Original Article

The Impact of Alpha Lipoic Acid Supplementation on Women with Polycystic Ovarian Syndrome who are Being Treated with Metformin

Fatima Ali Hussein, Sinaa Abdul Amir Kadhim and Asma Abdul Jaleel Swadi

ABSTRACT

Objective: To assess the impact of the simultaneous use of metformin and alpha lipoic acid on metabolic and fertility parameters in individuals with polycystic ovarian syndromes.

Study Design: Randomized, single-blind clinical trial study

Place and Duration of Study: This study was conducted at the Department of Clinical Pharmacology, University of Al-Qadisiyah, College of Medicine, Iraq from September 2024 and March 2025.

Methods: Ninety women were assigned randomly in two groups. Patients in the metformin group received glucophage, while those in the metformin plus alpha lipoic acid group were administered metformin as in the first group along with alpha lipoic acid. All treatments were administered over a period of 12 weeks.

Results: Both management methods exhibited a notable reduction in average levels of free testosterone, luteinizing hormone:follicular stimulating hormone ratio, gonadotropin-releasing hormone antibodies, and ovarian volume ($p<0.001$); the impact of metformin combined with ALA was significantly greater in comparison to the other treatment method ($p<0.05$). Nevertheless, none of the treatment strategies had a significant. Therefore, the concurrent administration of metformin and alpha lipoic acid supplements is linked to the most favorable hormonal and ultrasound features in women with polycystic ovarian syndrome by diminishing the harmful influence of anti gonadotropin-releasing hormone antibody levels.

Conclusion: The combined use of metformin therapy and alpha lipoic acid supplements is associated with the most optimum hormonal and ultrasound characteristic in polycystic ovarian syndromes women by reducing the pathogenic effect of anti gonadotropin-releasing hormone antibody level.

Key Words: Polycystic ovary syndrome, Alpha lipoic acid, Metformin

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INTRODUCTION

One of the most common hormonal disorders affecting women today is polycystic ovary syndrome (PCOS). A significant number of women around the world are affected by PCOS.[1] It impacts metabolism and reproductive well-being, making daily life more challenging.[2] Hormonal abnormalities that disrupt ovulation and cause irregular menstrual cycles are the hallmark of PCOS.

Department of Clinical Pharmacology, University of Al-Qadisiyah, College of Medicine, Iraq.

Correspondence: Fatima Ali Hussein, Department of Clinical Pharmacology, University of Al-Qadisiyah, College of Medicine, Iraq.
Contact No: 07825680688
Email: med.post24.32@qu.edu.iq

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Weight gain, particularly around the abdomen, oily skin, acne, thinning hair on the scalp, irregular or nonexistent periods, and excessive facial or body hair growth are all linked to the condition. PCOS can result in long-term health problems if it is not properly managed.[3] Among women, insulin resistance is common. Increased fat accumulation, particularly around the waist, and elevated blood sugar levels are the results of this condition. Fertility may be impacted by hormonal imbalances that interfere with ovulation. Insulin resistance is a primary contributor to the symptoms of PCOS.[4]

When the body has a poor response to insulin, the ovaries produce higher amounts of androgens. This surge disrupts ovulation and intensifies symptoms such as acne and excess hair growth and insulin resistance affects up to 70% of women with PCOS.[5] Restoring hormonal balance, reducing symptoms, and improving treatment efficacy can all be achieved by addressing this problem.[6] Metformin is a drug that is mainly used to treat type 2 diabetes, but it also works well to treat PCOS. It helps to lower blood sugar levels and stabilize hormonal balances by boosting the body's insulin

sensitivity. As a result of improved insulin function, the ovaries can restore regular ovulation, leading to more consistent menstrual cycles. Metformin can enhance blood sugar regulation, facilitate weight loss or make weight management easier, lower androgen levels to help with acne and excessive hair growth, increase the likelihood of ovulation, and improve menstrual regularity.[7] Metformin may, however, have adverse effects, just like any other medication. Nausea, upset stomach, and diarrhea are the most frequent side effects, particularly in the early stages of treatment. Starting with a lower dosage and increasing it gradually is crucial.[8]

Supplementing with alpha lipoic acid may help reduce the severity and frequency of metformin side effects, possibly reducing the need for higher dosages of the drug.[9-11] Supplements like alpha lipoic acid are becoming more and more popular as more women seek out natural solutions or medical treatments to control their symptoms.[11] When these supplements are paired with a tailored health plan, they can contribute to improved health results and enhanced quality of life.[9-11] According to research, ALA enhances insulin sensitivity, reduces inflammation-induced oxidative stress, balances hormones, enhances lipid profiles, lowers blood sugar, and promotes metabolic health.[12,13]

We propose that the integration of these therapies addresses various facets of PCOS. Alpha lipoic acid combats oxidative stress, while metformin enhances insulin sensitivity and promotes fertility. Consequently, the objective of this research project is to assess the impact of the combined use of metformin and ALA on metabolic and fertility measures associated with PCOS.

