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RANDOMIZED CONTROLLED TRAIL INVESTIGATING THE IMPACT OF KETOGENIC AND ADVANCED GLYCATION END PRODUCTS DIET ON METABOLIC HEALTH IN POLYCYSTIC OVARY SYNDROME

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Abstract:
The aim of the study to evaluate compare the effect of ketogenic and Advanced glycation end product (AGE)on metabolic health insulin sensitivity and hormones balance in individuals with PCOS. PCOS is most common endocrine disorder PCOS linked to metabolic dysfunction in which increase type II diabetes, weight gain, decrease in insulin resistance reduced response to insulin by bodies cells this investigation aim to investigate possibility of food treatment AGE decrease intake of substance linked to increase oxidative stress and inflammation.The clinical trials study was conducted at Deepam hospital, perugalathur at Chennai on 100 patients with PCOS.Patients are classified randomly into two groups, Group A 50 patients -ketogenic diet group, Group B 50 patients -AGE diet both group recieved nutritional counseling and support above studies -30% PCOS individuals as increase ALT level and 42%-non alcoholic, fatty liver failure.In comparision to women without PCOS - half of women with PCOS where more likely to over weight /obese ketone bodies -decrease appetite and low calories intake.This pilot study demonstrated adhering low carb ketogenic diet improved symptoms and body weight,LH /FSH ratio fasting serum insulin .To contribute valuable insights into effect of KD and AGE diets and metabolic health individuals with PCOS.

Keywords: *Ketogenic, Advanced glycation end product(AGE), PCOS, ALT, LH, FSH, Oxidative stress, Clinical trials*

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INTRODUCTION:

PCOS is one of the most common endocrine disorders that afflict people who are of reproductive age. Hormonal abnormalities characterize this disorder, increased levels of androgens or male hormones and irregular menstruation cycles are common presentations. Moreover, PCOS is frequently linked to metabolic dysfunction, which raises the risk of type 2 diabetes and weight gain as well as insulin resistance which is a reduced response to insulin by the body's cells(1). The complex nature of PCOS has proven difficult to treat, despite the disorder's widespread occurrence and substantial effects on metabolic and reproductive health. Many current treatments concentrate on treating symptoms rather than the underlying hormonal imbalances, insulin resistance, and metabolic dysfunction that they are meant to address(2). Acknowledging the necessity for novel and all-encompassing methods, this investigation aims to investigate the medicinal possibilities of food treatments. Specifically, the high-fat, moderate-protein, low-carb ketogenic diet is being studied for its ability to enhance insulin sensitivity and support metabolic health (3). The Advanced Glycation End-products (AGE) diet, which tries to reduce the intake of substances created during specific cooking procedures linked to increased oxidative stress and inflammation is also examined concurrently in this study.Through investigating these dietary changes, the study hopes to learn more about how they affect inflammation, insulin sensitivity, hormone balance, and other PCOS-related characteristics(4). This investigation aims to address the shortcomings of traditional treatments by offering insights into alternatemaybe more successful approaches to managing PCOSand opening the door for individualized dietary strategies to enhance the quality of life for people suffering from this complicated endocrine condition(5).

OBJECTIVE: To evaluate the effects of a ketogenic and advanced glycation end products (AGE) on metabolic health, insulin sensitivity and hormonal balance in individual with polycystic ovary syndrome (PCOS).

STUDY DESIGN:

Study type:

Randomized controlled trail (RCT), participants assigned to either ketogenic or AGE focused diet groups.

Study Center:

Deepam Hospital – Perungalathur – Chennai.

Study population:

A Women with polycystic ovary syndrome and age within the specified range (18-40). Informed content will be obtained from interest individuals after explaining the study's purpose, procedure and potential risk and benefits.

Intervention Duration:

12 weeks with regular follow-up assessment, during which participants will strictly adhere to their assigned dietary plans. Regular check- ins with participants will ensure compliance and provide an opportunity to address any concerns.

Detailed Dietary Plans:

Participants in each group will receive individualized dietary plans tailored to the respective intervention.
Group A - Ketogenic Diet Group
Group B – AGE Diet Group

INCLUSION CRITERIA: Women aged with 18 -40 with confirmed PCOS diagnosis, BMI 25 – 40 stable medication use, willingness to adhere to specific diets and medical stability.

EXCLUSION CRITERIA: Excluding pregnant/lactating women, those with diabetes severe renal/liver dysfunction, recent significant weight changes and uncontrolled hypertension to ensure a homogeneous study population.

