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Original Research Article

Effect of omega-3 and D-chiro inositol compared to D-chiro inositol alone on hormonal parameters in women with insulin resistant polycystic ovary syndrome

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a common endocrine-metabolic disorder marked by high androgen levels, irregular ovulation, and ovarian cysts. Recommended treatments include lifestyle and nutrition changes alongside medication. Omega-3 fatty acids support immune function, insulin sensitivity, cell health, and ovulation. D-chiro Inositol helps lower blood pressure, triglycerides, and glucose, enhances ovarian function, and reduces harmful oxidative stress in the ovaries. This study was designed to evaluate and compare the effect of omega-3 and D-chiro inositol and effect of D-chiro inositol alone on hormonal parameters in women with insulin resistant PCOS.

Methods: This randomized controlled trail study was conducted in the departments of reproductive endocrinology and infertility, Bangbandhu Sheikh Mujib medical university, Dhaka from January 2023 to June 2024. Total 60 individuals with PCOS were observed in this study.

Results: The mean age was 24.88 (± 4.81) years and mean BMI was 28.83 (± 2.72) kg/m². In group A, omega-3 plus D-chiro-inositol therapy is found more effective than D-chiro-inositol alone in reducing serum luteinizing hormone (LH), (follicle stimulating hormone) FSH, free testosterone and fasting glucose, fasting insulin and homeostasis model assessment for insulin resistance (HOMA-IR) after 12 weeks of treatment. But there was no statistically significant difference in post treatment LH, FSH, free testosterone, fasting glucose, fasting insulin and HOMA-IR between 2 groups.

Conclusions: Combining D-chiro inositol and omega-3 fatty acids can significantly improve insulin sensitivity and reduce the levels of LH, FSH and free testosterone in women with PCOS. But there is no significant difference in this post treatment hormonal and biochemical parameters between the two groups.

Keywords: Omega-3, D-chiro inositol, Hormonal parameters, Insulin resistant polycystic ovary syndrome

INTRODUCTION

Polycystic ovary syndrome (PCOS) is one of the most common endocrine-metabolic disorders that affects 5 to 10% of women of reproductive age, characterized by a series of manifestations of hyperandrogenemia, persistent anovulation, and ovarian polycystic changes.¹ Insulin resistance (IR) and hyperandrogenemia might be closely

associated with the pathogenesis of PCOS.² It can also be accompanied by obesity because central obesity could exaggerate IR and lead to hyperinsulinemia.³ Seventy percentages of overweight PCOS patients were accompanied by IR, with the majority of overweight PCOS patients also being accompanied by hyperinsulinemia, suggesting potential relationships between body fat with PCOS.⁴ Lifestyle intervention can

effectively alleviate the pathological manifestations of abnormal reproduction and metabolism in patients with PCOS, and dietary intervention may also exert important effects on the prevention and control of PCOS and its complications.⁵ Ensuring a certain level intake of dietary polyunsaturated fatty acids (PUFAs) might help improve the clinical manifestations of dyslipidemia, impaired vascular endothelial function, and IR in PCOS patients.⁶ The omega-3 fatty acids and omega-6 fatty acids are mainly dietary sources of the essential PUFAs, but the dietary sources of omega-3 fatty acids are relatively less abundant than omega-6 fatty acids, only found in plant foods (e. g., green leafy vegetables, vegetable oils, and seeds) and deep-sea fish.⁷ The recommended treatments for PCOS women are lifestyle modification and nutrition interventions along with medication. Metabolic disorders in patients with PCOS may be improved by the intervention of dietary factors such as anti-inflammatory foods.⁸ Among dietary factors, omega-3 fatty acids play an important role in immune regulation, insulin sensitivity, cellular differentiation, and ovulation. This dietary supplement may be used for improving excessive oxidative stress-caused folliculogenesis disorder and hyperinsulinemia in women with PCOS.⁹ The D-chiro inositol is hexahydroxycyclohexanes, with the same molecular formula as glucose. They are the two most abundant members of a family of nine stereoisomeric inositols, and are found widely in nature. Myo-inositol is a precursor of inositol triphosphate (InsP3). InsP3 is a second messenger for many hormones including insulin and follicle stimulating hormone (FSH). Defects in this pathway can lead to impaired insulin signaling and cause IR.¹⁰ Various authors have studied the effect of D chiro inositol (DCI) on endocrine, metabolic, and reproductive parameters in PCOS. Administration of 600 mg DCI/day for 6 to 8 weeks to lean women with PCOS (BMI 20.0-24.4 kg/m²) reduces insulin and free testosterone levels, while decreasing systolic blood pressure, diastolic blood pressure, and serum triglycerides. A higher rate of ovulation is noted with DCI, though the difference is not statistically significant.¹¹ In obese PCOS women (BMI >26 kg/m²) also, DCI is found to improve endocrine parameters including serum testosterone, serum androstenedione, and gonadotropin releasing hormone induced LH response. It also reduces BMI and improves insulin sensitivity markers in PCOS patients with diabetic relatives, who exhibit a greater response as compared to those with no family history of diabetes.¹² The effect of DCI extends to menstrual regularity, which improves with its supplementation. This regularity is associated with a decrease in serum AMH and in IR. High homeostatic model of assessment index and presence of oligomenorrhea at the first visit are the independent predictors of achieving menstrual regularity with DCI. This effect may be mediated through a decrease in follicular fluid oxidative stress status. DCI improved the maturity and quality of oocytes significantly, while reducing oxidative stress. The usage of DCI was not associated with any adverse effect.¹³ So, with this background this present study was conducted to compare the effects of omega 3

