA-IR. Reports were assessed and HOMA-IR level was recorded. Reduction in HOMA-IR in blood after 24 weeks of treatment was calculated. Information was recorded in proforma and analyzed in SPSS 23.

Results: The mean age of females in Myoinositol Group was 29.76 ± 9.11 years while the mean age of females in Metformin Group was 32.52 ± 8.81 years. In Myoinositol Group, 13(26%) had primary infertility and 25(50%) had secondary infertility. In Metformin Group, 7(14%) had primary infertility and 28(56%) had secondary infertility. In Myoinositol Group, the mean HOMA-IR at baseline was recorded as 27.59 ± 19.10 that was reduced to 21.28 ± 15.38 . In Metformin Group, the mean HOMA-IR at baseline was recorded as 24.13 ± 12.32 that was changed to 16.55 ± 7.56 . The difference in both Groups at baseline was insignificant as well as after 24 weeks, however the HOMA-IR was less in Metformin Group (p -value > 0.05).

Conclusion: Thus there is no difference in the HOMA-IR level whether Metformin is prescribed or Myoinositol is prescribed.

Keywords: Blood Glucose, Blood Insulin, HOMA-IR, Metformin, Myoinositol, Polycystic ovarian syndrome

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INTRODUCTION

The symptoms of PCOS, a heterogeneous endocrinopathy, include irregular menstruation, infertility, hyperandrogenemia, acanthosis nigricans, and a biochemical profile that includes elevated levels of androgen, hyperinsulinemia, dyslipidemia, obesity, and the luteinizing hormone/follicle-stimulating hormone (LH/FSH) ratio. About 21% of women in India who are of reproductive age have PCOS.¹ Insulin resistance has been reported in $>60\%$ patients with PCOS which include both obese and non-obese patients. Moreover, 10% women with PCOS develop diabetes by age of 40.

"Changes in intracellular signaling, which impact various metabolic disorders with or without changes in body mass index (BMI), are the hallmark of insulin resistance. The pathophysiology of anovulation and hyperandrogenism is mostly caused by IR with the ensuing hyperinsulinemia, which may lead to gonadal dysfunction and a serious metabolic disorder.

Reproductive patients.² Due to the central role of metabolic abnormalities in the pathophysiology of PCOS, insulin sensitizing agents have been proposed as a feasible treatment option.³

"Numerous oral insulin-sensitizing medications, including berberine, Metformin, thiazolidinediones, and inositols, have been shown to be safe and effective in addressing the endocrine, metabolic, and reproductive problems associated with PCOS, giving patients and healthcare professionals additional alternatives. Compared to injectable treatments, these oral insulin sensitizers are more affordable, practical, and handy. There is clinical confusion regarding the best course of treatment since the clinical efficacy of the four classes of oral insulin sensitizers for PCOS has not been compared.⁴ Insulin resistance, one of the main features of PCOS, can be effectively treated with the insulin sensitizer medications Metformin, myo-inositol, and D-chiro-inositol.^{5, 6"}

Myo-inositol is thought to be a component of the vitamin B complex and natural sugar, and it makes cells more sensitive to insulin.⁷ One of the most significant physiological functions of Myoinositol is the transmission of the intracellular signal of insulin.

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Myoinositol-mediated insulin signaling permits the release of GLUT-4.8-containing vesicles. Metformin has been used for a long time and promotes post-receptor insulin signaling by increasing insulin-mediated insulin tyrosine kinase activity.⁸ Metformin and exenatide together improved weight reduction, menstrual irregularities, and endocrine abnormalities in a Group of obese, overweight, insulin-resistant women with PCOS.^{9,10}

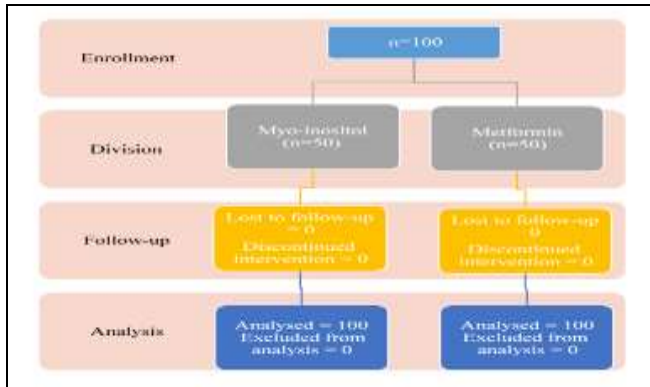


Figure: Patient Flow Diagram (n= 100)

The purpose of this study was to ascertain how Metformin and myo-inositol affected PCOS-afflicted women. According to published research, both medications can effectively treat PCOS. However, Metformin is often recommended for PCOS and, by lowering insulin resistance, improves insulin sensitivity. However, there hasn't been much prior study in this area. In order to gather local evidence and apply the findings in a local context, we therefore carried out this trial. In addition to improving insulin sensitivity, this would help us plan whether to administer Metformin or myo-inositol for PCOS, which would advance our understanding and practice.

