Effect of progressive resisted exercises and aerobic exercises in the management of polycystic ovarian syndrome among young women- A pilot randomized controlled trial

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ABSTRACT

Introduction and Aim: Polycystic ovarian syndrome (PCOS) is a heterogenous, multisystem endocrinopathy in women of reproductive age also called as Stein Leventhal syndrome. PCOS is a common female endocrine disorder with prevalence ranging from 2.2% to 26%. Prevalence of PCOS in Indian adolescents is 9.13%. This draws attention to the issue of early diagnosis in adolescent girls. The aim of this study was to determine the effect of progressive resisted exercises (PRE) and aerobic exercises in the management of subjects with PCOS.

Materials and Methods: This was an experimental comparative pre and post-test type study. The subjects in the age group of 18-25 years with the diagnosis of PCOS were selected based on Rotterdam criteria and with the BMI ranging between 25-29. Twenty four subjects were recruited and were randomly divided into two groups. group A was treated with PRE +aerobic exercises + diet and group B with aerobic exercises + diet. The duration of the study was 24 weeks and the outcome measures used were BMI, PCOSQ and hormonal levels (SHBG, Free testosterone, HOMA IR, Hs CRP)

Results: The result of the study showed that group A treated with PRE + aerobic exercises + diet had significant improvement in BMI at $P \leq 0.05$ and PCOSQ and specific hormonal levels at $P \leq 0.001$ when compared to group B.

Conclusion: A 24 weeks exercise intervention with a combined PRE +aerobic exercises +diet was superior to aerobic exercises +diet among young subjects with PCOS.

Keywords: BMI; quality of life; PRE; PCOSQ; Hormones.

INTRODUCTION

Polycystic ovarian syndrome is a heterogeneous clinical condition characterized by hirsutism, irregular menstruation, chronic anovulation and endocrine disorders such as hyperandrogenism that affects 7-14% of women of reproductive age (1). The aetiology of the PCOS is complex and poorly understood and both genetic and environmental factors contribute to the syndrome (2). PCOS is a condition of hormonal imbalance among women of child bearing age (15 to 44 years) and it is estimated between 2.2 and 26.7 percentage of women in this age group have PCOS.

There is an abnormally elevated level of testosterone hormone, which interferes with the ability of oestrogen to cause one of the follicles to produce a mature egg. Additionally women with insulin resistance have difficulty to lower blood sugar levels and excess blood sugar in turn triggers more insulin production. Too much insulin also increases testosterone levels. Excess LH and reduced FSH also make the condition worse. With excess LH, there could be no LH surge for the release of the egg, and it triggers more testosterone production. Reduced FSH causes poor egg development and inability to ovulate. Hence, it leads to fertility problems.

However, the consequences of PCOS go beyond the reproductive axis, with psychological and social impairments, including stress, depression, anxiety and sexual dissatisfaction. Metabolic features associated with the condition include visceral obesity, inflammation, high hypertension and elevated cardiovascular risk factors (3). Thus, the clinical manifestation of PCOS can lower self-esteem and reduce quality of life (4). The prevalence of obesity in general population is increasing, and this might result in an even higher incidence of PCOS in the future (5, 6). Studies done on the Indian population, though limited, have suggested that an abnormality of the insulin receptor is more common in Indian women with PCOS compared to white women with PCOS (7).

The treatment protocol for PCOS is divided into non-pharmacological and pharmacological approach. The former management consists of lifestyle changes, which include regular exercise for weight reduction and diet modification, preconception counselling and administering folic acids to reduce risk of neural tube defects in the foetus. The later consists of first line

drug administration with clomiphene citrate, second line treatment with gonadotropins and laparoscopic ovarian surgery and third line treatment using in vitro fertilization. Insulin sensitizing drugs, e.g., Metformin is commonly used in the management of symptoms with PCOS. Drugs possess their own side effects.

It is accepted that lifestyle modifications in the form of exercise and proper nutrition decrease the risk of developing the condition and type 2 diabetes. In addition, evidence based guidelines recommends lifestyle modification as a non-pharmacological treatment for PCOS (8).

