Ethno Med, 14(1-2): 75-81 (2020) PRINT: ISSN 0973-5070 ONLINE: ISSN 2456-6772 DOI: 10.31901/24566772.2020/14.1-2.610

Vegan or Low Calorie Diet for Weight Loss in Polycystic Ovary Syndrome Females: A Randomised Controlled Study

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KEYWORDS Intervention. Metabolic Disorder. Nutrient Profile. Vegan Diet. Weight Loss

ABSTRACT The major aim of this randomized study is to find the effect of a diet based intervention (vegan diet and low-calorie diet) among women suffering from polycystic ovary syndrome (PCOS). Overweight and obese (BMI- $33.7 \pm 4.8 \text{ kg/m}^2$) "females with PCOS" (n = 21; age, 33.1 ± 4.4 years) were assessed to participate in a 90 days random weight loss trail delivered and guided through diet and nutrition counseling (personalized and group). Body weight, BMI and waist circumference and dietary intake was assessed three times at 0, 45 and 90 days. It was hypothesized that weight loss would be more observed in the vegan group. All data were statistically analyzed and presented as median (inter quartile range). Vegan group participants reported significant weight loss at Day 90, -1.8% (-5.0%, -0.9%) vegan, 0.0% (-1.2%, 0.3%) low-cal; P=.04), Vegan group participants showed a greater decrease in energy (-265 (-469, 0)) kcal/d) and fat intake -8.2% (-9.8%, 0%) energy) at Day 90 compared with low-cal group participants (0 (0,173)) kcal/d, P = .02; 0 (0, 3.7%) energy, P = .02). The results depict that following a vegan diet can be more effective for achieving weight loss in addition to better nutrient intake profile in women with PCOS; however, a bigger sample size is required to validate these results.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is a common hereditary and heterogeneous hormonal fluctuation in females of reproductive age (Stein and Leventhal 1999; Norman et al. 2007) wherein, there is a significant increase in primary and secondary follicles (Sirmans and Pate 2014). PCOS is characterized by menstrual abnormalities, obesity, hyperandrogenism, infertility, and 10 or 12 follicles with a diameter of 2-9 mm or an ovarian volume of more than 10 cm (Stein and Leventhal 1999; Norman et al. 2007). The exact etiology of this condition is not well known but may involve a number of genetic and environmental factors (Norman et al. 2007; Astrup et al. 2014). PCOS prevalence has been estimated at 15-20 percent worldwide (Norman et al. 2007; Balen et al. 1995; Hull 1987). Women suffering from PCOS are usually overweight or obese and this worsens the complications of this disorder (Law et al. 2019). Despite the fact that most women with PCOS are obese, however, many thin

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females with PCOS are also considered to be at risk for metabolic disorders. PCOS has become one of the major causes of infertility and is linked to metabolic, reproductive and hormonal disorder and a greater combination of complications in pregnancy. PCOS females with ovulation-related menstrual irregularities may have trouble conceiving (Turner-McGrievy et al. 2014). Most females suffering from this disorder have insulin resistance (IR) and hyperinsulinemia, which play a very important role in the pathogenesis of the syndrome and can eventually go to failure of the glucose metabolism, excess androgen, higher abdominal fat, ovulatory disorder and polycystic ovaries (Papavasiliou and Papakonstantinou 2017). Females with PCOS have a higher chance of developing diabetes, cardiovascular diseases and certain types of cancer (Turner-McGrievy et al. 2014). Psychological disorders among women with PCOS include stress, anxiety, depression and low self-esteem (Bengmark 2004; Joshi et al. 2014).

There is no specific treatment for this condition but changes in lifestyle are recommended as the first-line of treatment. Management of PCOS focuses on weight loss through dietary modifications (Lin et al. 2019). Standard dietary

treatment of obesity and associated co-morbidities is nutritionally adequate, low fat (about 30 % calories and saturated fat), moderate protein (about 15%) and high intake of carbohydrates (about 55%) with increased fiber rich cereals, vegetables and fruits and moderate regular physical activity. Also, metformin plays a crucial role in managing PCOS, improving clinical characteristics (ovulation, cycle regulation and hirsutism) with positive cardio metabolic effects (Teede et al. 2010).

