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Effectiveness of lifestyle modification package among overweight and obese adolescent girls between 15-19 years with polycystic ovarian syndrome

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ABSTRACT

Background: Polycystic ovarian syndrome (PCOS) is the most common female endocrine disorder which is often diagnosed during late adolescence, with anovulation and hyperandrogenism. Adolescent girls with PCOS, are at an increased risk for the development of type 2 diabetes mellitus and metabolic syndrome. Early diagnosis and early intervention may prevent long term sequelae and improve quality of life. The objectives were to study the effectiveness of lifestyle modification package among overweight and obese adolescent girls between 15-19 years with polycystic ovary syndrome (PCOS).

Methods: In this study 144 adolescent girls (postmenarchal by 2 years) diagnosed as PCOS as per Rotterdam criteria after ruling out other causes of menstrual abnormality listed in the exclusion criteria, were selected. Informed consent taken from the participant or their parent if less than 18 years. Their anthropometric measurements and their menstrual cycles recorded at the beginning of the study and a lifestyle modification package including dietary modification and exercise, given to each of them. Participants were followed up telephonically every month to know their compliance towards the intervention program along with reinforcement of the package. After 6 months of intervention they were reviewed to assess the effectiveness of the intervention package.

Results: Significant weight loss was seen in 66.4% of the participants and 15.2% had weight stabilization (weight gain <1.5kg). There was significant change in BMI with mean change in BMI 1.9. 58.4% of the girls improved their menstrual cycle after 6 months. There was significant reduction in body fat% and W/H ratio.

Conclusions: Lifestyle modification is a simple, cost effective treatment in the management of overweight and obese adolescent PCOS in improving their BMI and regularization of menstrual cycles.

Keywords: Adolescent, Exercise, Lifestyle modification, Obesity, Polycystic ovaries

INTRODUCTION

Polycystic ovarian syndrome (PCOS) is the most common female endocrine disorder with a highly variable prevalence estimates, ranging from 2.2% to 26%. ¹⁻⁶ It is often diagnosed during late adolescence with anovulation and hyperandrogenism. Adolescent girls with PCOS,

similar to adult PCOS are at an increased risk of developing insulin resistance, type 2 diabetes mellitus and metabolic syndrome (glucose intolerance, dyslipidemia, hypertension and central obesity).

However hyperandrogenemia is a risk factor for metabolic syndrome independent of obesity and insulin

resistance. ⁷ Early intervention may prevent long term sequelae and improve quality of life. ⁸

The symptoms and signs that define this condition often overlap with the physiological changes of the reproductive axis that occur in normal girls during this period.9 Altered life style that includes high calorie diet and lack of exercise has been well recognized as a exacerbating factor. Association between stress and PCOS has also been documented. 8,11 Obesity exacerbates insulin resistance and favours the progression from impaired glucose tolerance to diabetes in these patients. The familial clustering of women with PCOS suggests that heredity is implicated in the origin of the syndrome. Approximately 50% of patients with PCOS are obese and most of them have the abdominal phenotype. 12,13 PCOS is also associated with adverse cardiovascular profile. 73% of obese PCOS also suffer from hirsuitism, compared with 56% of non obese. 14 A recent study has shown that maximizing caloric deficit in PCOS patients, may be a treatment strategy to achieve conception, and altering dietary composition may result in metabolic and reproductive improvements. 15 The first description of PCOS was made by Irving Stein and Michael Leventhal in 1935, who described 7 adult women with amenorrhea, hirsuitism, obesity and ovaries with "bilateral cystic degeneration". During the last 20 years, three separate groups of experts have established three different sets of diagnostic criteria, based on the presence of ovulatory dysfunction, clinical and biochemical hyperandrogenism, and ultrasonographic features of polycystic ovaries as diagnostic elements.

The first attempt in defining PCOS was made by the National Institutes of Health (NIH) which concluded that PCOS should be defined as a clinical disorder characterized by clinical and/or biochemical hyperandrogenism associated with a menstrual disorder, and that to make an accurate diagnosis, other conditions such as Cushing syndrome, congenital adrenal hyperplasia and hyperprolactinemia should be excluded.