METHODS

This randomly single-blind, and actively controlled, was conducted in Babylon, Iraq, from September 2024 until March 2025. The research followed the guidelines set forth in the Declaration of Helsinki and received ethical approval from the committee at the College of Medicine/Al-Qadisiyah University before starting. All participants provided informed consent. The sample size was calculated using a formula with significance level lower than 0.05 and a statistical power greater than 80% based on a prior trial[14], we established 4.4 µIU/ml as the standard deviation and 3.5 µIU/ml as the average change (D) in insulin, which was the main outcome measure. The calculation indicated that 12 participants were needed for each group; however, considering an estimated 3 dropouts per group, the final count was adjusted to 15 subjects for each group.

The diagnosis of PCOS was determined using the Rotterdam criteria.[15] The inclusion criteria were women between the ages of 20 and 39 with PCOS and a body mass index below 30 were included. Women who were menopausal, pregnant, or breastfeeding; those with diabetes; individuals with liver, kidney, thyroid, or heart conditions; and those with elevated prolactin levels were excluded. Participants who had used antioxidant supplements within the past three months, as well as those taking ovulation-inducing medications or drugs affecting hormonal levels, such as oral contraceptives, were not considered for enrollment. We also excluded participants who had engaged in a specific diet or exercise program and those who consume tobacco or alcohol.

Participants were assigned to two distinct groups through a process of randomization. This random selection was performed using random numbers generated by a computer. Individuals in Met. group received Glucophage (500 mg; Merck, West Drayton, UK) administered once daily for 2 weeks hen 2 times a day for the rest of the study; those in the Met.+ALA group were given the same metformin treatment along with ALA (600 mg, Batch no. 53642; neutec, Turkey) once/ day. All treatments were carried out over a 12-week period.

Serum samples were stored at -80°C until the time of analysis. The concentrations of insulin, follicle-stimulating hormone (FSH), luteinizing hormone (LH), testosterone, prolactin, and thyroid-stimulating hormone in the serum were quantified using ELISA (Bioassay Technology Laboratory, Shanghai Korean Biotech, Shanghai City, China) according to the manufacturer's protocol. The samples were evaluated for GnRHR-AAbs employing a synthetic 28-mer peptide (LifeTein, Somerset, NJ) derived from the ECL2 region of the human GnRHR as the coating antigen. Optical density (OD) measurements were recorded at 405 nm following a 60-minute incubation period.

A transvaginal ultrasound examination was conducted using a Voluson 730 pro at a frequency of 50/60 HZ with a transvaginal probe operating at 6 MHz. The volume of the ovaries was evaluated, typically located near the iliac vessels at their junction. The greatest dimensions of both ovaries were noted. Measurements of length and height were taken in centimeters, after which the probe was turned 90 degrees to assess the width in centimeters. The ovarian volume was then calculated using the prolate ellipsoid formula (Length × Width × Height × 0.523).[16] The Mean Ovarian Volume (MOV) was calculated when ultrasonography allowed for both ovaries to be measured. If only one ovary could be measured, that single measurement was used as the ovarian volume.

All statistical evaluations were analyzed by SPSS-26. To compare quantitative variables across groups, a student t-test was performed and $P<0.05$ was considered as significant.

RESULTS

The average of age was 31.73 and 32.11 years in Met. and Met. plus ALA. The difference in the average of

age between cohorts of study exhibited no significance (p=0.537) [Table 1]. Prior to treatment course, the averages of free Testosterone, FSH, LH, prolactin and TSH were comparable between Met., and Met. plus ALA groups. Post-treatment, all three forms of management showed significant decline in average free Testosterone, LH and LH:FSH ratio (p<0.001); the effect of Met. plus ALA was significantly more profound when contrasted to other mode of therapy (p< 0.05). However, none of these treatment approaches was able to affect serum levels of FSH, prolactin and TSH significantly (p>0.05) [Table 2].

Prior to treatment course, the average of GnRHR anti-body levels of Met. group, and Met. plus ALA group were 10.20, and 10.14 mg/dl, in that order. Statistically speaking, no significant variance existed between cohorts of the investigation (p=0.291). Post-treatment, all three forms of management showed significant (p<0.001) decline in average GnRH anti-body concentration of PCOS women; however, the amount of decline using Met. plus ALA is the most fruitful, with significant (p<0.001) differences when groups were contrasted to each other (Table 3).