Normal Indian Diet contributes more towards high serum pro inflammatory and lower anti inflammatory bio markers (Ganie et al. 2019). "Plantbased diets" are dietary behaviors that prioritize higher plant food intakes and are minimal in animal feed (Kim et al. 2019). Vegan diet excludes all animal products derived wholly or partly from animals, including eggs and dairy products (Appleby and Key 2016). It contains whole grains, nuts, pulses, legumes, vegetables, and fruits. The aim of this diet is to increase the consumption of nutrient-rich foods among the population while reducing consumption of processed foods, oils and animal foods (specially including dairy products and eggs) (Tuso et al. 2013). Vegan diets have recently gone up in popularity. A vegan diet is correlated with numerous nutritional benefits due to its high fiber content, vitamin C and E, folic acid, potassium and magnesium, various phyto-chemicals and a more unsaturated fat intake. Vegans eat a considerably high amount of fruits and vegetables compared with omnivores. Higher intake of vegetables and fruits, rich in folic acid, fiber and antioxidants are associated with lower concentration of blood cholesterol, decreased risk of stroke and lower incidence of ischemic heart disease mortality (Winston 2009). Vegan diet helps in reducing the risk of obesity. A research published in PLoS Medicine (Satija et al. 2016) reported that consuming a vegan diet full of highquality plant sources decreased the possibility of type 2 diabetes by 34 percent. The American Diabetes Association says this is likely because plant foods have low saturated fats than animal foods, which increases cholesterol rates and the risk of developing type 2 diabetes (Satija et al. 2016). Another research in Diabetes Care reported that the rate of type 2 diabetes was 7.6 percent among non-vegetarians, and just 2.9 percent among vegans (Tonstad et al. 2009). People who have changed from an omnivorous diet to low-fat vegan diet experience better weight reduction and improvement in nutritional quality and consumption of vegetables and fruits than those who turn to a low-fat, omnivorous diet (Barnard et al. 2005; 2009; Turner-Mc-Grievy et al. 2007). A low-fat vegan diet has proved to be as beneficial to patients as other specific therapeutic strategies (Barnard et al. 2004; 2007). It is important to investigate dietary habits as they contribute to diabetes in PCOS as the metabolic profile of PCOS and type 2 diabetes are common (Pelusi et al. 2004). People pursuing a vegan or vegetarian approach often have low type 2 diabetes incidence levels when compared to other diet strategies (Tonstad et al. 2009; Schwingshackl and Hoffmann 2014, Turner-McGrievy et al. 2007).

Aim of the Study

The aim of this dietary study was to find the effect of 2 different diets on weight loss in overweight/obese females with PCOS: a low-fat, low-glycemic index (GI) vegan diet without any caloric intake restriction (Vegan Group) and a standard, calorie restricted diet. It was hypothesized that the vegan diet group might show significant reduction in weight and report greater improvements in macro nutrient profile at the end of 3 months intervention than the low-calorie standard group.

METHODOLOGY

An intervention study was performed on a sample of women with PCOS (Confirmed by Physician), body mass index greater than $30~kg/m^2$ (BMI $\geq 30~kg/m^2$). Twenty six (n = 26) females with PCOS were selected from the community to participate in a 3 month diet based weight loss intervention. Women were eligible for the intervention if they were between 20 to 40 years of age and were willing to accept a vegan diet. Exclusion criteria were pregnancy, lactation, history disease, taking any type of medication and eating disorders. All participants gave written, informed consent to participate in the intervention.

All the participants were asked to attend an orientation session to brief them about the aim of the study and provided technical support in

order to "fill the consent form and learn more about the study. Participants filled questionnaires about demographics, dietary intake (1 week day and 1 week end day of surprise 24-hour dietary recall using the Automated Self-Administered 24-Hour Recall (Subar et al. 2012), and physical activity (Paffenbarger Physical Activity Questionnaire), a survey instrument that assesses leisure time activity in adults over the previous week (Paffenbarger et al. 1983) at baseline, day 45 and day 90". After completing the required information in questionnaires, the participant's height, weight and waist circumference were measured and then they were randomly divided to the vegan (test) or low-cal diet (standard).

Intervention Diets

A diet with different vegan options was given to the participants following a vegan diet. Furthermore, vegan subjects were advised to eliminate all animal products from their diet like dairy products, eggs, poultry, fish and meat and emphasized on plant based foods such as whole grains, legumes, beans, fruits and vegetables. Vegan participants were given a list of vegan recipes to be consumed during the study. Participants following standard diet were advised to follow a normal dietary pattern of around 1200-1500 kcal/day. Based on results of Paffenbarger Physical Activity Questionnaire participants were encouraged to perform physical activity

for 60 minutes each day and changes in physical activity were recorded weekly.

Intervention Delivery

Whatsapp groups of both the intervention groups were made and they all were e-counseled on different days. Participants were assembled at day 45 and day 60 for weight and waist circumference measurement, personal diet counseling and 24 Hr dietary recall.

