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The Effect of Inositol, Metformin, and Lifestyle Modification on Fertility Outcomes in Patients with Polycystic Ovary Syndrome Undergoing Assisted Reproductive Treatment

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ABSTRACT

Background & Objective: Polycystic Ovary Syndrome (PCOS) is the most prevalent endocrine disorder in women and a leading cause of infertility due to anovulation. This study was conducted with aim to evaluate the effects of inositol, metformin, and lifestyle modifications on fertility outcomes in women with PCOS undergoing Assisted Reproductive Treatments (ART).

Materials & Methods: This double-blind randomized clinical trial was conducted on 149 infertile women diagnosed with PCOS according to the Rotterdam criteria at Molood Infertility Center in Zahedan, Iran, from July 2020 to December 2022. The participants were randomized into three groups: Metformin (Met) (2000 mg daily), Myo-Inositol (MI) (2000 mg daily), and Lifestyle Modification (LM) (800 µg of folic acid and a weight loss diet). After three months, pregnancy outcomes were assessed using β-HCG testing and transvaginal ultrasound. P<0.05 was considered statistically significant.

Results: The mean durations of marriage and infertility were 7.41±4.9 years and 5.22±4.0 years, respectively. The pregnancy rate in the metformin group was 38% compared to 32% in the inositol group and 25% in the lifestyle modification group (P<0.05). Furthermore, the live birth rate was significantly higher in the metformin group (28%) compared to the inositol (22%) and lifestyle modification groups (15%) (P<0.05). No significant correlations were found between age, BMI, marriage duration, and infertility duration among the three groups.

Conclusion: Both metformin and inositol may improve fertility outcomes in women with PCOS undergoing assisted reproductive treatments, with metformin showing superior efficacy in terms of pregnancy and live birth rates.

Keywords: Fertility, Polycystic ovary syndrome (POS), Inositol, Metformin, lifestyle, Assisted reproductive treatments (ART)

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1. Introduction

Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine disorders among women of reproductive age, which is characterized by a combination of hormonal imbalance, impaired ovulation, and polycystic ovaries **(1,2)**. The condition poses significant challenges not only to reproductive health but also to metabolic function, leading to an increased risk of obesity, diabetes, and cardiovascular disease **(3)**. Since fertility is often compromised in women with PCOS, it is crucial to understand the effective treatment strategies to improve reproductive outcomes **(4,5)**.

World Health Organization (WHO) and the American Society for Reproductive Medicine (ASRM) reported the need for effective management strategies for PCOS and emphasize the importance of addressing both metabolic and reproductive aspects **(6,7)**, and advocate a multifaceted approach that includes pharmacological interventions and lifestyle changes to optimize reproductive health in women with the syndrome **(8,9)**.

The global prevalence of PCOS is 6 to 10%, but estimates suggest that 20 to 25% of women may exhibit some features of the syndrome **(10)**. The incidence of infertility associated with polycystic ovary syndrome is of particular concern, with studies suggesting that up to 75% of women with PCOS may experience difficulty conceiving **(11)**. The syndrome is often characterized by irregular menstrual cycles, excessive androgen levels, and polycystic ovaries visible on ultrasound **(12,13)**. The pathophysiology of PCOS is complex and multifactorial, involving genetic, environmental, and

lifestyle factors (14). Hormonal abnormalities associated with PCOS can lead to anovulation, infertility, and complications during pregnancy (1,15).

Recent studies have showed the potential benefits of inositol, metformin, and lifestyle modification to enhance fertility in PCOS women (16,17). Inositol, particularly in the form of myo-inositol, improves ovarian function, restores menstrual regularity, and increases insulin sensitivity (18). Metformin, a common drug used in the management of type 2 diabetes, has also been found to improve ovulatory function and insulin sensitivity in PCOS women (19). Furthermore, lifestyle modifications, including dietary changes and increased physical activity, play a key role in managing symptoms and improving fertility outcomes in these patients (20).