and D chiro-inositol with D chiro-inositol alone on hormonal parameters in women with IR PCOS.

Objectives

Objectives were to evaluate and compare the effect of omega-3 and D-chiro inositol and effect of D-chiro inositol alone on hormonal parameters in women with insulin resistant PCOS.

METHODS

This randomized controlled study conducted in the departments of reproductive endocrinology and infertility, Bangbandhu Sheikh Mujib medical university, Dhaka from January 2023 to June 2024. Total 70 insulin resistant PCOS patients were included in this study. All the patients were in the follicular phase of menstrual cycle. Eligible patients who gave their informed consent were allocated randomly into group A, were received omega-3 supplements with dose of 2 g/day (each capsule 1000 g) with tab. D-chiro-inositol 500 mg daily and patients in group B, were received tab. D-chiro-inositol 500 mg daily. The treatment was given for three months. Blood samples, were taken at the baseline and after the 3-month treatment period under similar conditions. All variables were measured before and after treatment periods. All patients in both groups were asked to maintain their usual dietary intakes and physical activity during study period. All data including medical history, clinical examination and laboratory investigation findings obtained were recorded in the predesigned structured data entry sheet. SPSS (Statistical package for social science) version 26 was used for analysis. Paired samples t test was done for comparing pre and post treatment hormonal and biochemical parameters. Comparison of hormonal and biochemical parameters between group A and B were done by independent samples t test. P<0.05 was considered to be statistically significant.

Inclusion criteria

Patients whom age were 18 to 40 years, infertile women, diagnosed case of PCOS according to Rotterdam criteria, BMI >26 kg/m² and HOMA-IR >2 were included.

Exclusion criteria

Any known case of kidney disease, hyperprolactinemia, hypothyroidism, hormonal and metformin, omega-3 and D-Chiro-inositol treatment at last 3 months and hyperreactivity to these drugs were excluded.

RESULTS

Table 1 shows the age distribution of the study subjects. Out of 60 individuals, the age ranged from 18 to 39 years; where the mean age was 24.88 (±4.81) years. In group A the mean age was 23.96 (±4.16) years and in group B the mean age was 25.80 (±5.32) years. Result indicated that,

there was no significant difference in age distribution between group A and B ($p=0.089$). Out of 60 individuals, the minimum BMI was 26 and maximum 37.7, where the mean BMI was $28.83 (\pm 2.72)$. In group A the mean BMI was $29.27 (\pm 2.81)$ and in group B the mean BMI was $28.40 (\pm 2.62)$. There was no significant difference in BMI ($p=0.132$) between group A and B. No significant difference was observed comparing the values of two groups in terms of occupational status, education level, residence, and infertility type ($p>0.05$). According to Table 2, the baseline comparison between group A (Omega-3+D-chiro-inositol) and group B (D-chiro-inositol alone) showed no statistically significant differences in hormonal or biochemical parameters, confirming group comparability at the start. Serum LH levels were 8.07 ± 1.93 $\mu\text{IU/ml}$ in group A and 8.47 ± 2.55 $\mu\text{IU/ml}$ in group B ($p=0.394$), while serum testosterone levels were 11.21 ± 2.65 ng/dl and 9.07 ± 1.76 ng/dl , respectively ($p=0.237$). Fasting insulin was slightly higher in group B (27.79 ± 3.02 $\mu\text{IU/ml}$) than in group A (23.54 ± 3.57 $\mu\text{IU/ml}$), but not statistically significant ($p=0.208$), and similar trends were seen in HOMA-IR (9.87 ± 1.85 vs. 7.0 ± 1.49 ; $p=0.232$). Table 3 presents that after 12 weeks, group A demonstrated significant reductions in several key parameters: serum testosterone decreased from 11.21 ± 2.65 to 6.01 ± 2.32 ng/dl ($p=0.028$), fasting insulin dropped from 23.54 ± 3.57 to 14.42 ± 2.55

