

Effect of holistic yoga program on anxiety symptoms in adolescent girls with polycystic ovarian syndrome: A randomized control trial

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ABSTRACT

Context: Yoga techniques practiced for varying durations have been shown to reduce state anxiety. This was never assessed in adolescents with polycystic ovarian syndrome (PCOS).

Aims: To compare the effect of a holistic yoga program with the conventional exercise program on anxiety level in adolescents with PCOS.

Settings and Design: Ninety adolescent (15-18 years) girls from a residential college in Andhra Pradesh, who satisfied the Rotterdam criteria, were randomized into two groups.

Materials and Methods: Anxiety levels were assessed at inclusion and after 12 weeks of intervention wherein yoga group practiced a holistic yoga module while the control group practiced a matching set of physical exercises (1 h/day, for 12 weeks).

Statistical Analysis Used: Mann-Whitney U test was used to compare difference scores (delta change) between the two groups

Results: Changes in state anxiety after the intervention were nonsignificantly different between the two groups ($P=0.243$), while changes after the intervention were significantly different between the two groups ($P=0.002$) for trait anxiety.

Conclusions: Twelve weeks of a holistic yoga program in adolescents with PCOS is significantly better than physical exercise program in reducing anxiety symptoms.

Key words: Anxiety; polycystic ovarian syndrome; yoga.

INTRODUCTION

Polycystic ovarian syndrome (PCOS) is the most prevalent female endocrine disorder with estimates ranging from 2.2% to as high as 26%.^[1,2] In a recent survey, we have found a 9.13% prevalence of PCOS in south Indian adolescent girls.^[3]

Patients with PCOS face challenges to their feminine identity including irregular menstrual cycles, hirsutism, acne, acanthosis nigricans, obesity, and infertility all likely to impact quality of life and mood and potentially precipitate

depression and anxiety. Indeed, it has a significant effect on adult women, resulting in diminished quality of life, altered feminine identity, and dysfunction in the family and work environment.^[4-6] Further, the risk of adolescents with PCOS, who are at the height of identity development and awareness of body image, having a more significant disturbance in quality of life, cannot be overlooked.

Studies prove that PCOS women show high prevalence of anxiety.^[7] Kerchner *et al.*,^[8] documented a prevalence of 11.6% of anxiety syndromes in PCOS women. Also, there is evidence to support the concept that anxiety is a risk factor for the development of depressive disorders^[9,10] and suicide attempts^[10,11] which have an increased prevalence in PCOS patients.^[12] Therefore, it is necessary to include assessment of anxiety symptoms while diagnosing adolescents with PCOS.

Lifestyle interventions are the first-line effective treatment for PCOS. Small changes in lifestyle are known to improve

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symptoms and psychological well being. Two studies have investigated the effect of exercise on psychological outcomes in PCOS. A small, non-randomized study in overweight and obese women with PCOS reported that a six-month, self-directed brisk walking program improved body image distress scores.^[13] Recently, Thomson *et al.*,^[14] observed improvements in quality of life and depression in overweight women with PCOS after 20 weeks following an energy-restricted diet with and without exercise (aerobic only or combined aerobic-resistance exercise).

Yogic life style, a form of holistic mind-body medicine, developed thousands of years ago, is simple and can be practiced by all. There is mounting evidence that Yoga reduces anxiety symptoms. A study on cyclic meditation on healthy male volunteers shows reduction in state anxiety as assessed by Spielberger's inventory.^[15] Also, a two-month (90 min twice a week) yoga intervention showed a significant decrease in state and trait anxiety in women suffering from anxiety disorders.^[16] However, till date, the effects of a yoga practice have not been assessed in adolescents with PCOS. The present study was planned to assess the effect of yoga on anxiety level in adolescent girls with PCOS.

MATERIALS AND METHODS

Participants

The study was carried out on adolescent girls aged 15 to 18 years from a residential college in Anantapur, Andhra Pradesh, India. Those who satisfied the Rotterdam criterion (2/3 of the features) for PCOS were included in the study. The following were the definitions of the three features.

