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ORIGINAL ARTICLE

Efficacy of Myo-Inositol plus D-Chiro-Inositol versus Metformin in the Management of Polycystic Ovary Syndrome among Obese Infertile Women in Bangladesh

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ABSTRACT

Background: *Polycystic Ovary Syndrome (PCOS) in obese infertile women is commonly associated with insulin resistance, hyperandrogenism, and ovulatory dysfunction. Metformin is widely used for improving metabolic and reproductive outcomes, while Myo-Inositol plus D-Chiro-Inositol (MI+DCI) offers a potentially safer, insulin-sensitizing alternative with fewer gastrointestinal side effects. Aim of the Study: To compare the efficacy of MI+DCI versus metformin in improving metabolic, hormonal, and reproductive outcomes among obese infertile women with PCOS in Bangladesh.* ***Methods & Materials:*** *In this randomized controlled study, 80 obese infertile women with PCOS were allocated into two groups: MI+DCI (n=40) and metformin (n=40). Baseline demographic, metabolic, and hormonal profiles were recorded. Participants received their respective therapies for six months. Post-treatment assessment included BMI, fasting glucose and insulin, HOMA-IR, LH, FSH, LH/FSH ratio, total testosterone, menstrual regularity, ovulation, conception rates, and adverse effects. Statistical analysis was performed using SPSS v26; p ≤0.05 was significant.* ***Results:*** *MI+DCI significantly reduced BMI (29.74±2.41 vs 30.85±2.33 kg/m², p=0.03), fasting glucose (90.52±7.65 vs 95.48±8.14 mg/dl, p=0.01), fasting insulin (12.35±3.02 vs 15.84±3.65 µIU/ml, p<0.001), HOMA-IR (2.62±0.84 vs 3.45±0.96, p<0.001), serum LH (7.12±1.94 vs 8.84±2.10 mIU/ml, p=0.001), LH/FSH ratio (1.15±0.41 vs 1.48±0.45, p=0.002), and total testosterone (49.28±11.42 vs 58.15±12.36 ng/dl, p=0.001) compared to metformin. Menstrual regularity (75% vs 55%, p=0.04) and ovulation rate (70% vs 47.5%, p=0.03) were also significantly higher. Adverse effects were significantly fewer with MI+DCI. Conception rates were higher but not statistically significant.* ***Conclusion:*** *MI+DCI is more effective than metformin in improving metabolic, hormonal, and ovulatory outcomes among obese infertile women with PCOS, with superior tolerability and fewer gastrointestinal adverse effects, supporting its use as a safer alternative or adjunct to metformin.*

Keywords: *Polycystic Ovary Syndrome, Obesity, Infertility, Myo-Inositol, D-Chiro-Inositol, Metformin, Insulin Resistance, Ovulation, Bangladesh*

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INTRODUCTION

Insulin resistance in PCOS underlies abnormalities in glucose metabolism, and hyperandrogenism helps to make sure insulin-sensitizing agents are a key therapeutic target. Metformin is a biguanide that is commonly used in type-2 diabetes, improves insulin sensitivity, and can moderately improve menstrual regularity, ovulation, and metabolic profiles in PCOS, especially among overweight or obese women [1]. Myo-Inositol (MI) and D-Chiro-Inositol (DCI) are known as naturally occurring stereoisomers of inositol that act as insulin second messengers. Their combination enhances insulin sensitivity, ovarian function, ovulation rates, and hormonal balance, such as LH/FSH ratio, testosterone, potentially offering a non-pharmaceutical alternative or adjunct to metformin with fewer gastrointestinal side effects [2]. Globally, PCOS affects approximately 6–10% of women when diagnosed using NIH criteria and 8–13% using Rotterdam criteria, where some population-based studies report prevalence rates as high as 15–20% [3]. In the context of Bangladesh, a nationwide cross-sectional survey using international evidence-based guideline criteria, including antimüllerian hormone (AMH) and clinical evaluation, found that the prevalence of PCOS among reproductive-aged women was 6.9%, with adult women showing a higher burden of metabolic syndrome compared with adolescents, demonstrating a significant population-level reproductive health issue in the country [4]. Diagnosis is based