A meta-analysis reported improved levels of FSH, sex-hormone binding globulin (SHBG), total Testosterone, androstenedione, FAI, and mFG score in women with PCOS as a result of lifestyle intervention (diet and physical activity). Similar improvements in metabolic indicators were also reported in few studies (9-11). Compared with women with other chronic conditions, including diabetes, back pain, and arthritis, women with PCOS have been shown to have similar physical health related quality of life (HRQOL) but poorer psychological HRQoL (12, 13).

Evidence suggests that a regular exercise intervention combined with a well-controlled diet had benefits in the management of physiological and psychological symptoms associated with PCOS. Published studies have demonstrated the positive effects of exercise training on maximal oxygen consumption (Max Vo2), weight and waist circumferences in PCOS subjects (14). Further weight loss may reduce pulse amplitude of luteinizing hormone (LH) in turn reducing androgen production as excess (15).

Defects within the skeletal muscle insulin signalling pathways are thought to contribute to PCOS intrinsic IR with post receptor abnormalities contributing to overall reduction in skeletal muscle responsiveness to glucose (16, 17). This lays the foundation for interventions such as strength training or progressive resistance training (PRT) recommended by the American college of sports medicine and American Diabetes Association as an integral component of daily exercise routine for healthy adults for prevention and treatment of chronic non-communicable disease (18).

Thus, PRE could be the most potent exercise modality for improving skeletal muscle mass and quality (19, 20). Two studies until date have investigated the isolated effects of PRE in women with PCOS (21, 22). There is a need to study the effects of PRE which when combined with the usually recommended aerobic exercises and diet among young PCOS subjects in Indian population. Hence, this study was intended to study the effects of progressive resisted exercise combined with aerobic exercises and diet on BMI, quality of life and hormonal profile among young subjects with PCOS.

MATERIALS AND METHODS

This pilot study was an experimental design comparative pre post-test type which was conducted at the Faculty of physiotherapy Dr MGR educational and research institute Deemed to be university. The institutional research and ethics committee approved the study (IRB 020/2017-2018) and the study was done strictly in accordance with the guidelines of Helsinki declaration, revised 2013 adopted by world medical association. A total of 24 subjects in the age group between 18-25 years diagnosed with PCOS based on the Rotterdam criteria and BMI range between 25-29 were recruited and divided into two groups by simple random sampling (random number tables from standard statistics book) to participate in this pilot study. Subjects with thyroid disease, prolactin excess, non-classical congenital adrenal hyperplasia, glucocorticoid dysfunction, subjects under anti hypersensitivity medications and Lipid lowering medications were excluded from the study.

All the subjects signed a written consent form before any therapy was initiated. After the demographics, recruited PCOS were randomly divided into two groups. Group A (n=12) was intervened with PRE +aerobic exercises +diet and group B (n=12) was intervened only with aerobic exercises + diet. Both the groups received the above said intervention for 24 weeks. Outcome measures used were BMI, PCOSQ and hormonal levels (SHBG, Free testosterone, HOMA IR, Hs CRP).

Procedure

Intervention for group A

PRE + aerobic exercises + diet was given to the recruited subjects in group A (n=12). Supervised PRE exercise session was carried out for 2 days in a week on consecutive days for 24 weeks at the Faculty of Physiotherapy. The exercise session lasted for 60 minutes including standardized (5 minute) warm-up and cool-down. The exercise protocol followed were lateral pull down, leg curl, seated row, calf raise, chest press, split squat, shoulder press, biceps curl, triceps extension and abdominal curl. Exercises like chest press, shoulder press, biceps curl, and triceps extension were also performed. All sets of exercise (except abdominal curl) were performed to neuro-muscular fatigue i.e. 8-12 repetitions maximum. Two sets of each exercise were given in the first 2 weeks. From week 3, all exercises except split squat and shoulder press was progressed to 3 sets. The subjects also performed calisthenic exercises on non PRE days, 4 days in a week which included lying external hip rotations (‘clam shells’), side leg raises, push-ups on knees, wall squats, oblique curls and core stabilization exercises (‘bird dog’ and abdominal hollowing), performed for 3 sets x 10 repetitions

each. The numbers of repetitions of each exercise performed were recorded. Additionally the subjects performed moderate intensity aerobic exercises in the form of brisk walking in a tread mill for 30 minutes in a day for 5 days in a week. Dietary advice from a nutritionist, which consisted of high protein, low fat and carbohydrate diet, was given to all the subjects.