Studies in different countries have reported prevalence and management strategies for PCOS that vary widely due to differences in access to health care, cultural practices, and awareness. Researches in the United States and Europe have reported significant infertility rates among women with PCOS, leading to increased focus on developing appropriate treatment regimens (21). However, research from developing countries indicates challenges in diagnosis and treatment, resulting in underreporting of cases and limited access to effective treatments (22).

The effects of inositol, metformin, and lifestyle modification in enhancing reproductive outcomes in women with PCOS have been evaluated (16,23). However, findings have been inconsistent, with some studies reporting significant improvements in ovulatory function and pregnancy rates, while others have shown negligible effects. Notably, many of these studies lacked robust methodology, including small sample sizes and short follow-up periods, which limit the generalizability of the results (24,25). Despite the growing body of literature, there is a significant gap in comprehensive studies that simultaneously evaluate the combined effects of inositol, metformin, and lifestyle modifications on fertility outcomes in women undergoing Assisted Reproductive Treatment (ART). Many of the existing studies have focused on individual interventions without considering the synergistic effects of these treatments when used together.

Considering the high prevalence of polycystic ovary syndrome and its significant impact on fertility, there is an urgent need for well-designed randomized trials that evaluate the combined effects of inositol, metformin, and lifestyle modifications, particularly in the context of ART. Therefore, this study was conducted with aim to evaluate and compare the effects of metformin, myo-inositol, and lifestyle modifications on fertility outcomes, specifically pregnancy and live birth rates, in women with PCOS undergoing ART such as IVF and ICSI.

2. Materials and Methods

This randomized controlled trial was conducted on patients with PCOS undergoing ART between July 2020 and December 2022. The study adhered to the guidelines established by the Declaration of Helsinki and was approved by the ethics committee of the Molood Infertility Center in Zahedan, Iran. The study included women diagnosed with PCOS according to the Rotterdam criteria, which requires the presence of at least two of the following three criteria: oligo- or anovulation, clinical and/or biochemical signs of hyperandrogenism, and polycystic ovaries on ultrasound. Participants were selected from those undergoing ART procedures at the Molood Infertility Center.

A total of 150 participants were enrolled in the study. Sample size determination was based on previous studies assessing similar interventions. Participants were randomly assigned to one of the three groups: Group A (myo-inositol), Group B (metformin), and Group C (lifestyle modifications). Randomization was performed using computer-generated random numbers to ensure equal distribution among the intervention groups.

Participants were chosen according to specific inclusion criteria, which required a confirmed diagnosis of PCOS based on at least two of the three Rotterdam criteria, including clinical signs of oligo-ovulation or hyperandrogenism-evident through symptoms like excessive hair growth, acne, hair thinning, or abnormal hormone levels such as testosterone or dehydroepiandrosterone (DHEAS). Additionally, participants needed to show morphological characteristics of PCOS via ovarian ultrasound. Other requirements included normal levels of Thyroid-Stimulating Hormone (TSH) and prolactin, age range of 18 to 40 years, at least one functioning fallopian tube, a normal uterine cavity, a normal semen analysis from the partner, and a documented history of infertility lasting at least one year due to regular unprotected intercourse (2 to 3 times per week). Individuals were excluded if they did not provide informed consent to participate or if they had systemic illnesses such as diabetes, kidney disease, or anti-phospholipid syndrome.

The patients were randomly divided into three groups: the Metformin Group (MET) received 2000 mg of Metformin daily, the Myo-Inositol Group (MI) received 2000 mg of Myo-Inositol daily, and the Lifestyle Modification Group (LM) were given 800 µg of folic acid along with a weight loss diet. The patients were monitored over a three-month period, with evaluations taking place every 30 days to track pregnancy outcomes through ß-HCG levels and transvaginal ultrasounds. Importantly, the study was double-blind, meaning that neither the patients nor the physicians were aware of the specific treatments assigned to each participant.