Oligo/amenorrhea: Absence of menstruation for 45 days or more and/or less than eight menses per year.^[17]

Clinical hyperandrogenism: Modified Ferriman and Gallway (mFG) score of 6 or higher.^[1] Biochemical hyperandrogenism: Serum testosterone level of >82 ng/dl in the absence of other causes of hyperandrogenism.

Poly cystic ovaries: Presence of >10 cysts, 2-8 mm in diameter, usually combined with increased ovarian volume of >10 cm³, and an echo-dense stroma in pelvic ultrasound scan.^[18]

Exclusion criteria were use of oral contraceptives/hormone treatment/insulin-sensitizing agents within previous six weeks, smoking, hyperprolactinemia, thyroid abnormalities, non-classic adrenal hyperplasia, prior

experience of yoga and those who did not consent for the study.

The study was approved by the Institutional Ethical Committee of Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA) University. Signed informed consent was obtained from the college authorities, the students and one of the parents.

Power calculation

Effect size of 0.61 was obtained by using the post intervention mean difference between the two groups from the study by Tang *et al.* on obese PCOS women that compared six months of metformin and lifestyle modification with a placebo, as there were studies on yoga for PCOS.^[19] A sample size of 86 with 43 subjects in each arm was calculated keeping this effect size of 0.61, with Type 1 error at 0.05 powered at 0.8.

Design

This was a prospective, randomized, active interventional controlled trial in which 90 participants were randomly divided into two study arms: One arm practiced yoga and the other arm practiced conventional physical exercises for the same duration.

Methods

All women students of standard 11 and 12 attended an interactive introductory lecture where the purpose and design of the study were elucidated. They were asked to report one week later after obtaining the signed consent from their parents. After obtaining the written consent, a clinical examination was performed. All girls with oligomenorrhea and/or hirsutism (as per the above said definitions) were asked to come for the ultrasound scan and blood tests. Those who satisfied the Rotterdam's criteria for PCOS were then randomly assigned to two groups using a computer-generated random number table by the pre labeled sealed envelope method. Based on random number table, participants were assigned to two interventions. Anthropometric measurements (BMI, waist and hip circumference), details of menstrual frequency and anxiety levels were documented.

Two different halls in the college premises were allotted for yoga and control group practices. Both groups practiced their respective set of practices, 1 h daily, 7 days a week for 12 weeks (total 90 sessions), under the supervision of trained instructors. The daily routine in the class consisted of lecture (5 min) followed by physical practices (40 min), pranayama (5 min) and relaxation (10 min). The instructors maintained the register of daily attendance and the reason for absence if any.

Blinding and masking

Double blinding was not possible as this was an interventional study. The medical officer, ultrasonologist and the laboratory staff were blind to the groups. Also the statistician who did the randomization and the final analysis was blind to the source of the data.

Assessments

Abdominal ultrasound scanning of the pelvis with special attention on ovaries was carried out by a certified postgraduate medical ultrasonologist using Philips HD 11XE ultrasound system. Vaginal ultrasound scanning was not acceptable to the girls or the parents.

Fasting sample of venous blood (10 ml) was analyzed at certified laboratories.

Hormone estimates including total testosterone (TT) and prolactin (PRL) were done by fully automated bidirectionally interfaced chemiluminescent immunoassay. Thyroid stimulating hormone (TSH) was measured by ultra sensitive sandwich chemiluminescent immunoassay. The intra- and inter-assay coefficients of variation were 4.0 and 5.6% for testosterone.

The state-trait anxiety inventory (STAI) is the most widely used, cross-cultural anxiety measure. It was originally developed as a research instrument to investigate anxiety in normal adults and has also been successfully used to measure anxiety in junior and senior high school students. The STAI is comprised of separate self-report scales for measuring two distinct anxiety concepts: It consists of 2 forms (Y1 and Y2) each comprising of 20 items rated on a 4 point scale.^[20]

Form Y1 assesses state anxiety, defined as ‘a transitory emotional state that varies in intensity, fluctuates over time and is characterized by feelings of tension and apprehension and by heightened activity of the autonomic nervous system’. It evaluates how the respondents feel right now at this moment. Form Y2 evaluates trait anxiety, which is ‘a relatively stable individual predisposition to respond to situations perceived as threatening’.

