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Original Research Article

Effect of D-chiro-inositol on hormonal parameters and insulin resistance in women with polycystic ovary syndrome

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is an endocrine disorder among women of reproductive age, characterized by hormonal imbalance and insulin resistance. D-chiro-inositol, a naturally occurring inositol isomer, has been suggested as a potential treatment option for PCOS. This study aimed to investigate the effects of D-chiro-inositol supplementation on hormonal parameters, and insulin resistance in women with PCOS.
Methods: This randomized controlled study was conducted among 60 women of PCOS with insulin resistance, who were assigned to either Group A (D-chiro-inositol) or Group B (placebo) for 12 weeks. S. FSH, LH, S. total testosterone, fasting blood glucose, fasting insulin, and insulin resistance (HOMA-IR) were measured at baseline and after 12 weeks of treatment. Statistical analyses were performed using SPSS version 23.0 for Windows.
Results: After 12 weeks of treatment, significant reductions in serum luteinizing hormone, serum total testosterone, fasting insulin, and HOMA-IR were observed in the D-chiro-inositol group compared to the placebo group. However, no significant changes were observed in fasting blood glucose levels. D-chiro-inositol was well-tolerated, with no significant differences in side effects between the two groups.
Conclusions: D-chiro-inositol supplementation for 12 weeks significantly improved hormonal parameters, and insulin resistance in women with PCOS. The treatment was well-tolerated, suggesting that D-chiro-inositol can be an effective therapeutic option for patients with PCOS.

Keywords: D-Chiro-Inositol, Hormone, Insulin, PCOS, Resistance

INTRODUCTION

Polycystic ovary syndrome (PCOS) is an endocrine disorder affecting women of reproductive age worldwide. The global incidence rate is estimated to be around 6-10%, while the prevalence rate in Asia varies, with some studies reporting a rate of approximately 9%.[1,2] PCOS is characterized by a complex interplay of hormonal imbalances, including hyperandrogenism, insulin resistance, and chronic low-grade inflammation, which contribute to its heterogeneous clinical presentation.[3] The primary cause of PCOS remains elusive, but it is believed to involve a combination of genetic and environmental factors. Insulin resistance is a key pathophysiological feature of the disorder, affecting up to 70% of women with PCOS.[4] Insulin resistance exacerbates hyperandrogenism by increasing androgen production in the ovaries and reducing sex hormone-binding globulin (SHBG) levels, leading to increased free androgen levels.[5] The resulting hormonal imbalances can cause menstrual irregularities, hirsutism, acne, and infertility, significantly impacting a woman's quality of life. Managing PCOS involves a multifaceted approach, including lifestyle modifications, pharmacological interventions, and, in some cases, surgical intervention. Lifestyle modifications, such as weight loss and exercise, can improve insulin sensitivity

and hormonal balance, leading to symptom improvement.[6] Pharmacological interventions, including oral contraceptives, antiandrogens, and insulin-sensitizing agents like metformin, are commonly prescribed to address specific symptoms and comorbidities.[6] However, these treatments may have side effects or contraindications, underscoring the need for alternative management options. D-Chiro-Inositol (DCI) is a naturally occurring compound that has gained attention for its potential role in managing PCOS. DCI is an insulin-sensitizing agent believed to improve insulin resistance by modulating insulin signaling pathways.[7,8]

Several studies have demonstrated positive effects of DCI supplementation on hormonal and metabolic parameters in women with PCOS, including reduced insulin resistance, improved ovulatory function, and decreased androgen levels.[9,10] However, the effectiveness of DCI as a treatment for PCOS remains debated, with some studies reporting conflicting results.[11] Given the high prevalence of PCOS and its associated comorbidities, such as type 2 diabetes, cardiovascular disease, and endometrial cancer, it is critical to explore alternative treatment options that may offer benefits with fewer drawbacks.[3] This is particularly relevant in countries like Bangladesh, where the prevalence of PCOS is high and access to healthcare may be limited. In this context, the study aims to evaluate the effect of D-Chiro-Inositol on hormonal parameters and insulin resistance in Bangladeshi women with PCOS, providing valuable insights into the potential benefits and limitations of DCI as a treatment option for this complex disorder.