In 2003, Rotterdam criteria defined PCOS as patients who met two of three criteria: clinical or biochemical hyperandrogenism (clinical hyperandrogenism with modified Ferriman Gallwey score ≥ 8), oligomenorrhoea (cycles >35days), anovulation (cycles >180 days) and PCO morphology. (Volume: one or two ovaries 10 cm³ and/or follicle count of (2–9 mm) size in one or two ovaries \geq 12 follicles).

The Androgen Excess Society in 2006 published a new diagnostic criterion that requires the obligatory presence of hyperandrogenism, with either PCOM (polycystic ovarian morphology) or oligo/anovulation in order to make the diagnosis of PCOS. The three classifications of PCOS which have been developed for adults are consistent in that neither the presence of insulin resistance nor increased LH/FSH concentrations, nor the presence of excess weight or obesity is diagnostic elements of PCOS. Also all definitions agree on the need

to exclude other conditions that could mimic this syndrome. Because there are no established criteria for the diagnosis of PCOS in adolescents the adult criteria are applied to adolescents as well.

There is evidence to suggest that lifestyle modifications should be included among the treatment of women with PCOS especially in those who are obese. Since PCOS and obesity are associated with infertility, weight reduction programs are essential components of infertility managements. Weight reduction and exercise have been shown to correct the menstrual dysfunction, infertility, and reduce the cardiovascular diseases associated with obesity and PCOS .Weight loss results in a reduction in central fat, testosterone levels, fasting insulin and LH levels, resulting in restoration of ovulation in them. Modifications should include dietary changes, increased exercise, cessation of smoking, a reduction in alcohol consumption, and reduction of psychosocial stressors.

PCOS accounts for 70-80% cause of female infertility. Approximately, one-third to one-half of all women with PCOS develop the metabolic syndrome which puts them at high risks for hypertension, high triglycerides, decreased high density lipoprotein (HDL) and increased low density lipoprotein (LDL), high blood sugar, excess body fat and breathing problems such as the obstructive sleep apnoea. 16 Genital tract cancers as a result of prolonged infertility and anovulation are also noted. Obese PCOS women have a greater severity of menstrual irregularities, anovulation, and infertility. Women with PCOS who lost 5 to 10 per cent of their body weight noticed an improvement in reproductive function.¹⁷ The purpose of the current study is to investigate the changes in anthropometric measurements and the menstrual dysfunction seen in the study population as a result of implementation of the dietary and lifestyle advice that these girls are given as part of their treatment.

METHODS

Study design: Quasi Experimental study (Before and after study).

Study duration: 15 months

Settings: Adolescent clinic of Child Development Centre (an autonomous centre under Government of Kerala).

Sample size

n= 144 (includes 30% drop outs also), calculated to detect a clinically significant reduction of 3.7 BMI points (obtained in other studies) using the formula;

$$N = \left(\frac{\sigma^2}{\delta^2}\right) (Z\alpha + Z\beta)^2$$
 where,

 σ = Standard deviation of change in BMI (11.5)

 δ = benefit anticipated from the study i.e; decrease in BMI (3.7kg/m²)

 α = Type 1 error fixed to 5%

 $(1-\beta)$ = power of the study should be more and or equal to 90%

$$(Z\alpha + Z\beta)^2 = 10.5$$

Study population

Overweight and obese adolescent girls of 15 - 19 years of age attending adolescent clinic of Child Development Centre (CDC) and diagnosed as PCOS using Rotterdam criteria 2003.

Inclusion criteria

All overweight and obese adolescent girls of 15 - 19 years with either 2 of the 3 symptoms of PCOS as per Rotterdam 2003 criteria, namely, menstrual irregularity, clinical hyperandrogenism or polycystic ovarian morphology on trans-abdominal ultra sound scan, who gave consent to participate in the study.

Exclusion criteria

- Those previously diagnosed as PCOS and on treatment.
- Those having other medical disorders like thyroid diseases, adrenal tumours, hyperprolactinemia.
- Those not willing to take part in the study.

