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Adnexal and clinical effects of myoinositol and lipoic acid in PCOs patients

Abstract

Background: Polycistic ovary syndrome (PCOs) is one of the most common endocrine and metabolic disorders in premenopausal women. Our team aimed to know an eventual significant effect of the therapy based on an Alfa Lipoic Acid (ALA)/Myoinositol (Myo) combined drug on adnexal parameters as assessed by ultrasound and follow up clinical analysis.

Methods: The following represents the results of a prospective trial considering data from thirty italian nulliparous women considered for the study, chosen from an initial group of fifty-eight women, compared to data taken from a healthy women group paired by age and nulliparous status. The mean age was 30.1 years old.

Patients underwent a Myoinositol (400 mg) plus ALA (800 mg) regimen twice a day in a continued fashion in a twenty four months period. Ultrasound examinations were coincident with the fifth day of menstrual period and were set as follows: Time 0 (first evaluation), Time 12 (after twelve months) and finally Time 24 (after 24 months).

Results: Comparisons were performed between Time 0 and Time 12 paired data,

No significant ultrasound parameters differences were found between paired patients regarding: endometrial width, number of follicles and ovarian volume at the time of the trial.

Regarding clinical symptoms, menstrual pelvic pain significantly decreased after a mean time of about four months and menstrual cycle tended to be regular in 12 from 30 patients after eight months under therapy.

Parameters dealing with ultrasound color Doppler velocimetry status were studied considering other twelve months and will be described in a further report considering only ultrasound parameters.

Conclusions: Considering the preliminary results of this study, we may hypothesize that Inositol may block the vascular effects of hyperadrogenism, and that the ALA in addition may play a role regarding anti oxidant and anti inflammatory pathways.

Keywords: PCOs, inositol, alfa lipoic acid, adnexal effects

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Piazze Juan,[1] Perruzza Marta,[1] Donfrancesco Cristina,[1] Rizzo Giuseppe[2]
[1]ASL Frosinone, Ospedale Santissima Trinità di Sora, Italy
[2]Università Roma Tor Vergata, Maternal Fetal Division, Italy

Correspondence: Piazze Juan, ASL Frosinone, Ospedale Santissima Trinità di Sora, Italy, Email juanpiazze@gmail.com

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Introduction

Polycistic ovary syndrome (PCOs) is one of the most common defects regarding endocrine and metabolic disorders in premenopausal women. Many times, it is approached taking in consideration single symptoms of androgen excess and ovarian dysfunction in the absence of other specific diagnoses.[1] Even genetic basis of PCOs has been discussed in recent bibliography.[2,3] Few studies have studied the eventual effects of Myoinositol (Myo) associated with Alfa Lipoic Acid (ALA) on the direct assessed parameters of ovarian blackblog, i.e., ovarian dimensions, number of follicles, and ovarian resistances, as assessed by ultrasound techniques. The data described is a first step in a pilot twelve month prospective study, with the aim to find out if any change could be detected in a twelve months period.

Patients and methods

Trial design and oversight: a prospective paired cases trial, with a single cohort (homogeneous cases choice) therapeutical study. The study was performed from January 2019 until January 2021. Cases and controls selection: we selected women coming to our clinic, recruited under the following criteria: nulliparous women, women with a documented diagnosis of PCOs, women not using contraceptive or any kind of hormonal therapy and women not affected by other comorbidities. Only bilateral ovarian micropolicystic pattern patients were considered for the study. The research group: the trial was designed by two of the authors. All authors analyses data, collaborated in the first draft of the report and participated in the decision of submitting the publication. Participants: Trying to insert complete data, we excluded from the selection: pregnant women, lost to follow up women and women who initially accepted but afterwards refused to participate. These results regard thirty PCOs italian nulliparous women considered for the study, chosen from an initial group of fifty-eight women, compared to data taken from a women control group paired by age and nulliparous status. The mean age was 30.1 years old.

Patients underwent a Myoinositol (400 mg) plus ALA (800 mg) regimen twice a day in a continued fashion in a twenty four months period. Ultrasound examinations and clinical evaluations were coincident with the fifth day of menstrual period and were set as follows: Time 0 (first evaluation), Time 12 (after twelve months) and finally Time 24 (after 24 months). Ethical approval was obtained at the trial site after a decision of the operative ethical committee (CDA 0013_19) and all women accepted participation signing an individual written informed consent.

Statistical analysis: Statistical data was analyzed by means of the Open Stat program

(Softonic) and the Jamovi Project 2021 Statistical Software (version 1.6), based meanly in paired T test analysis.

Results

In the present report, comparisons were performed between Time 0 and Time 12 paired data. The delay in the execution and conclusion of the trial, other than unexpected logistic difficulties, were the COVID/19 waves and all the concerning events. No significant ultrasound parameters differences were found between paired patients regarding: endometrial width, number of follicles and ovarian volume at the time of the trial. Regarding clinical symptoms, menstrual pelvic pain significantly decreased after a mean time of about four months continuously in 18/30 PCOs patients and menstrual cycle tended to be regular in 12 from 30 patients after eight months under therapy. Parameters dealing with ultrasound color Doppler velocimetry status were studied considering other twelve months and will be described in a further report considering only ultrasound parameters.[4]

Discussion

All the known and worldwide effects of Inositols in PCOs were not considered, many reports deal with this argument in literature.[5,6] Interesting studies have been published regarding ovarian changes assessed by ultrasound technique. In many of them sophisticated innovations such as pulsed Doppler,3D and MRI were highlighted. Ozay et al have found that the Myo therapy reduced ovarian vascularization after 3 months, and this decrease was specially noticeable in women with PCOs compared to healthy women.[7] Regarding the action of the combination of Myo and ALA, the Italian Advisory Board in Polycistic Ovary Syndrome published a report from observations to clinical experiences on the use of Myo/ALA combinations to improve the pictures of the syndrome.[8] These reports underline the increased sensibility of Insuline on targets cells, suppressing the Insuline resistance condition after Myo/ALA regimens. In PCOs, it is demonstrated that the endothelium acts as a real active organ, owing endocrine,paracrine and autocrine modulation activities by means of which it is able to regulate the vascular homeostasis.[9] Other studies have reported how ALA may regulate the transcription of genes associated with anti oxidant and anti inflammatory pathways.[10] The Myo/ALA combination in our pilot trial has shown a significant effect on menstrual pelvic pain and in the regulation of menses rhythm, however no significant differences were found on volume and and antral follicles number between PCOs cases versus controls.

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Conflicts of interest

No conflicts of interest.

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