Intervention for group B

Aerobic exercises + diet was given to the recruited subjects in group B (n=12). The subjects performed moderate intensity aerobic exercises in the form of brisk walking for 30 minutes a day for 5 days in a week. Dietary advice from a nutritionist was given to all the subjects.

Data analysis

The collected data were tabulated and analysed using both descriptive and inferential statistics. All the parameters were assessed using statistical package for social science (SPSS) version 24. Descriptive paired t-test was adopted to find the statistical difference within the groups & Independent t-test (Student's 't'-test) was adopted to find the statistical difference between the groups.

Table 1: Comparison of BMI score between group A and group B in pre and post test

BMI	Group A (PRE)		Group B (Aerobics)		t-test	df	Significance
	Mean	S.D.	Mean	S.D.			
Pre test	26.65	0.981	26.25	1.13	1.03	28	0.310*
Post test	24.06	0.713	24.90	1.02	-2.60	28	0.015**

Table 2: Comparison of PCOS questionnaire between group A and group B in pre and post test

PCOSQ	Group A		Group B		t-test	df	Significance
	Mean	S. D.	Mean	S. D.			
Pre test	21.40	3.60	21.50	4.65	0.011	28	0.999*
Post test	29.06	2.43	24.46	3.54	-20.18	28	0.000***

Table 3: Comparison of SHBG between group A and group B in pre and post test

SHBG	Group A		Group B		t-test	df	Significance
	Mean	S. D.	Mean	S. D. S. D.			
Pre test	28.0	0.755	27.7	0.832	0.064	28	0.949*
Post test	34.1	0.516	29.8	0.507	-4.63	28	0.000***

Table 4: Comparison of free testosterone hormone value between group A and group B in pre and post test

Free testosterone	Group A		Group B		t-test	df	Significance
	Mean	S. D.	Mean	S. D.			
Pre test	4.51	0.429	4.58	0.479	-3.85	28	0.703*
Post test	2.22	0.158	3.89	0.513	-12.0	28	0.000***

Table 5: Comparison of Homeostatic model assessment insulin resistance between group A and group B in pre and post test

HOMAIR	Group A		Group B		t-test	df	Significance
	Mean	S. D.	Mean	S. D.			
Pre test	3.57	0.494	3.55	0.540	0.092	28	0.928*
Post test	2.24	0.133	3.19	0.515	-6.87	28	0.000***

Table 6: Comparison of High Sensitive C- Reactive Protein between group A and group B in Pre and Post Test

Hs CRP	Group A		Group B		t-test	df	Significance
	Mean	S. D.	Mean	S. D.			
Pre test	4.30	0.620	4.48	0.603	-0.829	28	0.414*
Post test	2.33	0.228	4.09	0.591	-10.74	28	0.000***

Table 7: Comparison of Test Variables within group A between Pre and Post Test values

Group A	Pre test		Post test		t-test	Significance
	Mean	S. D.	Mean	S. D.		
BMI	26.65	0.981	24.06	0.713	12.37	0.000***
PCOS Q	21.40	3.60	29.06	2.43	44.28	0.000***

SHBG	28.0	0.755	34.1	0.516	11.00	0.000***
Free testosterone	4.51	0.429	2.22	0.158	25.80	0.000***
Homeostatic model assessment insulin resistance	3.57	0.494	2.24	0.133	10.19	0.000***
High sensitivity C-reactive protein	4.30	0.620	2.33	0.228	15.87	0.000***