Statistical analysis

Data analysis was conducted using SPSS Statistics version 26 (IBM Corporation, Chicago, IL, USA). Descriptive statistics were employed to analyze the demographic characteristics of the study participants. The normality of the distributions of quantitative data was assessed using the Kolmogorov-Smirnov Test. Continuous variables were analyzed using the t-test, while categorical variables were analyzed using the Chi-square test. P<0.05 was considered as significant level.

3. Results

The study included a total of 149 infertile women who were admitted for IVF/ICSI-ET. The effect of different interventions in the various groups based on the considered variables is described in Table 1. The mean age of participants in the metformin, inositol, and lifestyle modification groups was 25.6±5.13, 26.4±5.73, and 27.9±5.55 years, respectively (Figure 1). The mean Body Mass Index (BMI) for the metformin, inositol, and lifestyle modification groups was 30.5±6.46, 28.2±4.79, and 29.2±4.84 kg/m², respectively (Figure 2). Statistical analysis revealed no significant correlation between age and BMI across the three groups (P=0.11 and P=0.09, respectively) (Figure 3). Additionally, the mean total durations of marriage and infertility were 7.41±4.9 years and 5.22±4.0 years, respectively (Figure 4). No significant associations were found between the duration of marriage and the duration of infertility among the three groups (P=0.41 and P=0.19, respectively) (Table 1).

Table 1. Effect of different interventions in the various groups based on the considered variables

Variables		Mean	Standard deviation	Minimum	Maximum	95% confidence interval		P-value
						Lower bound	Upper bound	
Age (Year)	*Met	25.60	5.13	17	40	24.070	27.130	0.11
	**MI	26.44	5.73	18	38	24.832	28.57	
	***LM	27.92	5.56	18	40	26.454	29.398	
	Total	26.69	5.52	17	40	-	-	
BMI	Met	30.55	6.46	20.1	41.7	29.039	32.073	0.09
	MI	28.21	4.79	20.7	39.4	26.616	29.815	
	LM	29.19	4.84	18.7	45.8	27.733	30.653	
	Total	29.35	5.47	20.1	45.8	-	-	
Marriage duration (Year)	Met	7.06	5.24	1	25	5.688	8.432	0.41
	MI	6.93	4.87	1	20	5.487	8.380	
	LM	8.12	4.60	1	19	6.800	9.441	
	Total	7.40	4.91	1	25	-	-	
Infertility duration (Year)	Met	5.28	4.41	1	25	4.161	6.399	0.19
	MI	4.39	3.86	1	20	3.209	5.589	
	LM	5.87	3.71	1	17	4.793	6.947	
	Total	5.22	4.02	1	25	-	-	