$\mu\text{IU/ml}$ ($p=0.014$), and HOMA-IR declined from 7.0 ± 1.49 to 3.2 ± 0.88 ($p=0.010$). Serum FSH also decreased significantly from 6.37 ± 1.66 to 5.61 ± 1.26 $\mu\text{IU/ml}$ ($p=0.037$), and fasting glucose decreased from 5.46 ± 0.85 to 4.96 ± 0.47 mmol/l ($p=0.028$). Although serum LH declined from 8.07 ± 1.93 to 6.47 ± 1.17 $\mu\text{IU/ml}$, this was not statistically significant ($p=0.089$). Table 4 shows that in group B, significant improvements were seen in fasting insulin (from 27.79 ± 3.02 to 14.62 ± 2.42 $\mu\text{IU/ml}$, $p=0.0004$), HOMA-IR (from 9.87 ± 1.85 to 3.06 ± 0.52 , $p=0.031$), and fasting glucose (from 5.17 ± 0.63 to 4.88 ± 0.43 mmol/l , $p=0.032$). However, reductions in LH (8.47 ± 2.55 to 6.65 ± 1.69 $\mu\text{IU/ml}$, $p=0.073$), FSH (7.43 ± 1.72 to 5.94 ± 1.09 $\mu\text{IU/ml}$, $p=0.265$), and free testosterone (9.07 ± 1.76 to 7.29 ± 1.10 ng/dl , $p=0.186$) were not statistically significant. According to Table 5, post-treatment comparisons between the two groups showed no statistically significant differences in any of the parameters. For example, serum testosterone was lower in group A (6.01 ± 2.32 ng/dl) compared to group B (7.29 ± 1.10 ng/dl), but the difference was not significant ($p=0.198$). Similarly, HOMA-IR was slightly lower in group A (3.2 ± 0.88) than in group B (3.06 ± 0.52), with $p=0.366$. These results suggest that while both treatments improved IR, the combination of omega-3 and D-chiro-inositol had a more pronounced impact on hormonal parameters.

Table 1: Demographic characteristics of the study people, (n=70).

Demographic characteristics		Group A, (n=30)		Group B, (n=30)		P value
		N	%	N	%	
Age (in years)	Mean±SD	23.96±4.16		25.8±5.32		0.089*
	Min-max	18-38		19-39		
BMI (kg/m²)	Mean±SD	29.27±2.81		28.4±2.62		0.132*
	Min-max	26-35.7		26-37.7		
Occupational status	Housewife	17	56.66	14	46.66	0.7395**
	Job holder	8	26.66	10	33.33	
	Student	5	16.66	6	20.00	
Educational status	Primary	4	13.33	3	10.00	0.8675**
	SSC	7	23.33	5	16.66	
	HSC	10	33.33	11	36.66	
	Graduate	9	30.00	11	36.66	
Residence	Rural	9	30.00	11	36.66	0.5838**
	Urban	21	70.00	19	63.33	
Infertility	Primary	21	70.00	20	66.66	0.7813**
	Secondary	9	30.00	10	33.34	

*Independent samples t-test was done, **Chi square test was done.

Table 2: Comparison of hormonal and biochemical parameters at baseline between group A and B.

Variables	Group A, (n=30)	Group B, (n=30)	P value
	Mean (\pm SD)	Mean (\pm SD)	
Serum LH ($\mu\text{IU/ml}$)	8.07 (± 1.93)	8.47 (± 2.55)	0.394
Serum FSH ($\mu\text{IU/ml}$)	6.37 (± 1.66)	7.43 (± 1.72)	0.328
Serum testosterone (ng/dl)	11.21 (± 2.65)	9.07 (± 1.76)	0.237
Fasting blood glucose mmol/l	5.46 (± 0.85)	5.17 (± 0.63)	0.095
Fasting insulin ($\mu\text{IU/ml}$)	23.54 (± 3.57)	27.79 (± 3.02)	0.208
Insulin resistance by HOMA	7.0 (± 1.49)	9.87 (± 1.85)	0.232

*Independent samples t-test was done.