Study methodology

As part of the community service program of CDC, anganwadi based adolescent reproductive health camps conducted in selected anganwadis Thiruvananthapuram district and those girls who fit the inclusion criteria were followed up in the adolescent clinic of CDC. A detailed informed consent was taken for participation in the study and from the parents if less than 18 years. The baseline characteristics of the subjects were recorded before starting the intervention. Participants were given a questionnaire containing socio-demographic details, symptoms of PCOS in detail. General examination findings and a detailed medical history was obtained, gathering detailed anthropometry and focusing on the symptoms of PCOS, relevant gynaecological history, medical history, family history of PCOS. Height, weight, waist circumference (WC), Hip circumference (HC) and Waist to Hip (WC/HC) ratio were taken pre and post intervention.

Height was measured in standing position using a standard measuring scale avoiding parallax error. Weight and percent body fat obtained using a bio-impedance body analyzer. BMI measured as weight in kg divided by height in meter². Classification was made as per modified ELIZ chart for adolescent:¹⁸

Underweight: (<15kg/m²)
Normal: (15 to <22 kg/m²)

• Overweight: (22 to 25 kg/m²)

• Obese: $(> 25 \text{ kg/m}^2)$

Waist circumference (WC) was measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, using a stretch-resistant tape that provides a constant 100 g tension. ¹⁹

Hip circumference (HC) was measured around the widest portion of the buttocks, with the tape parallel to the floor.²⁰

WC/HC ratio was obtained by dividing both.

Menstrual irregularity: Menstrual irregularity was taken as the presence of chronic amenorrhea (cycle length of >180 days) or a usual cycle length of more than 45 days.

Clinical hyperandrogenism: Clinical hyperandrogenism was assessed as the degree of hirsuitism using the modified Ferriman-Gallwey (mf-G) scoring method. This involves assessing the amount of body hair they have in nine regions as per the chart and a score of 8 or more, was taken as clinical hyperandrogenism.

Transabdominal sonography: Transabdominal sonography was done in the premenstrual period and data was quantified as positive if ovarian volume was >10 ml or having ≥ 12 follicles of 2-9mm in one or both ovaries. ²¹

Intervention: Each participant was personally interviewed regarding their eating habits, especially intake of junk foods and thus approximate daily calorie intake was estimated. Daily physical activity was noted and they were grouped into sedentary, moderate & heavy physical activity group. An intervention package to include an approximate calorie intake as per the caloric requirement proposed by ICMR 2010 (energy required for BMR ie; 25kcal/kg/day + energy for daily physical activity+ energy for SDA)^[22] was given as per their pre study weight & BMI. Each participant was given a diary having prescribed caloric diet to be taken (as prescribed by dietician) and hours of physical activity to be done. Diet schedule to be followed everyday was calculated from the RDA (Recommended daily allowance) chart as per their age.

Girls aged 15-16 years were advised a reduction in caloric intake to 1800kcal/day. This included 225 grams of cereals/day, 50gms of pulses/day, meat including egg up to 100gms, vegetables including green leafy & tuberous roots of 350 grams/day, and skimmed milk 200ml/day, sprouts & salads 100gms /day, a 4pm snacks that includes a fruit/ sugar free biscuits. Also a restriction of oil intake to 20gms /day and consumption of sugar to minimum was suggested.

For girls aged 17-19 years, advised a reduction in calorie intake to 1600kcal/day that included cereals 225gms/day, pulses 25 grams/day, meat including egg to 100 gram/day, skimmed milk up to 100ml/day, sprouts

&salads up to 100gms /day, vegetables including green leafy & tuberous roots of 350 grams/day, oil restricted to 20 gm /day and a strict sugar free diet.

Vegetarian diet included pulses & legume intake of 100gms more.

All groups were advised to do physical activity like brisk walking or cycling for 45min - 1hr beyond their routine daily activity and exercise to large muscles including abdomen and thigh muscles. We recommended an intake of minimum 2000ml of drinking water per day.

Participants were followed up telephonically every month for up for 6months to know their compliance towards the intervention program and were counselled accordingly. After three months of intervention they were offered medical consultation at CDC along with reinforcement of the package.

Outcome measurement: The following outcome measurements were done at the end of 6 months intervention;

- BMI (kg/m^2)
- Waist-Hip ratio
- Fat percentage
- Regularization of menstrual cycles in terms of interval between each cycle (between 21 to 45 days).

Data analysis

The data was tabulated using Microsoft Excel 2010 and analysis was done by comparing the pre intervention variables and after 6 months post intervention variables using SPSS version (13.0). The result obtained was considered statistically significant if p<0.05. The results indicating p<0.001 implies highly significant difference between variables.