Statistical Analysis

All statistical analyses were done with the "intention-to-treat" with baseline observations carried forward to 30 and 45 days. "Independent-samples Mann-Whitney U tests" were used to examine differences in percent weight loss and weight circumference reduction between groups at Day 45 and Day 90 as well as changes in macronutrient intake outcomes. All analyses were done using SPSS software, version 21, with a P value of 0.05 used to indicate significant differences.

RESULTS

Consort flow diagram Figure 1 shows the steps of the study. Of the 26 women who were assessed and finalized for the study, 21 completed all baseline information and were randomly

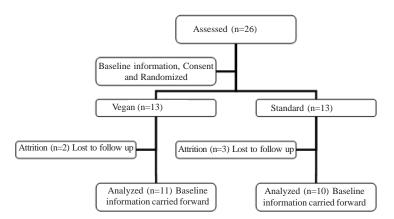


Fig. 1. Flowchart of the study *Source*: Author

distributed in two groups (n =11 vegan; n =10 low-cal).

As depicted in Table 1 there were no significant differences in baseline information (consisting of age, marital status, BMI, waist circumference, medication or associated metabolic disorder) among groups. Only 7 out of 21 (30%) participants were recommended weight loss by the physician before entering the study. Data is presented as median (inter quartile range).

Table 2 represents the major results of the study. It depicts the percent -weight loss in females of both the groups and changes in BMI and Waist Circumference and dietary intake at 45th and 90th day in the study. Vegan group candidates reported significant reduction in weight at Day 90. However,in females of both the groups at Day 45 of the study. There were significant differences at Day 45 in physical activity, vegan group scoring high at Day 45.

The differences in calorie and macronutrient intake at Day 45 were not significant, but at Day 90, vegan group participants showed decreased energy when compared to low-cal group participants. Also, vegan group participants showed a higher reduction in percent energy from fat, saturated fat and protein and a higher increment in percent energy from carbohydrates at the end of the intervention period.

DISCUSSION

The results of the present study showed a significant weight reduction in the vegan group. Prior research studies have also observed better weight reduction among women after adopting a low-fat vegan diet compared to a low-fat diet (Barnard et al. 2009). Such studies, which provide the review of literature basis for the current intervention, contribute to positive effects of a vegan diet on body weight, inflammation, hemoglobin A1c and nutritional consumption, all of which are significant results for PCOS females to evaluate. Many researches recorded no discrepancies between diets for anthropometric results, with only one research documenting an acute low-carbohydrate eucaloric diet being correlated with 0.8-kg significant weight loss compared to a diet high in MUFA (Moran et al. 2012).

The study stated a significant difference in the BMI of vegan participants compared to the standard diet group. Marzouk and Ahmed assessed the effect of vegan diet on obese women with PCOS. They reported a significant reduction in the BMI of weight loss group (Marzouk and Ahmed 2015). Another study comparing the effect of vegan diet and low-fat standard diet on women with PCOS stated no significant difference in the BMI of vegan group (Turner et al.

Table 1: Baseline information, demographic and anthropometric profiles of participants (n=21)

	Vegan group	Low-cal group	P value for difference between groups a
N	11	10	
Age	33.1 ± 4.4	34.4 ± 5.0	.77
Spousal Status			.99
Married	7 (63.6%)	6 (60%)	
Single	4 (36.3%)	4 (40%)	
Weight	79.6 ± 5.9	78.0 ± 4.4	0.16
BMI (kg/m2), mean (SD)	33.7 ± 4.8	32.2 ± 5.9	.06
Waist circumference(cm)	112.7 ± 8.5	109.5 ± 6.6	.08
Insulin Sensitivity + PCOS			.30
Yes	4 (36.3%)	4 (40.74%)	
No	5 (45.4%)	4 (40%)	
Not sure	2 (18.1%)	2 (10%)	
Any Medication	` ′	` ,	.34
Yes	4 (36.3%)	3 (30%)	
No	7 (63.6%)	7 (70%)	

[&]quot;Data represented as mean ± SD or n (%), unless otherwise indicated.

a P values are for independent-samples t tests for continuous variables and χ^2 test of independence for categorical variables"

Table 2: Percent -weight loss and changes in BMI and waist circumference and dietary intake at 45^{th} and 90^{th} day in the study (n = 21)