Prior to treatment course on ultrasound, average ovary volume of Met. group, and Met. plus ALA group was 14.19, and 13.95 cm, in that order. Statistically speaking, there was no significant variance in average ovary volume between cohorts of the investigation (p=0.610). Post-treatment, the two forms of management showed significant decline in average ovary volume of PCOS women (p = 0.001); however, the amount of decline using Met. plus ALAis the most fruitful, with significant differences (p<0.001) when groups were contrasted to each other (Table 4).

Table No. 1: Descriptive statistics of age in PCOS patients (n=90)

Age (years)	Met. Group	Met.+ALA Group	p-value
	31.73 ±2.77	32.11 ±3.01	0.537

Table No. 2: Effect of different treatment approaches on serum hormonal levels (n=90)

Hormone	Met. Group	Met.+ ALA Group
Free testosterone (ng/dl)		
Prior to therapy	21.10±7.24	20.58±6.07
Post-therapy	16.59±7.04*b	18.42±5.63*a
FSH (mIU/ml)		
Prior to therapy	5.35±0.41	5.42±0.45
Post-therapy	5.39±0.43	5.46±0.53
LH (mIU/ml)		
Prior to therapy	16.49±2.66	16.78±4.34
Post-therapy	14.41±2.31*b	15.01 ±3.95*a
LH:FSH ratio		
Prior to therapy	3.08±0.06	3.10±0.10
Post-therapy	2.67±0.05*b	2.75±0.07*a
Prolactin (ng/ml)		
Prior to therapy	21.03±3.70	20.93±6.56
Post-therapy	20.99±3.82	20.14±7.27
TSH (mIU/ml		
Prior to therapy	2.31±0.78	2.36±0.58
Post-therapy	2.35±0.76	2.30±0.47

*Significant paired t-test (before treatment vs. after treatment)

Table No. 3: GnRH receptor auto-antibody level of enrolled PCOS patients according to group pre- and post-treatment

GnRH antibody	Met. Group	Met.+ ALA Group
Prior to therapy	10.20±3.93	10.14±2.90
Post-therapy	8.31±3.92*b	8.75±2.65*a

*Significant paired t-test (before treatment vs. after treatment)

Table No. 4: Ovary volume of enrolled PCOS patients according to group pre- and post-treatment

Ovary volume (cm)	Met. Group	Met.+ ALA Group
Prior to therapy	14.19±1.95	13.95±2.47
Post-therapy	12.14±1.91*b	13.31±1.84*a

*Significant paired t-test (before treatment vs. after treatment)

DISCUSSION

After completing treatment course, the two modalities showed significant reduction in mean free testosterone concentration of PCOS women; however, the amount of reduction using metformin+ALA was the greatest with significant difference when contrasted to other group in the present study. Thus, addition of ALA improved the effect of metformin optimizing serum free testosterone in women with PCOS. Jannatifar et al[17] evaluated the combination of metformin and ALA against metformin alone in women with PCOS; they reported reduction in mean total testosterone in both groups, but, unfortunately, the magnitude of reduction did not reach statistical significance. Therefore, our results are in disagreement with that of Jannatifar et al[17], however, in our study we estimated free testosterone rather than total testosterone level.

In the current study, the two modalities showed no significant change in mean FSH concentration of PCOS women. By enrolling 32 obese PCOS patients who received 400 mg ALA per day for three months, Genazzani et al[13] assessed the effects of ALA administration on the hormonal and metabolic parameters of these patients. They found no discernible change in the mean blood FSH level. Genazzani et al[13] also supports the findings of the current investigation. This result is consistent with our observation. Vincenzo et al[18] and De Leo et al[19] reported a small but non-significant increase in FSH levels.

In this study, the two modalities showed significant reduction in mean LH concentration of PCOS women; however, the amount of reduction using metformin+ALA was the greatest with significant difference when contrasted to other group. To be clear, an essential pathogenic disturbance in hormonal milieu observed in PCOS is the high serum LH accompanied by increasing ratio of LH/FSH[20], so lowering of LH concentration and related LH:FSH ratio is an essential result in our study in which we have demonstrated that using combination of ALA and metformin is better than using metformin alone in achieving this therapeutic goal.

In one study 34 individuals received 400-mg-ALA for 12 weeks, a substantial decrease in amounts of LH was observed.[21] Estradiol significantly improved and LH and testosterone significantly decreased. By lowering LH and raising estradiol levels, the research appeared to indicate that ALA can enhance function that are ovarian and egg features; conversely, ALA may also lessen hyperandrogenism by lowering testosterone. A recent meta-analysis study concluded that ALA treatment can cause significant reduction in LH level 22[34], thus supporting our findings.