RESULTS

Of the total of 144 girls who initially enrolled in the study 36 girls were 19 years old, 31 girls were of 18 years of age, 30 each were in the age group of 16 and 17 years and 17 girls were of 15 years of age. Around 70.8% were

from rural background and 80% were Hindus. 55.6% of the participants belonged to upper lower class of Kuppuswamy classification, 35.4% belonged to lower middle, 8.3% belonged to upper middle and 0.7% belonged to upper class. A positive family history of PCOS especially in mothers was present in 12.5% of girls.35.4% of girls had a positive family history of menstrual disorder. At the beginning of the study 93% of girls (134 girls) had abnormal cycles mostly oligomenorrhoea of mild and severe variety and only 6.5% had normal cycles (Table 1).

Table 1: Menstrual cycle length.

Pre intervention cycle length	Frequency	Percent
<21 days	1	0.7
21-35 days	5	3.5
35-45 days	4	2.8
45-60 days	58	40.3
>60 days	72	50.0
>6 months	4	2.8
Total	144	100.0

The duration of flow was between 3-7 days in majority (93.8%) of girls. 66% of girls gave a history of dysmenorrhoea. After 6 months of intervention 58.4% had normal menstrual cycles (Table 2).

Table 2: Post intervention menstrual cycle.

Menstrual cycle	Frequency	Percent
Normal	73	58.4
Abnormal	42	33.6
Total	125	100.0

Grade 1 acanthosis nigricans was noted in 34.7% cases and 0.7% had Grade 4 acanthosis whereas 51.4% of participants had no acanthosis. Acne grade 1 was noted in 25.7% of girls and grade 3 acne was noted in 1.4% girls, 47.9% of girls had no acne. There was significant difference in weight, BMI, fat %, hip circumference, waist circumference and waist/hip ratio following lifestyle modification package (Table 3).

Table 3: Pre and post study comparisons

N=125	Mean		Sd	Sd		Paired difference		
N=125	Pre	Post	Pre	Post	Mean	Sd	t	p
Weight	57.54	55.82	8.62	7.90	1.714	2.989	6.410	< 0.001
BMI	24.05	23.38	3.05	2.69	0.677	1.257	6.021	< 0.001
Fat %	28.24	27.32	6.69	5.84	0.91	2.5	4.049	< 0.001
Waist circumference	80.23	79.63	10.38	9.71	0.604	1.643	4.111	< 0.001
W/H Ratio	0.88	0.87	0.04	0.04	0.003	0.015	2.469	0.015

At the beginning of the study 79.2% were overweight and 20.8% were obese. After 6 months 66.4% of girls had weight loss (83 girls), 15.2% had weight gain (\leq 1.5%) considered as weight stabilization (19 girls) and 18.4% had weight gain >1.5 kg (23 girls) (Table 4).

Significantly two thirds of girls had a decrease in BMI and one third had an increase. Of the 125 girls in the post intervention group 96 girls were overweight and 29 were obese. Mean change in BMI was 0.43kg/m^2 for

overweight group and 1.85kg/m² Thus obese group had better change in BMI than overweight group (Table 5).

Table 4: Post intervention change in weight.

Change in weight	Frequency	Percent
Weight loss	83	66.4
Weight gain <1.5	19	15.2
Weight gain >1.5	23	18.4
Total	125	100.0

Table 5: Post study change in BMI in overweight and obese participants.

		N	BMI		Paired D	ifferences		
		IN	Mean	Sd	Mean	Sd	t	p
Over weight	Pre	06	22.93	0.71	0.43	1.32	3.210	0.002
	Post	96	22.50	1.35	0.43		5.210	
Obese	Pre	20	28.15	3.96	1 05	0.26	27.010	< 0.001
	Post	29	26.30	3.81	1.85		37.919	