Table 8: Comparison of Test Variables within group B between Pre and Post Test values

Group B	**Pre test**		**Post test**		**t-test**	**Significance**
	Mean	**S. D.**	**Mean**	**S. D.**		
BMI	26.65	1.13	24.90	1.02	7.45	0.000***
PCOS Q	21.50	4.65	24.46	3.54	16.73	0.000***
SHBG	27.7	0.832	29.8	0.507	4.31	0.000***
Free testosterone	4.58	0.479	3.89	0.513	11.32	0.000***
Homeostatic model assessment insulin resistance	3.55	0.540	3.19	0.515	11.94	0.000***
High sensitivity C-reactive protein	4.48	0.603	4.09	0.591	10.36	0.000***

RESULTS

On comparing the mean values of groups A and B on BMI, group A showed better improvement at $P \leq 0.05$ (Table 1). On comparing the mean values of groups, A and B on PCOSQ, group A showed better improvement in quality of life at $P \leq 0.001$ (Table 2). On comparing the mean values of groups A and B on hormonal levels (SHBG, Free testosterone, HOMA IR and Hs CRP), group A showed better improvement at $P \leq 0.001$ (Tables 3-6).

DISCUSSION

The findings of this study reinforce the positive effects of PRE on BMI, quality of life and hormonal levels in women with PCOS. There have been reports on exercise intervention and changes in lifestyle in women with PCOS, but few reports have examined the effects of PRE. It was also hypothesized that PRE can improve menstrual cyclicity in women with PCOS. PRE may counteract the aetiology of PCOS through its effect on body composition (23). This study investigated the combined effects of PRE + Aerobic exercises and diet in the management of PCOS among young women. The effects of Aerobic exercises and diet are well established. The additional benefit observed in group A where PRE was combined with this conventional modality is that PRE improved muscle strength and the muscle's ability to use insulin. In this study, the subjects had changes in hormonal levels (SHBG, HOMA IR, HsCRP, and free testosterone), BMI and low quality of life. Insulin metabolism is a characteristic of metabolic syndrome in PCOS women (24).

The primary goal of PCOS challenge is to educate, create awareness and diagnose PCOS among very young women at an early stage. As PCOS and obesity are very closely related, the importance of physical activity is to be emphasized among young women. For overweight or obese women with PCOS, a weight loss exercise program results in more regular ovulation and thus the chances of getting pregnant increases. A combined diet and exercise in the form of aerobic activities, resisted exercises or yoga are all effective in women with PCOS.

This study enrolled 24 women with PCOS, 12 each in PRE+ aerobics + diet group and aerobic + diet group respectively. The duration of the study was 24 weeks, having intervention session for six days in a week. The changes experienced in group A in the present study, includes improvement in body mass index and a better quality of life. The group A also demonstrated better symptomatic improvements compared to the group B (25). Previous literature has shown various effects of exercise among PCOS subjects and if the intervention is initiated much earlier, it can actually do wonders both in the symptomatic management as well as in preventing the long-term complications of X syndrome (Hypertension, Diabetes, Hyperlipidaemia and cardiovascular disease).

PRE combined with the conventional aerobic exercises and diet is the modality of choice in subjects with PCOS. This pilot study revealed that 24 weeks of combined exercise intervention with PRE+ aerobic exercises+ diet resulted in improvements on BMI, quality of life and better hormonal profile (Tables 7 and 8). The results can be generalized after performing large-scale clinical trials.

CONCLUSION

A 24 weeks exercise intervention with PRE + aerobic exercises + diet was effective in subjects with PCOS. The combined effect of PRE seems to be more superior to aerobic exercise and diet alone on the BMI parameters, quality of life improvement on PCOSQ and specific hormonal levels.

Limitations and recommendations of the study

The sample size was small and the study included subjects only in the age group between 18-25 years

and a BMI range of 25-29. There was no follow up after 24 weeks of intervention. Future studies can be done using large sample size, follow up can be done and effects of different interventions can be studied.

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