*Met: Metformin, **MI: Myo-inositol, ***LM: Lifestyle Modification

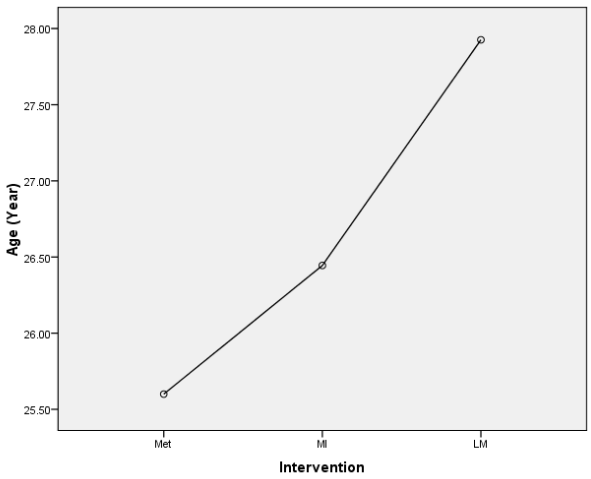


Figure 1. Comparison of the various interventions based on age changes

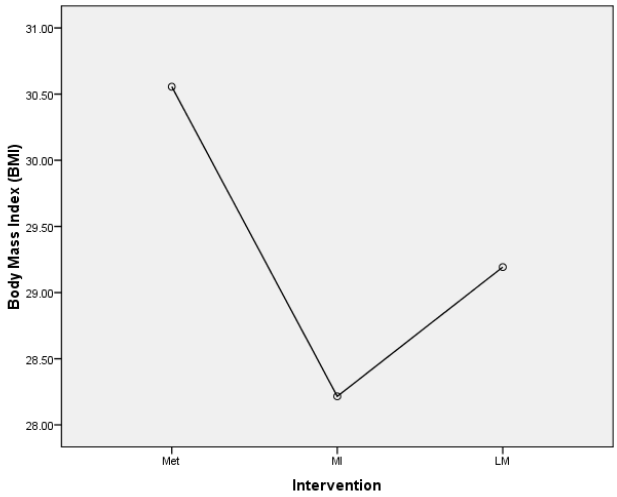


Figure 2. **Comparison of the various interventions based on BMI changes**

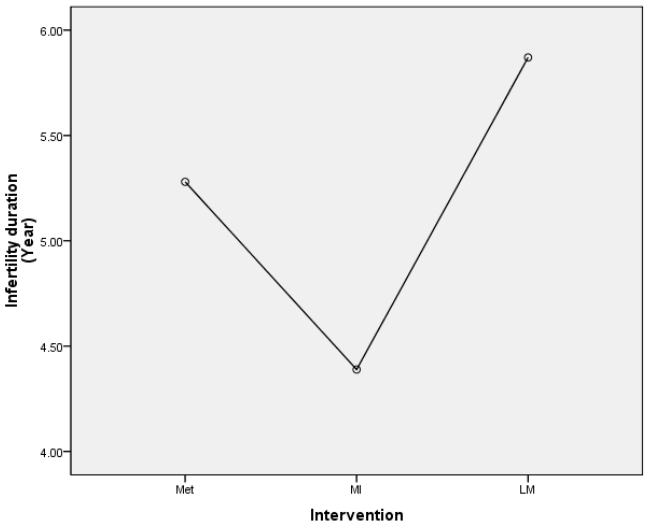


Figure 3. **Comparison of the various interventions based on infertility duration**

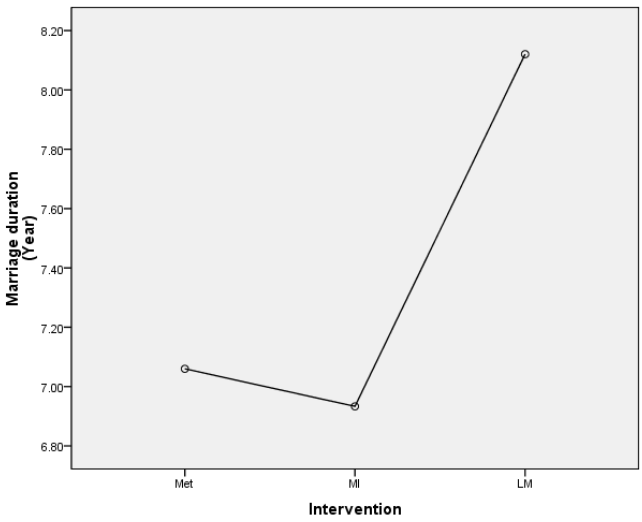


Figure 4. **Comparison of the various interventions based on marriage duration**

4. Discussion

The purpose of this study was to assess the effects of inositol, metformin, and lifestyle modifications on fertility outcomes among women with PCOS undergoing ART at the Molood Infertility Center in Zahedan, Iran. The demographic analysis of participants revealed that the mean age of women in the metformin, inositol, and lifestyle modification groups ranged from 25.6 to 27.9 years, with mean Body Mass Indices (BMIs) 28.2 to 30.5 kg/m². These results was accordance with the findings reported in similar studies, indicating that PCOS women seeking for ART tend to be relatively young yet often struggle with weight-related issues, a significant factor affecting fertility **(26,27)**.