DISCUSSION

Lifestyle intervention like weight loss in obese girls suffering from PCOS is associated with a decrease in androgen levels and normalization of menstrual cycles. 144 adolescent girls from various places in Trivandrum district participated in this study. Informed consent was obtained from the participant after explaining the objectives of this study. Before intervention the average weight was 57.26±8.05kg and average BMI 23.97±2.81 kg/m2, of them 114 (79.2%) belonged to overweight BMI (mean 22.93kg/m2) and 30 girls(20.8%) to obese BMI(mean 28.15kg/m2)[BMI South Asian Guidelines]. Mean body fat % was 28.24% ± 6.69, mean waist circumference 80.23 ± 10.38 cm, and mean waist hip ratio 0.88 ± 0.04 . In a study on adolescent PCOS by Gieir LM et al the average BMI at the initial visit was 34.7 kg/m2, with 76% having a BMI above the 95th percentile and 17% below the 85th percentile.²³ He studied the effect of a multidisciplinary program on weight loss in them. Ornstein et al studied the effect of weight loss on menstrual function in adolescent PCOS and reported improvement.²⁴ Thomson et al also reported improved reproductive function with dietary restriction and exercise.²⁵

Post intervention after 6 months, 125 participants completed the study (13.2% dropouts, 19 girls). Weight loss was noted in 83 girls (66.4%). Gieir L M et al conducted a similar study on 110 adolescent PCOS girls of an average age of 15.9 years. With 29% dropouts, he inferred that 57% succeeded at weight loss (average loss of 3.5 kg per patient), 10 girls (12.6%) showed no significant weight gain, defined as weight gain less than 1.5 kg. Thus, 70% demonstrated weight loss/stabilization. In our study weight loss averaged 3.91kg (6.8% weight loss), mean change in BMI 1.61kg/m2, body fat %

reduced to 27.32±5.84(Δ fat % 2.29,p<0.001),and W/H ratio to 0.87±0.04(Δ W/HR 0.01 p=0.015). These changes were statistically significant with p<0.001 as in the study by Ornstein et al. ²⁴ Waist circumference significantly decreased from 103.3±12.3 cm to 97.6±13 cm (P<0.01) for all participants during the dietary intervention period. Thompson et al studied the effect of addition of exercise to energy restricted diet, which provided more beneficial changes in body composition with an approximately 45% greater reduction in fat mass. ²⁵

Before intervention 134girls (93%) had oligomenorrhoea. 73 girls (58.4%) showed improvement in their menstrual function after 6 months of intervention and 52 girls remained abnormal (41.6%). Lass et al [26] similarly concluded that weight loss due to lifestyle intervention was associated with an improvement in menstrual irregularities. Ornstein and colleagues [24] demonstrated in a small study that participants who lost weight were 3.4 times more likely to have improvement in their menstrual function (P<0.001).²⁴ Thomson et al studied 94 overweight and obese women with PCOS for a 20wk period and they concluded that substantial weight loss and improvements in reproductive function occurred after a structured energy-restricted high-protein diet in overweight and obese women with PCOS.²⁵ Pasquali et al demonstrated that weight loss reduces menstrual abnormalities and improves fertility rate.²⁷ Kiddy et al (1990) also conducted a similar study and the same findings were subsequently confirmed in women who had obtained even moderate weight loss (>5 kg) after longterm low calorie regimen.²⁸ They opined that effects of dietary-induced weight loss on androgens were peculiar to obese hyper androgenic women.

Clark L M et al reported improvement in reproductive outcome with weight loss in obese infertile women. ¹⁷ In

his study women who attended the programme over the 6 months had a significant weight loss (10.2±4.3 kg, range 3.5–15; P < 0.001). ¹⁷ In contrast, the 'drop-out' group had an insignificant weight loss (1.2±3.6 kg, range +3.2 to -2.8) . At the end of the 6 months, 90% of the previous anovulatory women in the study group were ovulating spontaneously compared to none of the 'drop-out' group. Moran LJ et al conducted a study under Cochrane Collaboration to assess the effectiveness of lifestyle treatment in improving reproductive, anthropometric (weight and body composition), metabolic and quality of life factors in PCOS women and found that lifestyle intervention, provided benefits when compared to minimal treatment for hirsuitism by the Ferriman-Gallwey score They also concluded that medium to longterm lifestyle intervention resulted in significant reduction in weight.²⁹

CONCLUSION

Lifestyle modification is a simple, cost effective treatment in the management of overweight and obese adolescent PCOS in improving their BMI and regularisation of menstrual cycles. Dietary intervention along with exercise can be considered as a first line management in adolescent PCOS especially in the obese category.

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