METHODOLOGY

This Quasi-experimental study was done at Department of Obstetrics and Gynecology, Avicenna Medical College and Hospital Lahore for 06 months (Oct-2022 to March-2023) after attaining permission from ethical review board (IRB-26/12/22-AVC dated 29 Sep 2022). Sample size of 100 females; 50 in each Group is calculated with 80% power of study, 95% confidence level and mean change in HOMA-IR i.e. 1.32 ± 0.02 with myo-inositol and 1.1 ± 0.5 with Metformin.⁵ Females who fulfilled following selection criteria were enrolled after applying consecutive sampling technique (Non-probability).

Inclusion Criteria: Females of age 16-45 years diagnosed with PCOS were enrolled in the study. It was confirmed if females had history of oligomenorrhea, presence of >12 large sized cysts (on ultrasound), hirsutism and acne with LH/FSH ratio >1. According to Rotterdam criteria presence of at least two of the three criteria, namely, chronic anovulation, hyperandrogenism (clinical or biological) and polycystic ovaries on ultrasound

Table-I: Demographics of Females Recruited in the Study (n = 100)

	Myoinositol 1g	Metformin 500mg
n	50	50
Age (in years)	29.76±9.11	32.52±8.81
Height (m)	1.58±0.04	1.58±0.04
Weight (kg)	80.48±7.62	83.66±7.34
BMI (kg/m ²)	32.15±3.38	33.53±3.57
Marital status		
Married	38(76%)	35(70%)
Unmarried	12(24%)	15(30%)
Infertility		
Primary	13(26%)	7(14%)
Secondary	25(50%)	28(56%)
Not applicable (unmarried)	12(24%)	15(30%)
Parity		
Nulliparous (primary infertility)	13(26%)	7(14%)
Parity 1	12(24%)	13(26%)
Parity 2	13(26%)	15(30%)
Not applicable (unmarried)	12(24%)	15(30%)
Occupation		
Housewife	20(40%)	25(50%)
Working lady	30(60%)	25(50%)
Lifestyle		
Active (>working hours)	19(38%)	22(44%)
Sedentary (>8 lazy hours)	28(56%)	23(46%)
Gym / exercise	3(6%)	5(10%)
Residence		
Rural	24(48%)	24(48%)
Urban	26(52%)	26(52%)
Diet routine		
Home-made	33(66%)	35(70%)
Fast-food	5(10%)	6(12%)
Street-food / oily food	4(8%)	3(6%)
Following diet chart	8(16%)	6(12%)

Exclusion Criteria: PCOS with pregnancy and nursing, neoplastic disease, hyperprolactinemia >20ng/ml, Cushing's disease, Hypothyroidism /

Hyperthyroidism (TSH>5 mIU), Active liver disease (ALT & AST >40 IU), renal impairment (creatinine >1.8 mg/dl), Established type 1 or type 2 diabetes mellitus (BSR>200 mg/dl), history of drug intake-Anti diabetic (or) oestrogen and progesterone, already taken treatment in last 3 months for PCOS or smokers and alcoholic subjects, inability to come for regular follow-ups were excluded from the study.

Table-II: Comparison of Mean Homa-Ir In Both Groups During Follow-Up (n=100)

	Group		p-value
	Myoinositol 1g	Metformin 500mg	
n	50	50	
Blood glucose fasting at baseline (mg/dl)	99.00±12.51	98.36±11.92	0.794*
Blood insulin fasting at baseline (mg/dl)	6.24±4.18	5.68±3.09	0.448*
HOMA-IR at baseline	21.38 (25.03)	24.13 (20.87)	0.801!
Blood glucose fasting after 24 weeks (mg/dl)	77.26±9.40	82.50±10.54	0.010*
Blood insulin fasting after 24 weeks (mg/dl)	6.08±4.16	4.62±2.25	0.032*
HOMA-IR after 24 weeks	17.35 (18.43)	16.55 (12.49)	0.517!

* = independent sample t-test

! = Mann-Whitney U-test

After enrollment, informed consent was obtained after explaining them the pros and cons of the research. The following demographic details were noted i.e. name, age, height, weight, BMI, marital status, type of infertility. Blood sample was taken in a 3cc disposable syringe and sent to the laboratory of the hospital for assessment of HOMA-IR. Reports were assessed and HOMA-IR level was recorded by using following formula:

$$\text{HOMA-IR} = (\text{Blood Glucose fasting} \times \text{Blood insulin Fasting}) / 22.5$$

Then females were randomly divided in two Groups by using lottery method. In Group A, females were given Myo-inositol 1g twice daily. In Group B, females were given Metformin 500 mg thrice daily.¹ In both Groups treatment was given for 24 weeks. After 24 weeks, blood sample was taken in a 3cc disposable syringe and sent to the laboratory of the hospital for assessment of HOMA-IR. Reports were assessed and HOMA-IR level was recorded. Reduction in HOMA-

IR in blood after 24 weeks of treatment was calculated. All this information was recorded in proforma.