on the Rotterdam criteria, which require at least two such as oligo/anovulation, clinical or biochemical hyperandrogenism, or polycystic ovarian morphology on ultrasound, supported by hormonal and metabolic tests to measure insulin resistance, androgen levels, and ovarian function [5]. Clinical diagnosis is made using the Rotterdam criteria, for instance, oligo/anovulation, clinical or biochemical hyperandrogenism, or polycystic ovarian morphology on ultrasound, supported by serum hormone measurements and metabolic screening [6]. PCOS is mainly caused by many factors, including insulin resistance and hyperandrogenism, which disrupt ovarian steroidogenesis and follicular development, with obesity and genetic predisposition worsening metabolic and reproductive dysfunction [7]. In many randomized studies, inositol supplementation improved HOMA-IR and reduced circulating testosterone, contributing to better endocrine and ovulatory outcomes [8]. Compared with metformin, MI+DCI is well tolerated for long-term use, with minimal gastrointestinal discomfort, headache, or nausea, making it more reasonable for patients who experience metformin-related side effects [9]. Metformin, while effective at lowering fasting insulin and glucose levels and enhancing ovulatory rates, is frequently associated with gastrointestinal negative effects such as nausea, diarrhea, and abdominal discomfort, which can limit compliance [10]. In addition, the response to both therapies may vary according to baseline BMI and severity of insulin resistance, and neither therapy uniformly corrects all metabolic disturbances, highlighting the need for individualized treatment approaches [11]. This study aimed to evaluate and compare the efficacy of Myo-Inositol plus D-Chiro-Inositol versus Metformin in the management of Polycystic Ovary Syndrome (PCOS) among obese infertile women in Bangladesh, focusing on improvement in ovulation rates, menstrual regularity, hormonal balance, and insulin sensitivity.

METHODS & MATERIALS

This randomized controlled clinical study was conducted conducted at the Department of Obstetrics and Gynecology, Bnagladesh Medical University, Dhaka, Bangladesh over a period of 12 months from January 2024 to December 2024, to evaluate the comparative efficacy of Myo-Inositol plus D-Chiro-Inositol versus Metformin in the management of obese infertile women diagnosed with Polycystic Ovary Syndrome. A total of 80 obese infertile women fulfilling the diagnostic criteria for PCOS were enrolled in this study using purposive sampling technique. After obtaining informed written consent, all participants were randomly allocated into two equal groups:

Group A (n = 40): Patients received Myo-Inositol plus D-Chiro-Inositol (MI+DCI) combination therapy
Group B (n = 40): Patients received Metformin therapy

Inclusion Criteria

- Women aged between 20–35 years
- Diagnosed cases of PCOS based on Rotterdam criteria
- BMI ≥30 kg/m^2 (obese)
- History of infertility for at least 1 year

Exclusion Criteria

- Known diabetes mellitus or thyroid disorders
- Hyperprolactinemia or Cushing's syndrome
- Use of hormonal therapy within the last 3 months
- Severe hepatic or renal impairment
- Other causes of infertility such as tubal blockage or male factor infertility

Data Collection

Baseline demographic data including age, BMI, duration, and type of infertility were recorded for all participants. Hormonal parameters such as serum luteinizing hormone (LH), follicle-stimulating hormone (FSH), LH/FSH ratio, total testosterone, and fasting insulin levels were assessed at enrollment. Participants were then treated according to their respective group allocation for a duration of 6 months.
Post-treatment evaluation included metabolic parameters such as BMI, fasting blood glucose, fasting insulin, and Homeostatic Model Assessment of Insulin Resistance (HOMA-IR). Hormonal profiles were reassessed after completion of therapy. Clinical outcomes including menstrual regularity, ovulation rate, and conception rate were also documented during the follow-up period. Additionally, treatment-related adverse effects such as nausea, diarrhea, and abdominal discomfort were recorded.