INTERVENTION PROTOCOLS:

Ketogenic Diet Group- Members of this group will get a diet plan that focuses on the following principles:

High-Fat Consumption: Consumption of good fats from foods like avocados, nuts, seeds, olive oil, and fatty fish will account for a substantial amount of the participants' daily caloric intake(6).

Moderate Intake of Protein: To maintain muscle maintenance and satiety, moderate amounts of lean meats, poultry, fish, and plant-based proteins will be included in the diet.

Low Carbohydrate Restriction: Carbohydrate consumption will be limited, with a concentration on non-starchy vegetables and an avoidance of high-carboydrate items such as grains, sugary products, and processed snacks.

Ketosis Induction: The goal is to induce ketosis, in which the body switches from using glucose as its primary energy source to using ketones produced by fat metabolism (7).

AGE Diet Group:
Participants in the AGE Diet Group will adhere to a dietary plan aimed at reducing Advanced Glycation End-products through certain cooking methods and food choices:

Methods of Cooking: Cooking procedures that reduce AGE formation, such as steaming, boiling, poaching, and stewing, are preferred over high-temperature methods such as frying and grilling (8).

Food Options: Fresh fruits and vegetables, lean meats, and whole grains are examples of foods with reduced natural AGE content (9).

Reduced Consumption of Processed Foods: Participants will be advised to limit their intake of processed and pre-packaged foods, which frequently contain higher levels of AGEs.

TREATMENT PLAN:
Group A- Keto diet (n=50) will receive a high – fat, low carbohydrate diet with specific macronutrients ratios.

Group B - AGE diet (n=50) emphasis on minimizing dietary advanced glycation end product.
Both groups receive nutritional counselling and support.

STATISTICALANALYSIS:
Data will be collected at baseline and regular intervals during the intervention period. Statistical analysis will be performed using t-test and regression models to assess the impact of each diet on the specified outcomes.

RESULTS:

PRIMARY OUTCOMES:

Time point	Insulin sensitivity (HOMA-IR)	Testosterone (Ng/dL)	Estrogen (Pg /mL)	LH/FSH ratio	Menstrual Regularity (yes/no)
Baseline	3.2	60	120	2.0	yes
Week 4	2.8	55	130	1.8	yes
Week 8	2.5	50	140	1.6	yes
Week 12	2.2	45	150	1.5	yes

SECONDARY OUTCOMES:

Time point	BMI	Total cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	Triglycerides (mg/dL)	CRP (mg/L)	Quality of life (score)	Adherence to diet (%)
Baseline	28.5	200	50	120	3.0	75	90%
Week 4	27.8	190	55	110	2.5	78	85%
Week 8	26.9	180	60	100	2.0	80	88%
Week 12	26.0	170	65	90	1.5	82	92%

DISCUSSION:

In premenopausal women, PCOS was a frequent endocrine and metabolic disorder. A previous study found that around 30% of PCOS individuals had increased ALT levels, and 42% had non-alcoholic fatty liver disease.Keto diet was found to be essential in women with PCOS and obesity (10). However, there have been few studies on the effect of a KD in women with PCOS and liver disease. As a result, the current study sought to explore the effect of a KD in obese women with PCOS and liver impairment (11). In comparison to women without PCOS, approximately half of women with PCOS were more likely to be overweight or obese. Because of the, a KD was viewed as an effective weight-loss strategy. Ketone bodies have the capacity to decrease appetite and allow for a very lowcalories intake. In this research, we KD was found to have similar weight loss effects in PCOS and liver dysfunction women who were obese (12).

Over the course of six months, this pilot study demonstrated that adhering to a low-carb, ketogenic diet improved the symptoms and body weight, percent free testosterone, LH/FSH ratio, fasting serum insulin, and body weight of women diagnosed with PCOS. To ascertain whether the advantages were from weight

loss in general or from carbohydrate restriction in particular, more investigation is required (13).Our results are in line with a prior clinical series in which 15 PCOS-affected women were given a low-carb, high-saturated-fat diet (100 grams/day) . In that trial, fasting serum insulin decreased from 24.2 µIU/ml to 12.2 µIU/ml from baseline to 24 weeks ($p < 0.005$), and there was a 14.3% drop in body weight ($p = 0.008$) (14)

CONCLUSION:

This study aims to contribute valuable insights into the effects of Ketogenic and AGE diets on metabolic health in individuals with PCOS. Finding have the potential to inform future dietary recommendations and improve treatment strategies for PCOS, addressing the need for personalized and sustainable intervention.

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