The idea that insulin secretion and metabolic patterns impact the signaling system involved in hyperandrogenism and ovulation regulation explains the impact of ALA.[12] ALA is well-known for its antioxidant qualities and capacity to lessen oxidative stress, which has been linked to insulin, testosterone, and LH levels and is a contributing factor in the development of numerous disorders, including PCOS. A helpful supplement that efficiently fights reactive oxidative species (ROS) and replenishes antioxidant molecules, ALA is a strong antioxidant that has been demonstrated to lower oxidative stress and insulin resistance. ALA can improve insulin production, lower testosterone levels, and control menstrual cycles, although there have been relatively few studies on inflammation and reproductive hormones in PCOS.[23]

In this study and after completing treatment course, the two modalities showed significant reduction in mean GnRH Ab concentration of PCOS women and the amount of reduction using metformin +ALA was the greatest. In fact, a new research and treatment focus for PCOS is the recently discovered agonistic autoantibodies (AAb) against the GnRHR.[24] Immune and inflammatory abnormalities may affect receptors and functions of GnRH by impairing the axis linking the hypothalamus, pituitary gland and ovary and this may affect fertility characteristics of patients.[24] A retrospective investigation by Kem et al[25] showed that PCOS patients had AAb against the GnRHR extracellular loop-2 (ECL2), which may be pathophysiologically significant due to their capacity to chronically activate GnRHR.

Regarding effect of metformin, researchers have evaluated its therapeutic role concerning AAb against the GnRHR. The latter investigation was published by Mahdi and Kadim[26] and it has been shown by hem that the drug therapy may diminish the amount the autoantibody in a significance way in P-COS-women, therefore, giving support to our results. The actual mechanistic effect via which this drug resulted in such decline is not clear completely, nonetheless, one may suppose that the capacity of anti-inflammation by metformin may resulted in alterations in levels of cytokine that eventually impeded the synthesis of these agonistic antibodies. As a matter of fact, articles have shown that the drug metformin possess inflammatory suppression effect and illness-protective acts. Metformin drug has been shown to impede cytokines with pro-inflammatory potential, set into action process of apoptosis, and diminish proliferation of cells in arthritis and cancer.[27]

It is worth to highlight, the lack of previous studies evaluating the pharmacological acts of ALA on AAb against GrHR- in P-COS-women. Therefore, it is an originality point in the present academic work. The mechanistic contribution of action of ALA in lowering levels of these autoantibodies in PCOS- women is possibly the result of its oxidation-preventive acts, therefore, lowering response of inflammation in those patients and by this way declining synthesis of cytokines that are pro-inflammatory and have the capacity to induce increment in the antibody concentration.

In the present study and after completing treatment course, the two modalities showed significant reduction in mean ovary volume and mean AFC of PCOS women and the amount of reduction using metformin +ALA was the greatest. Metformin reduces the total count of antral follicles and this reduction will directly lead to overall decrement in size of ovary[28]; this effect is due probably to improved insulin senility with eventual decline in androgen level and hence improvement in ovulatory function resulting in less number of ovarian follicles. Secondly, previous observation concluded a direct relationship between weight and ovary volume[29], therefore, metformin ability in weight reduction is going to reduce overall ovary volume in addition; nevertheless, the true effect connecting high weight to greater ovary volume is still enigmatic. Thirdly, the hormonal optimization concerning (free testosterone, hormone LH, and ratio of LH:FSH), losing excess body weight and enhancement of physiological functions related to ovulation are going to interact as a whole to normalize volume of ovary and counts of follicles in women with PCOS treated by metformin.

Previously it has been shown that ALA via its anti-oxidant capacity can improve fertility characteristics, ovarian physiology and oocyte features.[12] For that reason, one may suppose that optimization of volume of

ovary after ALA supplements in our research is the result of enhancement of ovulation in PCOS women, and hence resulting in decrement of counts of antral follicles and eventually, there will be decrement in size of ovary. The optimization of ovarian physiology in current research is most probably attributed to anti-oxidation effect of ALA.

CONCLUSION

The combined use of metformin therapy, and ALA supplements is associated with the most optimum hormonal and ultrasound characteristic in PCOS women by reducing the pathogenic effect of anti GnRHR antibody level.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Fatima Ali Hussein, Sinaa Abdul Amir Kadhim
Drafting or Revising Critically:	Fatima Ali Hussein, Sinaa Abdul Amir Kadhim
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

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