Statistical Analysis

All collected data were analyzed using Statistical Package for Social Sciences (SPSS) software version 26. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequency and percentage. Intergroup comparisons of quantitative variables were performed using the unpaired Student's t-test, while the chi-square test was applied for categorical variables. A p-value of ≤0.05 was considered statistically significant for all analyses.

RESULT

A total of 80 obese infertile women with polycystic ovary syndrome (PCOS) were enrolled in the study, equally divided into the MI+DCI group (n=40) and the Metformin group (n=40). There were no statistically significant differences between the two groups regarding age (28.42 ± 3.65 vs 29.10 ± 4.02 years, p=0.42), BMI (31.84 ± 2.75 vs 32.15 ± 2.63 kg/m^2, p=0.58), duration of infertility (3.82 ± 1.94 vs 4.01 ± 2.10 years, p=0.67), or type of infertility (primary: 67.5% vs 62.5%, secondary: 32.5% vs 37.5%, p=0.64) (**Table I**).

Table – I: Baseline Demographic Characteristics of the Study Population (*n* = 80)

Variables	MI+DCI Group (n=40)	Metformin Group (n=40)	p-value
Age (years)	28.42 ± 3.65	29.10 ± 4.02	0.42
BMI (kg/m^2)	31.84 ± 2.75	32.15 ± 2.63	0.58
Duration of Infertility (years)	3.82 ± 1.94	4.01 ± 2.10	0.67
Primary Infertility, n (%)	27 (67.50)	25 (62.50)	0.64
Secondary Infertility, n (%)	13 (32.50)	15 (37.50)	0.64

Demonstrates no significant differences in serum LH (11.42 ± 2.61 vs 11.78 ± 2.54 mIU/ml, p=0.51), FSH (5.84 ± 1.15 vs 5.67 ± 1.28 mIU/ml, p=0.48), LH/FSH ratio (1.95 ± 0.52 vs 2.07 ± 0.48, p=0.29), total testosterone (72.35 ± 14.42 vs 74.10 ± 13.95 ng/dl, p=0.59), or fasting insulin (19.42 ± 4.28 vs 20.05 ± 4.63 µIU/ml, p=0.52) (**Table II**).

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Table – II: Baseline Hormonal Profile of the Study Participants

Parameters	MI+DCI Group (n=40)	Metformin Group (n=40)	p-value
Serum LH (mIU/ml)	11.42 ± 2.61	11.78 ± 2.54	0.51
Serum FSH (mIU/ml)	5.84 ± 1.15	5.67 ± 1.28	0.48
LH/FSH Ratio	1.95 ± 0.52	2.07 ± 0.48	0.29
Total Testosterone (ng/dl)	72.35 ± 14.42	74.10 ± 13.95	0.59
Fasting Insulin (µIU/ml)	19.42 ± 4.28	20.05 ± 4.63	0.52

After six months of therapy, BMI was reduced to 29.74 ± 2.41 vs 30.85 ± 2.33 kg/m^2 (p=0.03), fasting blood glucose to 90.52 ± 7.65 vs 95.48 ± 8.14 mg/dl (p=0.01), fasting insulin to 12.35 ± 3.02 vs 15.84 ± 3.65 µIU/ml (p<0.001), and HOMA-IR to 2.62 ± 0.84 vs 3.45 ± 0.96 (p<0.001) (**Table III**).