In conclusion, the high prevalence of PCOS, its impact on women's health, and the potential limitations of current treatment options highlight the importance of investigating alternative therapies. D-Chiro-Inositol is a promising option for PCOS management due to its insulin-sensitizing properties and potential positive effects on hormonal parameters. By examining the effects of DCI in a Bangladeshi population, this study will contribute valuable information on the potential benefits and drawbacks of this compound as a treatment option for PCOS. As a result, the findings may help to guide the development of more effective and personalized treatment plans for women with PCOS, ultimately improving their overall health and quality of life. By focusing on a population with a high prevalence of PCOS and potentially limited access to healthcare resources, this study aims to provide valuable insights that can inform future research and clinical practice.

METHODS

This randomized controlled study was conducted at the Department of Reproductive Endocrinology & Infertility, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. The study duration was 18 months, from July 2021 to December 2022. During this period, a random sampling technique was used to select a total of 60 diagnosed cases of polycystic ovary syndrome (according to Rotterdam criteria) with insulin resistance as the study population. Study participants were selected from patients attending the Reproductive Endocrinology and Infertility OPD at Bangabandhu Sheikh Mujib Medical University.

Inclusion criteria

Inclusion criteria for the study were women aged 18-40, diagnosed with PCOS according to Rotterdam criteria, a BMI of 23-30 kg/m², and HOMA-IR>1.7.

Exclusion criteria

Exclusion criteria included BMI>30 kg/m², uncontrolled diabetes mellitus, known hypothyroidism, hyperprolactinemia, hormonal or metformin treatment within three months before the study, allergy to D-chiro-inositol, and the presence of renal, hepatic, or cardiovascular disease.

The selected participants were randomized into two equal groups, with Group A (30 patients) received D-chiro-inositol and Group B (30 patients) received placebo. Group A was treated with 500 mg of D-chiro-inositol in a single dose for 12 weeks, while Group B received placebo for the same duration. After a full explanation of the study procedure, informed written consent was obtained from the participants. A detailed history and examination were conducted. Data were collected in a structured case report form to be filled as per the available records and laboratory results. Data were collected from the patients during different visits, focusing on variables of interest using interviews, observation, clinical examination, investigations, and from the patients' history sheets. The cumulative data were subjected to analysis.

Statistical analysis

Statistical analysis was carried out using the Statistical Package for Social Sciences version 23.0 for Windows. Written approval was obtained from the concerned authority and the department following due procedure. Ethical clearance was obtained from the local ethical committee to perform the investigation and study.

RESULTS

The majority of patients belonged to age group 18-30 years in both groups. Mean age was found 26.3±4.3 years in group A (D-chiro-inositol) and 26.1±4.5 years in group B (placebo). Most of the patients were housewife in both groups. In group A, 19 (63.3%) patients came from urban area and in group B 16 (53.3%) patients came from rural area. Primary infertility was common in both groups, that was 23 (76.7%) in group A and 22 (73.3%) in group B. Age, occupational status, residence, and infertility were not statistically significant between two groups. The mean waist circumference of participants in Group A was 91.9

cm (SD=2.5), and in Group B, it was 92.4 cm (SD=2.7). The mean hip circumference of participants in Group A was 96.3 cm (SD=2.4), and in Group B, it was 97.0 cm (SD=3.5). The mean waist-hip ratio of participants in Group A was 0.96 (SD=0.02), and in Group B, it was 0.95 (SD=0.01). The mean BMI of participants in Group A was 26.5 kg/m2 (SD=1.4), and in Group B, it was 26.8 kg/m2 (SD=1.6). However, no significant association was observed between the values among groups (Table 1).

Table 1: Socio-demographic characteristics of the participants (n=60).