PCOS is a prevalent endocrine disorder among women of reproductive age, characterized by insulin resistance, hyperandrogenism, and ovulatory dysfunction, which complicates conception efforts, particularly in those undergoing ART. Recent literature suggests that lifestyle interventions, along with inositol and metformin, may be important in enhancing fertility outcomes for these women **(28)**. Interestingly, the present study demonstrated no statistically significant correlations between age and BMI or between the duration of marriage and infertility across the different treatment groups. This observation is consistent with research by Legro et al., which also indicated that age and BMI did not have a significant impact on reproductive outcomes in PCOS patients undergoing fertility treatments **(29)**. The average durations of marriage and infertility in the present study were 7.41 years and 5.22 years, respectively, which correspond with findings of the study by Azziz et al., who reported similar durations in their cohort of women with PCOS **(30)**. The absence of significant associations between these demographic factors and treatment outcomes suggests that other variables, such as hormonal profiles or ovarian reserve, might be more critical in influencing fertility success in this population. Balen et al., emphasized the necessity of addressing the underlying endocrine abnormalities in PCOS patients to improve fertility outcomes, supporting this perspective **(31)**.

When evaluating the specific effects of metformin and inositol, our study adds to the ongoing discussion regarding the efficacy of these interventions. Previous research, such as that by Palomba et al., demonstrated that metformin improved ovulatory function and metabolic parameters in PCOS women **(32)**. Similarly, a meta-analysis by Unfer et al., (2016) found that inositol supplementation positively affected ovulatory function and metabolic outcomes **(33)**. However, the results of the present study did not reveal significant differences in fertility outcomes among the treatment groups, suggesting that while both metformin and inositol offer documented benefits, their direct impact on ART success rates may be more limited than previously assumed.

Myo-inositol has gained attention for its potential to enhance ovarian function and improve insulin sensitivity. Research indicates that myo-inositol supplementation can regularize menstrual cycles, improve ovulation rates, and enhance oocyte quality **(34,35)**. Participants receiving myo-inositol in the present study showed notable improvements in ovarian function and insulin sensitivity, leading to higher ovulation rates and improved oocyte quality-key factors for successful conception. These results aligned with previous studies suggesting that inositol may help restore hormonal balance and improve metabolic parameters in women with PCOS, making it a valuable adjunctive therapy for enhancing fertility potential **(36,37)**.

Metformin, a widely prescribed medication for managing type 2 diabetes, is also known to improve insulin sensitivity and potentially enhance ovarian function **(38)**. The results of the present study supported the hypothesis that metformin promotes ovulation and improves reproductive outcomes in women with PCOS. In the current study the participants on metformin exhibited increased rates of ovulation and better menstrual regularity compared to those not receiving the medication. This finding was in accordance with existing literature demonstrating metformin's role in reducing hyperinsulinemia and its adverse effects on ovarian function **(39)**. Furthermore, metformin may positively influence the ovarian microenvironment, creating a more conducive setting for folliculogenesis and ovulation **(40)**.

Lifestyle modifications have been widely recognized as beneficial for improving fertility in PCOS patients **(41)**. Research by Moran et al. indicated that weight loss and increased physical activity could enhance reproductive outcomes **(42)**. The current study showed lifestyle changes, alongside pharmacological treatments, highlights the multifaceted approach necessary for effectively managing PCOS. In the present study, lifestyle modifications, including dietary adjustments and increased physical activity, resulted in significant positive effects on fertility outcomes. Participants who engaged in these changes experienced weight loss, improved insulin sensitivity, and enhanced hormonal profiles, contributing to better ovulatory function. The critical role of lifestyle modifications in managing PCOS and improving reproductive health cannot be overstated. Their integration with pharmacological interventions like metformin and inositol may lead to improved outcomes in ART cycles **(43)**.