Table – III: Post-Treatment Changes in Metabolic Parameters after 6 Months

Parameters	MI+DCI Group (n=40)	Metformin Group (n=40)	p-value
BMI (kg/m^2)	29.74 ± 2.41	30.85 ± 2.33	0.03*
Fasting Blood Glucose (mg/dl)	90.52 ± 7.65	95.48 ± 8.14	0.01*
Fasting Insulin (µIU/ml)	12.35 ± 3.02	15.84 ± 3.65	<0.001*
HOMA-IR	2.62 ± 0.84	3.45 ± 0.96	<0.001*

**Statistically significant*

The MI+DCI group achieved significantly greater reductions in serum LH (7.12 ± 1.94 vs 8.84 ± 2.10 mIU/ml, p=0.001), LH/FSH ratio (1.15 ± 0.41 vs 1.48 ± 0.45, p=0.002), and total testosterone (49.28 ± 11.42 vs 58.15 ± 12.36 ng/dl, p=0.001). FSH levels were not significantly different between groups (6.15 ± 1.08 vs 5.94 ± 1.11 mIU/ml, p=0.39) (**Table IV**).

Table – IV: Post-Treatment Changes in Hormonal Profile after 6 Months

Parameters	MI+DCI Group (n=40)	Metformin Group (n=40)	p-value
Serum LH (mIU/ml)	7.12 ± 1.94	8.84 ± 2.10	0.001*
Serum FSH (mIU/ml)	6.15 ± 1.08	5.94 ± 1.11	0.39
LH/FSH Ratio	1.15 ± 0.41	1.48 ± 0.45	0.002*
Total Testosterone (ng/dl)	49.28 ± 11.42	58.15 ± 12.36	0.001*

Shows that regular menstrual cycles were achieved in a significantly higher proportion of the MI+DCI group compared to Metformin (75.00% vs 55.00%, p=0.04). Ovulation rates were also higher in the MI+DCI group (70.00% vs 47.50%, p=0.03). Although the conception rate was greater in the MI+DCI group (37.50% vs 22.50%), this difference did not reach statistical significance (p=0.13) (**Table V**).

Table – V: Clinical Outcome Following Treatment

Outcomes	MI+DCI Group (n=40)		Metformin Group (n=40)		p-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Regular Menstrual Cycle	30	75.00	22	55.00	0.04*
Ovulation Rate	28	70.00	19	47.50	0.03*
Conception Rate	15	37.50	9	22.50	0.13

Nausea occurred in 7.50% vs 27.50% (p=0.02), diarrhea in 5.00% vs 22.50% (p=0.03), and abdominal discomfort in 10.00% vs 32.50% (p=0.01) (**Table VI**).

Table – VI: Adverse Effects Observed in Study Participants

Adverse Effects	MI+DCI Group (n=40)		Metformin Group (n=40)		p-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Nausea	3	7.50	11	27.50	0.02*
Diarrhea	2	5.00	9	22.50	0.03*
Abdominal Discomfort	4	10.00	13	32.50	0.01*

DISCUSSION

Polycystic ovary syndrome (PCOS) is a multifactorial endocrine–metabolic disorder characterized by insulin resistance, hyperandrogenism, and chronic anovulation, which significantly contribute to infertility among obese women of reproductive age [12]. In this study, we evaluated the comparative efficacy of Myo-Inositol plus D-Chiro-Inositol (MI+DCI) versus Metformin in improving metabolic, hormonal, and reproductive outcomes in obese infertile women diagnosed with Polycystic Ovary Syndrome. In the present study, baseline demographic parameters were statistically comparable between the two groups, with mean age recorded as 28.42 ± 3.65 years in the MI+DCI group and 29.10 ± 4.02 years in the Metformin group (p=0.42). Similarly, mean BMI was 31.84 ± 2.75 kg/m^2 versus 32.15 ± 2.63 kg/m^2 (p=0.58), and mean duration of infertility was 3.82 ± 1.94 years compared to 4.01 ± 2.10 years (p=0.67), respectively. Primary infertility was observed in 67.50% of participants in the MI+DCI group and 62.50% in the Metformin group (p=0.64). These findings are consistent with those reported by Legro et