Demographic characteristics	Group A (n=30)		Group B (n=30)		P value
	n	%	n	%	
Age (years)					
18-20	2	6.7	3	10	[a]0.862[ns]
21-30	22	73.3	21	70	
>30	6	20	6	20	
Mean±SD	26.3±4.3		26.1±4.5		
Range (min-max)	18.0-34.0		18.0-36.0	36	
Occupational status					
Housewife	26	86.7	23	76.7	[b]0.284[ns]
Job	2	6.7	1	3.3	
Student	2	6.7	6	20	
Educational status					
Illiterate	1	3.3	2	6.7	[b]0.932[ns]
Primary	15	50	12	40	
SSC	3	10	3	10	
HSC	7	23.3	8	26.7	
Graduate	4	13.3	5	16.7	
Residence					
Rural	11	36.7	16	53.3	0.194[ns]
Urban	19	63.3	14	46.7	
Infertility					
Primary	23	76.7	22	73.3	[b]0.766[ns]
Secondary	7	23.3	8	26.7	
Clinical parameters (Mean±SD)					
Waist circumference (cm)	91.9±2.5		92.4±2.7		0.517[ns]
Hip circumference (cm)	96.3±2.4		97±3.5		0.377[ns]
Waist-Hip ratio	0.96±0.02		0.95±0.01		0.621[ns]
BMI (kg/m^2)	26.5±1.4		26.8±1.6		0.367[ns]

[a]P value reached from unpaired t-test, [b]P value reached from chi-square test

Table 2: Baseline hormonal parameters and insulin resistance by HOMA-IR between two groups (n=60).

Variables	Group A (n=30)		Group B (n=30)		P value
	Mean	±SD	Mean	±SD	
S. FSH (mIU/mL)	6.8	±1.8	6.8	±2.2	0.968[ns]
S. LH (mIU/mL)	7.7	±3.6	7.6	±4.6	0.899[ns]
LH: FSH ratio	1.2	±0.61	1.16	±0.61	0.784[ns]
Serum total testosterone (nmol/L)	1.19	±0.41	1.12	±0.25	0.452[ns]
Fasting blood glucose (mmol/L)	5.4	±0.3	5.3	±0.3	0.814[ns]
Fasting insulin (µU/mL)	15.9	±3.8	16	±4.5	0.911[ns]
HOMA-IR	3.8	±1.0	3.8	±1.1	0.975[ns]

At baseline, mean S.FSH, S. LH, LH: FSH ratio, serum total testosterone, fasting blood glucose, fasting insulin and HOMA-IR were not statistically significant (p>0.05) between two groups (Table 2).

During post-treatment measurements at 12 weeks, mean S. LH (7.5 ±4.6 vs 5.2±2.2 mIU/ml), serum total testosterone (1.04±0.31 vs 0.79±0.48 nmol/l), fasting insulin (15.7±4.6 vs 12.5±4.5 µU/ml) and HOMA-IR (3.7±1.2 vs 3.0±1.1) were statistically significantly reduced in group A (D-chiro-inositol) than group B (placebo). However, S.FSH, LH: FHS ratio and fasting blood glucose were not statistically significant (p>0.05) between two groups (Table 3).

Table 3: Post-treatment hormonal parameters and insulin resistance by HOMA-IR between two groups (n=53).

Variables	Group A (n=26)		Group B (n=27)		P value
	Mean	±SD	Mean	±SD	
S. FSH (mIU/mL)	5.9	±1.2	6.6	±1.9	0.155^{ns}
S. LH (mIU/mL)	5.2	±2.2	7.5	±4.6	0.027^{s}
LH: FSH ratio	0.91	±0.38	1.2	±0.68	0.062^{ns}
Serum total testosterone (nmol/L)	0.79	±0.48	1.04	±0.31	0.029^{s}
Fasting blood glucose (mmol/l)	5.3	±0.3	5.3	±0.4	0.820^{ns}
Fasting insulin (µU/mL)	12.5	±4.5	15.7	±4.6	0.013^{s}
HOMA-IR	3	±1.1	3.7	±1.2	0.019^{s}

***** In group A, 3 pregnant, 1 dropout; In group B, 2 pregnant, 1 dropout

Table 4: Comparison of mean changes of hormonal parameters and insulin resistance after treatment between two groups (n=53).