The overall median alpha co-efficient is 0.92 and the tool has adequate concurrent, convergent, divergent and construct validity.^[20]

Intervention

The specific modules of intervention were developed by a team of experts that included a physiatrist, a gynecologist

and yoga therapy physician. Care was taken to match the lectures, practical classes and the type of relaxation technique used in the two modules.

Yoga intervention

The concepts for the intervention were taken from traditional yoga scriptures (Patanjali yoga sutras, Upanishads and Yoga Vasishtha) that highlight a holistic approach to health management.^[21] The practices consisted of asanas (yoga postures), pranayama, relaxation techniques, meditation, and lectures on yogic lifestyle and stress management through yogic counseling. All girls received at least one session (about 1 h each) of individualized counseling that was aimed at cognitive restructuring based on yoga philosophy.

Control intervention

Table 1 shows the hour-long module of practices for the control group that consisted of a set of physical movements, non-yogic safe breathing exercises followed by supine rest (without instructions) that were matched with the yoga module. One session of counseling was ensured for the students in the control group also. Care was taken by the counselors not to introduce any of the yogic concepts during these sessions [Table 1].

Data analysis

All statistical analyses were performed using SPSS version 17.0. Kolmogorov–Smirnov test was used to check for normal distribution. As our objective was to compare the changes after yoga with that of exercise and the data was not normally distributed, non-parametric analysis was done by using Mann-Whitney U test to compare difference scores (delta change) between the two groups wherein difference score was calculated by subtracting pre from post values for each variable.

RESULTS

Figure 1 describes the trial profile. The recruitment was carried out between December 2009 and January 2011. Of 986 girls who agreed for clinical examination, 154 girls with oligomenorrhea and/or hirsutism (as per the above said definitions) were asked to come for ultrasound and hormonal investigations. After the laboratory evaluations, 90 girls who satisfied Rotterdam criteria of PCOS were randomized into two groups. Of these, there were total 18 dropouts, 8 in the yoga group and 10 in the control group because of less than 75% attendance. The reasons (not confirmed) given for withdrawal were (a) sick leave and (b) unexpected events in the family. The final analysis was done on 72 participants, 37 in the yoga group and 35 in the control group.

Table 1: Matched practices between yoga and control groups

Yoga group	Time	Control group	Time
Group lecture		Group lecture	
Lectures, in the form of cognitive restructuring based on the spiritual philosophy underlying yogic concepts	8 min	Lectures on conventional modern medical concepts about a healthy lifestyle including diet, exercise	15 min
Surya namaskara (sun salutation)	10 min	Brisk walk	15 min
Prone asanas		Prone exercises	
Cobra pose (bhujangasana)	1 min	Prone head lift	1 min
Locust pose (salabhasana)	1 min	Prone leg rising	1 min
Bow pose (dhanurasana)	1 min	Tiger leg stretch	1 min
Standing asanas		Standing exercises	
Triangle pose (trikonasana)	1 min	Spread leg side bending	1 min
Twisted angle pose (parsva -konasana)	1 min	Spread leg twisted bending	1 min
Spread leg intense stretch (prasarita padottanasana)	1 min	Spread leg forward bend	1 min
Supine asanas		Supine exercises	
Inverted pose (viparita karni)	1 min	Straight leg raising	1 min
Shoulder stand (sarvangasana)	1 min	Straight leg supine twist	1 min
Plough pose (halasana)	1 min	Cycling - bended knee crunches	1 min
Sitting asanas		Sitting exercises	
Sitting forward stretch (paschimottanasana)	1 min	Spread leg forward bend	1 min
Fixed angle pose (baddha- konasana)	1 min	Spread leg alternate toe touching	1 min
Garland pose (malasana)	1 min	Squat pose	1 min
Guided relaxation (savasana)	10 min	Supine rest	10 min
Breathing techniques (pranayama)		Normal breathing	8 min
Sectional breathing (vibhagiya- pranayama)	4 min		
Forceful exhalation (kapala bhati)	2 min		
Right nostril breathing (suryanuloma viloma)	2 min		
Alternate nostril breathing (nadi suddhi)	2 min		
OM meditation (OM dhyana)	10 min		