Table 3: Comparison of pre and post treatment hormonal and biochemical parameters in group A.

Variables, (n=30)	Base line	At 12 weeks	P value
	Mean(±SD)	Mean (±SD)	
Serum LH (μIU/ml)	8.07 (±1.93)	6.47 (±1.17)	0.089
Serum FSH (μIU/ml)	6.37 (±1.66)	5.61 (±1.26)	0.037
Serum Testosterone (ng/dl)	11.21 (±2.65)	6.01 (±2.32)	0.028
Fasting blood glucose mmol/l	5.46 (±0.85)	4.96 (±0.47)	0.028
Fasting insulin (μIU/ml)	23.54 (±3.57)	14.42 (±2.55)	0.014
Insulin resistance by HOMA	7.0 (±1.49)	3.2 (±0.88)	0.010

*Paired samples t-test was done.

Table 4: Comparison of pre and post treatment hormonal and biochemical parameters in group B (D chiro-inositol).

Variables, (n=30)	Base line	At 12 weeks	P value
	Mean (±SD)	Mean (±SD)	
Serum LH (μIU/ml)	8.47 (±2.55)	6.65 (±1.69)	0.073
Serum FSH (μIU/ml)	7.43 (±1.72)	5.94 (±1.09)	0.265
Serum testosterone (ng/dl)	9.07 (±1.76)	7.29 (±1.10)	0.186
Fasting blood glucose mmol/l	5.17 (±0.63)	4.88 (±0.43)	0.032
Fasting insulin (μIU/ml)	27.79 (±3.02)	14.62 (±2.42)	0.0004
Insulin resistance by HOMA	9.87 (±1.85)	3.06 (±0.52)	0.031

*Paired samples t-test was done

Table 5: Comparison of post treatment hormonal and biochemical parameters between group A and B.

Variables	Group A. (n=30)	Group B. (n=30)	P value
	Mean (±SD)	Mean (±SD)	
Serum LH (μIU/ml)	6.47 (±1.17)	6.65 (±1.69)	0.418
Serum FSH (μIU/ml)	5.61 (±1.26)	5.94 (±1.09)	0.164
Serum testosterone (ng/dl)	6.01 (±2.32)	7.29 (±1.10)	0.198
Fasting blood glucose mmol/l	4.96 (±0.47)	4.88 (±0.43)	0.348
Fasting insulin (μIU/ml)	14.42 (±2.55)	14.62 (±2.42)	0.455
Insulin resistance by HOMA	3.2 (±0.88)	3.06 (±0.52)	0.366

*Independent samples t-test was done.

DISCUSSION

In this study, we focused on the efficacy of nutrient supplementation in management of PCOS because almost all vitamin and mineral deficiencies are seen in PCOS. In this present study, 60 individuals with PCOS were observed. The age ranges from 18 to 39 years; where the mean age was 24.88 (±4.81) years. The minimum BMI was 26 and maximum 37.7, where the mean BMI was 28.83 (±2.72) kg/m². Akhter et al found mean age 26.3 (±4.3) years and mean BMI of 26.5 kg/m² (±1.4).¹⁴ Lu et al found mean age of 29.3 (±6.45) years and mean values of BMI of 21.5 (±3.36) kg/m².¹⁵ Troisi et al observed mean age of 19.7 (±1.9) years and mean BMI of 28.4 (±1.7) kg/m².¹⁶ Nadjarzadeh et al observed mean of age was 26.9 (±5.9) years and mean of BMI was 31.46 (±5.74) kg/m² in their study.¹² Result of this present study showed that, in Group A (Omega 3 and D chiro-inositol) the observation values were significantly lowered in most hormonal and biochemical parameters (p<0.05) in post post-treatment observations. At baseline mean serum LH was 8.07 (±1.93) μIU/ml and after 12 weeks of treatment was 6.47