Data was analyzed by using Statistical Package for Social Sciences (SPSS) 22.00. Normality of data was checked by Shapiro-Wilk test. Quantitative data was represented using mean ± standard deviation and median (IQR). Qualitative data was represented by using percentage and frequency. Independent Sample t-test (for normally distributed variables) and Mann-Whitney U-test (for non-normal data) were applied and p-value of ≤ 0.05 was considered as statistically significant.

RESULTS

In this trial, we recruited 100 females with PCOS and randomized them in two equal Groups. The mean age of females in Myoinositol Group was 29.76±9.11 years while the mean age of females in Metformin Group was 32.52±8.81 years. In Myoinositol Group, the mean height (m), weight (kg) and BMI (kg/m²) of females were 1.58±0.04 meter, 80.48±7.62 kg, and 32.15±3.38 kg/m², respectively. In Myoinositol Group, the mean height (m), weight (kg) and BMI (kg/m²) of females were 1.58±0.04 meter, 83.66±7.34 kg, and 33.53±3.57 kg/m². In Myoinositol Group, there were 12(24%) unmarried while 38(76%) married females, out of which 13(26%) had primary infertility and 25(50%) had secondary infertility. In Metformin Group, there were 15(30%) unmarried while 35(70%) married females, out of which 7(14%) had primary infertility and 28(56%) had secondary infertility. In Myoinositol Group, there were 20(40%) housewives and 30(60%) working ladies. In Metformin Group, there were 25(50%) housewives and 25(50%) working ladies. Details of their lifestyle, dietary habits and residence is given in table below Table I

In Myoinositol Group, the mean blood glucose fasting at baseline was recorded as 99.00±12.51 mg/dl that was reduced to 77.26±9.40 mg/dl. In Metformin Group, the mean blood glucose fasting at baseline was recorded as 98.36±11.92 mg/dl that was reduced to 82.50±10.54 mg/dl. The difference in both Groups at baseline was although insignificant but after 24 weeks, blood glucose level was significantly less with Metformin as compared to Myoinositol (*p*-value <0.05). In Myoinositol Group, the mean blood insulin fasting at baseline was recorded as 6.24±4.18 mg/dl that was changed to 6.08±4.16 mg/dl. In Metformin Group, the mean blood insulin fasting at baseline was recorded as 5.68±3.09 mg/dl that was changed to 4.62±2.25 mg/dl. The difference in both Groups at

baseline was although insignificant but after 24 weeks, blood insulin level was significantly less with Metformin as compared to Myoinositol (p -value <0.05). In Myoinositol Group, the median HOMA-IR at baseline was recorded as 21.38 (IQR: 25.03) that was reduced to 17.35 (IQR: 18.43). In Metformin Group, the median HOMA-IR at baseline was recorded as 24.13 (IQR: 20.87) that was changed to 16.55 (IQR: 12.49). The difference in both Groups at baseline was insignificant as well as after 24 weeks, however the HOMA-IR was less in Metformin Group (p -value >0.05). Table II

DISCUSSION

One of the most common endocrinological issues affecting women in their reproductive years is polycystic ovarian syndrome, or PCOS. Infertility, irregular menstruation, and increased androgens are the three signs that it manifests. One of the main contributing factors to the pathophysiology of PCOS may be insulin resistance. For doctors, controlled ovarian stimulation in women with PCOS in the context of assisted reproductive technology is never easy. It is yet unknown, nevertheless, if decreased ovarian sensitivity to exogenous gonadotropin is associated with insulin resistance in PCOS-afflicted women. 10" In this experiment, we found that the mean HOMA-IR at baseline was 21.38 (IQR: 25.03), but that Myoinositol decreased it to 17.35 (IQR: 18.43). When using Metformin, the mean HOMA-IR decreased from 24.13 (IQR: 20.87) at baseline to 16.55 (IQR: 12.49). The HOMA-IR was lower in the Metformin Group (p -value >0.05), but the difference between the two Groups at baseline and 24 weeks was not statistically significant."