Table 2: Demography

Variables	Yoga (n=42)	Control (n=43)
Age, years (mean±S.D.)	16.22 ± 1.13	16.22 ± 0.93
Height, m (mean±S.D.)	1.54 ± 0.06	1.56 ± 0.05
Weight, kg (mean±S.D.)	47.92 ± 6.20	51.14 ± 7.39
BMI, kg/m ² (mean±S.D.)	20.30 ± 1.92	21.22 ± 2.99
No. of girls with BMI≤23	37	34
No. of girls with BMI>23	5	9
mFG score	4.60 ± 2.02	4.20 ± 2.13
No. of girls with mFG score <6	30	32
No. of girls with mFG score ≥6	15	13
Menstrual frequency in months (mean±S.D)	1.41 ± 0.8	1.47 ± 0.87
No. of girls with cycle length of 45 to <60 days	9	9
No. of girls with cycle length of 60 to <90 days	14	16
No. of girls with cycle length of ≥90 days	19	18

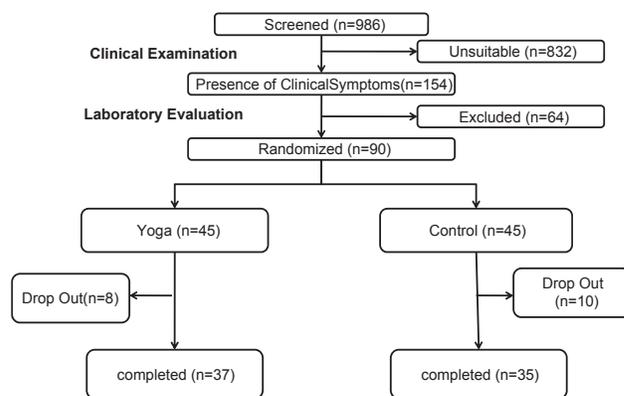


Figure 1: Trial profile

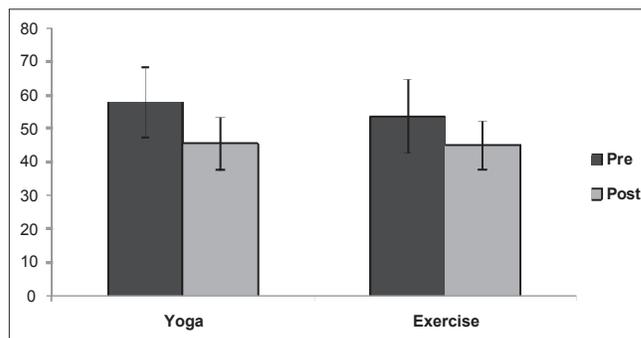


Figure 2: State anxiety

Table 2 shows the demographic data. Of the 90 girls recruited, 82.2% (74/90) were of normal weight (BMI=18.5 to 23) and only 17.78% (16/90) were overweight (BMI> 23) and 31.11% (28/90) had mFG score ≥6. Maximum 66.67% (60/90) numbers of the girls had their menstrual cycle length between 60 and 90 days.

Mann-Whitney U test on difference score showed that the changes in state anxiety after the intervention were non-significantly different between the two groups ($P=0.243$), although yoga group (-12.27) observed a greater reduction than the exercise group (-8.55) [Table 3, Figure 2].