	Vegan		Low-cal		P value for difference between groups ^a
Percent Weight Loss b					
Day 45	0.0	(-5.1, 0.0)	0.0	(-0.3, 0.0)	.39
Day 90	-1.8	(-5.0, "0.9)	0.0	(-1.2, 0.3)	.04*
Changes in BMI (%)					
Day 45	0.0	(-3.2,0.0)	0.0	(-1.8,0.0)	.56
Day 90	-2.6	(-5.7, -0.9)	-0.7	(-2.3, -0.2)	.02*
Changes in Waist Circumference (%)					
Day 45	-0.4	(-2.8,0.0)	-0.3	(-3.1,0.0)	.79
Day 90	-0.2	(-3.3, -0.4)	-0.5	(-2.7,0.0)	.56
Change in Physical Activity (kcal/week)					
Day 45	0	(-880.18)	-612	(-1183.33)	.03*
Day 90	0	(-191.276)		0 (0.0)	.86
Change in Cal Intake (kcal/d)					
Day 45	-119	(-412.0)	0	(-315, 0)	.67
Day 90	-265	(-469.0)	0	(0, 173)	.02*
Change in Carbohydrate Percent (%)					
Day 45	5.8	(0.10.5)	0	(-5.9, 6.7)	.18
Day 90	9.6	(0.18.7)	0	(-5.6.0)	.02*
Change in Fat Percent (%)					
Day 45	-2.1	(-8.4.0)	0	(-5.5, 6.7)	.09
Day 90	-8.2	(-9.8.0)	0	(0, 3.7)	.02*
Change in Saturated Fat Percent (%)					
Day 45	-0.9	(-3.6.0)	0	(-2.7, 1.2)	.11
Day 90	-2.3	(-5.8.0)	0	(0, 1.9)	.04*
Change in Protein Percent (%)					
Day 45	0	(-4.9, 0.6)	0	(-1.2, 5.5)	.34
Day 90	-0.7	(-2.60.0)	0	(0, 9.7)	.02*

[&]quot;a P-value for Independent Samples Mann-Whitney U tests.

b Data are presented as median (interquartile range)."

2007). Both the groups did not show a significant difference in the waist circumference. However, earlier research conducted in 2015 reported significant reduction in the waist circumference by 7.8 cm in women with PCOS (Marzouk and Ahmed 2015).

Vegan group participants reported a significant reduction in protein energy level and an increase in energy from carbohydrate. One explanation for the weight reduction is that whole foods and vegetables are comparatively low on the glycemic index, meaning they are digested more slowly and fruits incorporate fiber and antioxidants, which according to research published in the *Journal of General Internal Medicine* in 2016, helps to prolong fullness (Huang et al. 2016). Vegan group incorporated more fibrous fruits and vegetables in their diet. As PCOS can be managed by controlling weight, vegan diet may prove beneficial because it is a high

fiber diet which helps in weight management. The results of the present diet study emphasis on significant effects of vegan diet for females who have PCOS for both weight loss and changes in nutrient consumption. However, low count eligible females were the major drawback of the study. A population-based study reported lower saturated fat and low glycemic index diet along with higher fiber consumption to be better in PCOS females relative to non- PCOS women (Moran 2013). Although the findings of one longitudinal study revealed that the PCOS community appeared to eat more common high glycemic index foods than healthy females, the mean energy intakes, macronutrients and micronutrients in two groups were not substantially different (Douglas et al. 2006b). Stamets et al. showed that adhering to two separate energy-restricted diets (high carbohydrate and high protein) enhanced biological function and no disparity was

observed between those two diets (Stamets et al. 2004). Additionally, a further analysis evaluated the effect of low carbohydrate and high monounsaturated fatty acids diet relative to conventional diet. This research concluded that low carbohydrate diet improved insulin sensitivity, but had no impact on hormonal levels (Douglas et al. 2006a). In a case-control study, Ahmadi et al. studied the dietary habits in females with PCOS and "reported a higher total energy and fat intake in the PCOS females, with no difference in protein and carbohydrate intake" (Ahmadi et al. 2013).

CONCLUSION

The results of the present study depicted that a vegan diet produced significant weight loss in 3 month intervention study as compared with a standard diet women with PCOS trying to lose weight can follow vegan dietary approach in long-term to experience positive effects on body composition and other necessary outcomes. However, such findings are very preliminary and have to be validated in a much bigger sample group.

RECOMMENDATIONS

The intervention needs to be carried out on a bigger group of PCOS females to validate the results. Also, investigations on serum biomarkers of pro and anti inflammatory nature will further establish the positive effects of vegan diet.

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Paper received for publication in June, 2020 Paper accepted for publication in October, 2020