(±1.17) μIU/mL (p=0.089) and before treatment mean serum FSH was 6.37 (±1.66) μIU/ml and after 12 weeks of treatment was 5.61 (±1.26) μIU/ml (p=0.037). Likewise, mean serum testosterone was 11.21 (±2.65) ng/dl and after 12 weeks of treatment was 6.01 (±2.32) ng/dl (p=0.028) and mean fasting blood glucose was 5.46 (±0.85) mmol/l and after 12 weeks of treatment was 4.96 (±0.47) mmol/l (p=0.028). Again, before treatment mean Fasting insulin was 23.54 (±3.57) μIU/ml and after 12 weeks of treatment was 14.42 (±2.55) μIU/ml (p=0.014) and baseline insulin resistance by HOMA-IR was 7.0 (±1.49) and after 12 weeks of treatment was 3.2 (±0.88) (p=0.010). However, in group B (D chiro-inositol) the values of hormonal parameters did not lower significantly in post-treatment observations. But, mean fasting blood glucose, mean fasting insulin and Insulin resistance by HOMA-IR were lowered significantly (p<0.05). The observations of this present study are supported by similar previous studies. Akhter et al observed significant reductions in serum luteinizing hormone, serum total testosterone, fasting insulin, and HOMA-IR in the D-chiro-inositol group

compared to the placebo group after 12 weeks of treatment.¹⁴ But, they did not report any significant changes in fasting blood glucose levels. Similarly, Troisi et al also found that, average blood glucose, insulin and HOMA-IR values did not significantly change after 3 months of treatment with myo-inositol, D-chiro-inositol and glucomannan.¹⁶ But, Benelli et al also evaluated the effects of myo-inositol and D-chiro-inositol in patients with PCOS and reported a statistically significant reduction of LH, free testosterone, fasting insulin, and HOMA index only in the group treated with the combined therapy of myo-inositol and D-chiro-inositol.¹⁷ Whereas, Onyegbule et al showed that, the mean serum FSH, LH, free testosterone, prolactin, and estradiol levels decreased significantly after 12 weeks of omega 3 supplementation in women with PCOS when compared with the levels at baseline ($p < 0.05$).¹⁸ Again, Lu et al found that, dietary intake of omega-3 PUFAs, can decrease HOMA-IR significantly ($\beta = -0.089$, $p = 0.040$).¹⁵ Nadjarzadeh et al also evaluate the effect of omega-3 supplementation on hormone profiles in PCOS women and they observed that, after 8 weeks of supplementation, the mean of LH decreased and the mean of LH/FSH ratio decreased ($p < 0.005$) in omega-3 supplement group but, no significant change in FSH concentration.¹² Guidelines recommend insulin-sensitizers for women with metabolic abnormalities, while lifestyle changes are key for overweight PCOS patients.¹⁹ Myo-and D-chiro-inositol are crucial in PCOS treatment.²⁰ Omega-3s have also shown to reduce BMI, insulin, glucose, FSH, LH, SHBG, and free testosterone.^{21,22} Since PCOS is linked to insulin resistance and hyperandrogenism, omega-3s may be beneficial.²³ D-chiro-inositol, with a lower caloric value than fats, positively affects hyperandrogenism and metabolic profiles by restoring FSH signaling, aiding fertility. Omega-3s may also improve insulin resistance in PCOS.⁸ Together, D-chiro-inositol and omega-3s may enhance insulin sensitivity, reduce inflammation, and support ovulation.²⁴

Limitations

In our study, there was small sample size and absence of control for comparison. Study population was selected from one center in Dhaka city and so external validity of study findings is challenged. The present study was conducted at a short period of time.

Selection bias was eliminated by random allocation and allocation concealment, but there were other types of bias such as-performance bias: absence of blinding of participants and personnel dispensing the drugs and detection bias: absence of blinding of outcome assessment

CONCLUSION

Omega-3 combined with D-chiro inositol and D-chiro inositol along, both therapies reduce serum LH, FSH and free testosterone as well as fasting glucose, fasting insulin and HOMA-IR significantly in women with PCOS. But

there is no significant difference in post treatment hormonal and biochemical parameters between these two groups. Further research on the effects of omega-3 as treatment of PCOS is needed. Prospective multicenter clinical trial would be valuable to confirm the beneficial potential of omega-3 in the treatment of insulin resistant PCOS. To further validate omega-3 as a treatment for PCOS randomization controlled double-blind clinical trial needs to be conducted. Further studies with large sample size are warranted to determine the optimal strategy for the treatment of PCOS through these agents.

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