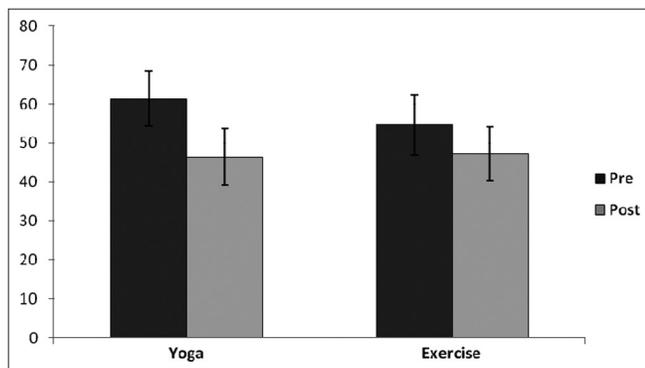
Mann-Whitney U test on difference scores of trait anxiety showed that changes after the intervention were significantly different between the two groups ($P=0.002$; Figure 3) with yoga group (-14.97) observing a higher reduction than the exercise group (-7.42).

DISCUSSION

This is the first randomized controlled trial comparing the effect of a holistic yoga program with physical exercise on state and trait anxiety in adolescents with PCOS.

Table 3: Changes in state and trait anxiety post intervention

Variable	Yoga (n=37)			Exercise (n=35)			Mann-Whitney on diff score (sig.)
	Pre (mean±SD)	Post (mean±SD)	Diff score (mean±SD)	Pre (mean±SD)	Post (mean±SD)	Diff score (mean±SD)	
State	57.79±10.46	45.52±7.82	12.27±14.33	53.55±10.98	45.00±7.19	8.55±12.56	0.243
Trait	61.36±7.02	46.39±7.28	14.97±9.87	54.64±7.77	47.21±6.99	7.42±7.57	0.002

**Figure 3: Trait anxiety**

Present study observed higher values for state and trait anxiety as compared to Spielberger's^[20] normative data on 377 high school juniors (190 males, 187 females) at Long Beach, New York, Senior High School. These normal female students had a mean±SD of 37.57±11.76 with an α of 0.92 for A-state while in the present study mean±SD was 55.67±10.85. The mean±SD for A-trait was 41.61±11.29 with an α 0.92 while in the present study mean±SD was 58.00±8.09.

The baseline scores in our study were higher than healthy Indian girls who had A-trait score of 22.5±5.6 (our PCOS girls=41.61±11.29) as reported by Deb *et al.*,^[22] in their study on 240 healthy adolescent girls from Kolkata city, West Bengal, India.

The values reported by Spielberg *et al.* and Deb *et al.* are from normal high school girls, whereas the data presented by this study are girls from the same age group with PCOS and hence have higher anxiety levels.

The changes in trait anxiety were significantly different between the two groups after 12 weeks of intervention and 5 days of detraining, wherein yoga group (-14.97) observed a higher reduction than the exercise group (-7.42).

The results observed in this study may have occurred because of the calmness of mind achieved after the yoga practice. There are evidences proving efficacy of yoga in reducing stress arousal by modulating sympathetic nerve activity^[23] and reducing anxiety levels.^[24] Also, the mental silence facilitates greater awareness by altering the individual's cognitive appraisal and perceived self-efficacy with regard to stressors and thus reduces anxiety symptoms.^[25] The cognitive-behavioral effects are

thought to result from the yogic practitioner's increased awareness of how thoughts and emotions arise in response to various environmental events, thereby allowing them to achieve more clear perception, reduced negative emotions, and improved vitality and coping.^[26]

Yoga not only reduces trait anxiety in adolescents with PCOS but also may prevent the long-term sequelae such as CVD, diabetes etc. Further, yoga as a self corrective therapy is potentially more cost-effective and enduring. Hence we recommend yoga as both a primary intervention and/or as adjunct to standard medical care.

This study was performed on a captive adolescent population with a highly selective age group, which raises the question of generalizability of the conclusions of this study. However, the fact that this was a randomized control trial with a large sample participating in each arm provides evidence for this intervention being effective.

CONCLUSION

Twelve weeks of a holistic yoga program in adolescents with PCOS is significantly better than physical exercise program in reducing anxiety symptoms. Thus, we recommend yoga to be incorporated as complimentary in management of adolescents with PCOS as this may help in reducing the progression of the disease.

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Ethical approval

The study was approved by the Institutional Ethical Committee of Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA) University (vide project # SVYASA0012/08).

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