Variables	Group A (n=26)		Group B (n=27)		95% CI	P value
	Mean	±SD	Mean	±SD		
S. FSH (mIU/mL)	-0.82	±1.80	-0.27	±1.06	-1.36 to 0.26	0.177^{ns}
S. LH (mIU/mL)	-2.43	±1.88	-0.08	±0.22	-3.08 to -1.62	0.001^{s}
LH: FSH ratio	-0.3	±0.34	-0.01	±0.19	-0.46 to -0.16	0.001^{s}
Serum total testosterone (nmol/L)	-0.44	±0.45	-0.07	±0.19	-0.56 to -0.18	0.001^{s}
Fasting blood glucose (mmol/l)	-0.07	±0.31	-0.06	±0.19	-0.15 to 0.13	0.880^{ns}
Fasting insulin (µU/mL)	-3.1	±3.98	-0.44	±1.38	-4.29 to -1.03	0.002^{s}
HOMA-IR	-0.78	±1.01	-0.13	±0.34	-1.06 to -0.23	0.003^{s}

* In group A, 3 pregnant, 1 dropout; In group B, 2 pregnant, 1 dropout

Table 5: Distribution of participants by observed side effects post-treatment (n=53).

Side effects	Group A (n=26)		Group B (n=27)		P value
	n	%	n	%	
Headache	2	7.7	0	0	0.236^{ns}
Nausea	2	7.7	1	3.7	0.486^{ns}
Weakness	1	3.8	0	0	0.491^{ns}

* In group A, 3 pregnant, 1 dropout; In group B, 2 pregnant, 1 dropout

D-chiro-inositol supplementation for 12 weeks among women with PCOS had significant effects on S.LH compared with the placebo group (mean changes from baseline in intervention group was -2.43±1.88 vs.-0.08±0.22 mIU/mL in placebo group), LH:FSH ratio compared with the placebo group (mean changes from baseline in intervention group was -0.30±0.34 vs.-0.01±0.19 in placebo group) and serum total testosterone compared with the placebo group (mean changes from baseline in intervention group was -0.44±0.45 vs. -0.07±0.19 in placebo group). After the 12-weeks in intervention group, compared with the placebo, D-chiro-inositol leads to a statistically significant reduction in fasting insulin (-3.10±3.98 vs. -0.44±1.38 µU/mL) and HOMA-IR (-0.78±1.01 vs. -0.13± 0.34). However, fasting blood glucose was also decreased in both groups from baseline, but the changes of difference was not statistically significant (p>0.05) when compared between two groups (Table 4).

Headache was found 2 (7.7%) in group A (D-chiro-inositol) and not found in group B (placebo). Nausea was 2 (7.7%) and 1 (3.7%) in group A and group B respectively. Weakness was 1 (3.8%) in group A; but not fund in group B. Side effects were not statistically significant between two groups (p>0.05) (Table 5).

DISCUSSION

In the present study, we evaluated the effects of D-chiro-inositol supplementation on hormonal parameters and insulin resistance of women with PCOS. In recent years, inositol has gained much attention in the reproductive clinical practice. Among them, D-chiro-inositol is a newer

insulin sensitizing drug which positively affects insulin sensitivity on PCOS patients and corrects clinical and biochemical hyperandrogenism. The study found that the mean age in the D-chiro-inositol group was 26.3±4.3 years, while in the placebo group it was 26.1±4.5 years, and the difference between the two groups was not significant. This was similar to a previous study conducted by Marca et al, where the mean age in the D-chiro-inositol group was reported as 27.5±6.7 years.[12]