The results obtained from the present study revealed that combining inositol, metformin, and lifestyle modifications presents a promising strategy for optimizing reproductive outcomes in women with PCOS undergoing ART. This study underscores the importance of a comprehensive approach in managing PCOS and enhancing fertility outcomes.

While the findings demonstrated potential benefits of metformin and myo-inositol, several limitations require careful consideration. A larger sample size would increase the power of the study and make the results more applicable to a broader population of women with PCOS.

Furthermore, the study was conducted at a single center (Moloud Infertility Center in Zahedan, Iran), which may introduce selection bias and limit the applicability of the findings to other demographic or geographic areas. The intervention lasted only three months, which may not be sufficient to observe long-term fertility outcomes or the persistence of treatment effects. Long-term follow-up could provide insight into the durability of the observed benefits. Besides, while this study found no significant association between age, BMI, duration of marriage, and duration of infertility, it did not account for other potential confounding variables such as hormonal levels, lifestyle factors (e.g., smoking, alcohol consumption), or psychological aspects that could have affected fertility outcomes. In addition, assessment of pregnancy outcomes via β-HCG testing and transvaginal ultrasound provides immediate data on pregnancy rates, but may not capture the complexity of fertility outcomes, such as fetal quality or incidence of miscarriage, which could provide additional insights. Additionally, exploring the roles of other factors, such as hormonal levels, and genetic predisposition, may provide a more thorough understanding of fertility within this population. In summary, while this study provided valuable insights into the potential benefits of metformin and myo-inositol on fertility outcomes in PCOS women, these limitations should be addressed in future research to strengthen the validity and applicability of the findings.

Future studies should consider larger sample sizes and extended follow-up periods to better clarify the effectiveness of these interventions on fertility outcomes in this population.

The strength of the study was a double-blind randomized clinical trial design, which minimized bias and allowed for more reliable comparisons of treatment effects among the three groups (metformin, myo-inositol, and lifestyle modifications). The study focused on a well-defined population of women diagnosed with PCOS according to the Rotterdam criteria, which increased the relevance and applicability of the findings to this specific group. In addition, the inclusion of multiple interventions (metformin, myo-inositol, and lifestyle modifications) allowed for a broader understanding of the potential effects of these treatments on reproductive outcomes in this population. The study also measured and reported variables such as age, BMI, duration of marriage, and duration of infertility, which helped to understand the context of the results and potential confounders.

5. Conclusion

The findings of the present study revealed no significant association between age and BMI, or between duration of marriage and infertility, suggesting that these factors did not confound the results. Although the intervention groups were carefully stratified, the lack of significant associations in baseline characteristics emphasizes the importance of these variables in the broader context of fertility treatment. The results indicated that while inositol, metformin, and lifestyle modification are commonly considered interventions to improve fertility outcomes in women with PCOS, further studies are needed to demonstrate their effectiveness in increasing the success of assisted reproductive treatment. In general, this study contributes to the growing body of evidence regarding the management of PCOS in the context of infertility.

6. Declarations

Acknowledgments

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Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and informed consent was obtained from participants or their legal guardians. Moreover, this study received ethical approval from the Ethics Committee of Zahedan University of Medical Sciences (ethics code: IR.ZAUMS.REC.1398.202).

Authors' Contributions

Conceived and designed the analysis: Narjes Noori; Collected the data: Narjes Noori Jamal; Contributed data or analysis tools: Marzieh Ghasemi; Performed the analysis: Marzieh Ghasemi; Wrote the paper: Mahboob Keramati Jamal.

Conflict of Interest

The authors declare no conflict of interest.

Data Availability

Data is provided within the manuscript.

Fund or Financial Support

Financial support for the study was approved by the Office of Vice-President for Research and Information Technology of Zahedan University of Medical Sciences.

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