Nehra *et al.*, We out a comparable experiment and found that HOMA-IR significantly improved in both Groups. After 24 weeks of follow-up, the mean glucose/insulin ratio improved in the Myoinositol Group from 6.77 ± 0.99 to 7.87 ± 1.03 and in the Metformin Group from 5.5 ± 0.42 to 6.90 ± 0.47 . The relative HOMA-IR readings dropped from 4.18 ± 0.4 to 2.88 ± 0.27 and 4.38 ± 0.43 to 2.99 ± 0.29 . They came to the conclusion that both Metformin and myo-inositol significantly improved the biochemical profile. Myo-inositol may therefore be a novel tool in the toolbox for PCOS therapy.¹¹ According to a 2019 study by Facchinetti *et al.*, HOMA-IR dropped from 2.4 ± 0.3 to 2.0 ± 0.3 while using Metformin and from 2.1 ± 0.5 to 1.5 ± 0.4 when taking Myoinositol ($p > 0.05$).⁷ According to another study, myo-inositol reduced HOMA-IR

from 3.96 ± 0.23 to 2.64 ± 0.21 while Metformin reduced it from 3.93 ± 0.36 to 2.83 ± 0.31 ($p > 0.05$).⁵

"But Anu *et al.*, carried out a comparable research and found that Myo-inositol significantly decreased serum fasting insulin levels and HOMA-IR (p -value <0.05) when compared to Metformin. Only 12% of patients in the Myo-inositol Group experienced adverse effects, mostly gastrointestinal problems, compared to 65% of individuals in the Metformin Group. The results of this study support the use of myo-inositol as a safe, effective substitute and a new tool in the toolbox of PCOS therapy because of its improved therapeutic effectiveness, safety, and tolerance profile.¹²" Gudovic *et al.*, further noted that both the Myoinositol and Metformin Groups saw notable alterations in HOMA-IR following therapy. At the conclusion of therapy, there was no change in any of the parameters between the two treatment Groups. These results offer important new information on how well both therapies work to control insulin and glucose levels.^{13,14}

While the BMI of participants was greater, studies comparing Metformin with Myoinositol showed similar outcomes on improving glucose-insulin parameters using similar methods, including duration of therapy, drug dose, and number of patients.^{14,15} In the study by Shokrpour *et al.*, Compared to Metformin, Myoinositol supplementation significantly improved glycaemic control in women with PCOS, according to a 12-week RCT comparing the two medications.¹⁶ The HOMA index ($p = 0.635$), BMI ($p = 0.265$), and fasting insulin ($p = 0.697$) did not differ between the two drugs in the big meta-analysis of randomised trials comparing two therapies.¹⁷

"Angik *et al.*, found that the Myoinositol Group's HOMA index showed a significant decline, but the Metformin Group's fall was not statistically significant.¹⁸ In contrast, Awalekar *et al.* discovered that the Metformin Group's mean HOMA index decreased from 25.85 to 15.21 ($p = 0.000$), which was statistically significant; however, the Myoinositol Group's decrease was not.¹⁹ Nehra *et al.* observed that, the degree of insulin resistance significantly decreased in both Groups. The mean glucose/insulin ratio increased from 6.77 ± 0.99 to 7.87 ± 1.03 and from 5.5 ± 0.42 to 6.90 ± 0.47 with Myoinositol and Metformin. For Myoinositol and Metformin, the HOMA index dropped from 4.18 ± 0.4 to 2.88 ± 0.27 and from 4.38 ± 0.43 to 2.99 ± 0.29 , respectively.¹¹ According to Nabi *et al.*,

when compared to Metformin, Myoinositol significantly decreased fasting insulin. But Metformin's reduction was more potent than Myoinositol's.²⁰ Facchinetti et al. observed no difference between Metformin and Myoinositol in fasting insulin and HOMA index.²¹

In the study by Thalamati *et al.*, as measured by the glucose-insulin ratio and HOMA-IR, insulin resistance improved statistically significantly in both Groups. In the Myoinositol Group, HOMA-IR dropped by 1.32 and the glucose-insulin ratio rose by 1.20. In contrast, the HOMA-IR dropped by 1.10 and the glucose-insulin ratio rose by 1.03 in the Metformin Group.²² Agarwal et al. observed that Metformin improved blood sugar levels while having a comparable impact on insulinemic markers (insulin, HOMA-IR).²³ Kutanaei et al., showed that the Metformin Group had lower estimated levels of insulin and FBS than the Myoinositol Group. Nevertheless, there was no statistically significant difference in the two therapies' efficacy.²⁴ Zhang et al., found no discernible variations in the Myoinositol and Metformin Groups for fasting insulin.²⁵

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CONCLUSION

Thus, there is no difference in the HOMA-IR level whether Metformin is prescribed or Myoinositol is prescribed. We conclude that both Metformin and Myoinositol have similar efficiency and favorable results in improving the insulin resistance in females with PCOS. Thus, in future, we will recommend the drug with least adverse effects to improve insulin resistance as well as resolve PCOS.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SA & GW: Data acquisition, data analysis, critical review, approval of the final version to be published.

SN: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Comparison of Metformin and Myoinositol

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