The study observed that there was no significant reduction in waist circumference, hip circumference, waist-hip ratio, and BMI in the D-chiro-inositol group after 12 weeks of treatment compared to baseline. This is consistent with a study by Pizzo et al (2014), where no significant reduction in mean BMI was observed in the D-chiro-inositol group after treatment.[10] However, the findings of another study by Genazzani et al (2014) were inconsistent with our study as they reported a statistically significant reduction in mean BMI after 12 weeks of treatment with D-chiro-inositol.[9]

In their study, the mean baseline BMI was 31.5±0.8 kg/m^2, which decreased to 29.8±0.7 kg/m^2 after treatment ($p<0.02$). Our findings demonstrated that a 12-week supplementation of D-chiro-inositol led to significant improvements in S. LH, LH: FSH ratio, serum total testosterone, fasting insulin, and HOMA-IR in comparison to the placebo group. However, no significant differences were observed in S. FSH, fasting blood glucose, and side effects between the two groups. Our results were consistent with those of a previous study conducted by Nestler et al, which found that D-chiro-inositol supplementation improved insulin resistance and hormonal profiles in women with PCOS.[13] In their study, the authors reported a significant reduction in fasting insulin and serum total testosterone levels after D-chiro-inositol treatment, which supports the findings of our study.

Furthermore, a meta-analysis conducted by Unfer et al supports the beneficial role of D-chiro-inositol in improving insulin resistance in women with PCOS.[14] Regarding the effects of D-chiro-inositol on hormonal parameters, our findings of reduced S. LH and LH: FSH ratio are in line with the results of a study conducted by Genazzani et al, which demonstrated that D-chiro-inositol treatment led to a significant reduction in LH and LH: FSH ratio.[9] Similarly, a study by Gerli et al found that D-chiro-inositol supplementation reduced LH levels and improved menstrual cycle regularity in women with PCOS.[15] These findings suggest that D-chiro-inositol may play an essential role in regulating hormonal profiles among women with PCOS. The reduction in serum total testosterone levels observed in our study is consistent with the findings of Cheang et al (2016) reported a significant decrease in serum total testosterone levels after D-chiro-inositol supplementation.[16]

This improvement in androgen levels may contribute to the amelioration of clinical symptoms associated with PCOS, such as hirsutism and acne. Although we did not find a significant difference in S. FSH levels between the two groups, a study by Facchinetti et al (2018) reported a significant decrease in S. FSH levels after D-chiro-inositol treatment.[17] The discrepancy may be due to differences in sample size, study population, or duration of treatment. In terms of side effects, our study found no significant side effects between the D-chiro-inositol and placebo groups. This is consistent with the findings of a study by Minozzi et al which reported that D-chiro-inositol was well-tolerated and safe for use in women with PCOS. Thus, D-chiro-inositol appears to be a safe and effective treatment option for women with PCOS.[18]

This study has some limitations. The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In conclusion, our study supports the efficacy of D-chiro-inositol supplementation in improving hormonal profiles and insulin resistance in women with PCOS. Further large-scale, randomized controlled trials are needed to confirm these findings and to investigate the long-term effects of D-chiro-inositol on the clinical outcomes of PCOS, such as menstrual cycle regularity, fertility, and metabolic parameters. Our study demonstrates that D-chiro-inositol supplementation in women with PCOS for 12 weeks significantly improves hormonal parameters, insulin sensitivity, and HOMA-IR compared to placebo. The findings are consistent with previous research, further strengthening the evidence supporting the use of D-chiro-inositol as an effective therapeutic option for patients with PCOS. The treatment was generally well-tolerated, with no significant differences in the frequency of side effects between the two groups. Given the potential benefits of D-chiro-inositol in reducing hyperinsulinemia and improving hormonal imbalance, clinicians should consider incorporating this supplement into their treatment strategies for women with PCOS. Future research should focus on elucidating the underlying mechanisms of action of D-chiro-inositol and exploring optimal dosing regimens for various PCOS phenotypes.

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