al. and Gerli S et al., who also demonstrated no statistically significant baseline demographic differences between treatment groups in women with PCOS [13,14]. Regarding metabolic outcomes after 6 months of treatment, our study demonstrated a significantly greater reduction in BMI in the MI+DCI group (29.74 ± 2.41 kg/m^2) compared to the Metformin group (30.85 ± 2.33 kg/m^2) (p=0.03). Fasting blood glucose was also significantly lower in the MI+DCI group (90.52 ± 7.65 mg/dl) than in the Metformin group (95.48 ± 8.14 mg/dl) (p=0.01). Furthermore, fasting insulin levels decreased to 12.35 ± 3.02 µIU/ml in the MI+DCI group compared to 15.84 ± 3.65 µIU/ml in the Metformin group (p<0.001), and HOMA-IR values were significantly improved (2.62 ± 0.84 vs 3.45 ± 0.96; p<0.001). These findings are in agreement with those of Benelli et al., who reported improved insulin sensitivity and metabolic profile following MI+DCI supplementation in PCOS patients [15]. Similarly, post-treatment hormonal analysis revealed significantly lower serum LH levels in the MI+DCI group (7.12 ± 1.94 mIU/ml) compared to the Metformin group (8.84 ± 2.10 mIU/ml) (p=0.001). The LH/FSH ratio was also significantly reduced in the MI+DCI group (1.15 ± 0.41 vs 1.48 ± 0.45; p=0.002), along with total testosterone levels (49.28 ± 11.42 ng/dl vs 58.15 ± 12.36 ng/dl; p=0.001). However, no statistically significant difference was observed in serum FSH levels between the two groups (6.15 ± 1.08 mIU/ml vs 5.94 ± 1.11 mIU/ml; p=0.39). These results are comparable to previous reports, which demonstrated significant reductions in LH levels and androgen concentrations following inositol therapy [16-18]. From a clinical perspective, regular menstrual cycles were achieved in 75.00% of participants in the MI+DCI group compared to 55.00% in the Metformin group (p=0.04). Ovulation was observed in 70.00% of women in the MI+DCI group versus 47.50% in the Metformin group (p=0.03). Although conception rates were higher in the MI+DCI group (37.50%) compared to the Metformin group (22.50%), this difference was not statistically significant (p=0.13). Similar findings were documented by Raffone et al., where ovulation rates improved significantly with inositol therapy despite non-significant differences in pregnancy rates [19]. In terms of safety profile, adverse gastrointestinal effects were significantly more frequent in the Metformin group, including nausea (27.50% vs 7.50%; p=0.02), diarrhea (22.50% vs 5.00%; p=0.03), and abdominal discomfort (32.50% vs 10.00%; p=0.01). These findings are consistent with those reported by Russo et al., who highlighted better tolerability and compliance with MI+DCI therapy compared to Metformin [20].

LIMITATIONS

This study was limited by its relatively small sample size (N=80) and single-center design, which may affect the generalizability of the findings to the broader population of obese infertile women with PCOS in Bangladesh. The follow-up period of six months was short, restricting assessment of long-term fertility outcomes and metabolic effects. Additionally, lifestyle factors such as diet and physical activity were not strictly controlled, which could influence metabolic and hormonal responses. Larger multicenter trials with longer follow-up are warranted.

CONCLUSION

This study demonstrates that Myo-Inositol plus D-Chiro-Inositol (MI+DCI) is superior to metformin in improving metabolic, hormonal, and clinical outcomes among obese infertile women with Polycystic Ovary Syndrome in Bangladesh. MI+DCI significantly reduced BMI, fasting glucose, fasting insulin, HOMA-IR, serum LH, LH/FSH ratio, and total testosterone levels compared with metformin, while enhancing menstrual regularity and ovulation rates. Although conception rates were higher in the MI+DCI group, the difference was not statistically significant. Furthermore, MI+DCI was associated with markedly fewer gastrointestinal adverse effects, highlighting its better tolerability and potential as a safer, effective, non-pharmacological alternative or adjunct to metformin in the long-term management of PCOS in obese women.

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