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A Controlled Clinical Study to Evaluate the Efficacy of *Aasana* and *Pathyaahara* in Polycystic Ovarian Syndrome

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ABSTRACT

Polycystic ovarian syndrome (PCOS) is a diverse and complex female endocrine and metabolic disorder. Estimated global prevalence of PCOS are extremely variable, ranging from 2.2% to as high as 26%. *Ayurveda* has description of various *Yonivyapada* like *Arajaska*, *Asrija*, *Pushpaghni Jatahaarani* etc. PCOS bears resemblance with many of them taken together. Etiology of PCOS is still not clear but it seems that modern lifestyle plays important role in causation of PCOS. Present study was conducted in National Institute of Ayurveda Jaipur. Thirty Female Patients belonging to the age group 15 to 40 years were selected for the study and divided into two groups of 15 patients each. Treatment Group was advised *Dashamoola Yavagu* (*Gruel preparation*) and *Kulattha Yoosha* (*lentil soup*) along with *Yoga* regimen consisting of *Suryanamaskara* and *Shavasana* for duration of 3 months. Control Group received *Kanchanara Tvaka Kashaya* as oral medicine. Interval of menses, duration of menses, hirsutism, sleep disturbance etc. were among subjective criterias and Pelvic USG to assess number and size of dominant and non dominant follicles, volume of ovary was objective criteria of assessment of outcome in both the groups. Results of the study showed that PCOS patients responds better to *Pathyaahara* and *Yoga* with *p value* <0.001 in majority of criterias. Dietary modification and Yoga can play major role in non pharmaco therapeutic management of PCOS.

KEYWORDS

PCOS, *Yonivyapada Lifestyle*, *Pathyaahara*, *Suryanamaskara*



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INTRODUCTION

Polycystic ovarian syndrome (PCOS) is a diverse and complex female endocrine and metabolic disorder. Estimated Global prevalence of PCOS are extremely variable, ranging from 2.2% to as high as 26%.¹

Most prevalence studies conducted in India are in hospital set-ups and recently a few studies among adolescents in schools reported prevalence of PCOS between 9.13% to 36%.²⁻³ It is appropriately pointed by Gainie and Kalra,⁴ that PCOS is economic burden & the health budget of India is improbable to meet the expenses posed to tackling the associated multiple complications of PCOS.⁵ This syndrome accounts for 30 per cent of all infertility cases with 73 percent of women afflicted from PCOS experiencing infertility due to anovulation.

This syndrome is characterized by oligo-anovulation, hyperandrogenism and polycystic ovaries. Mainly the symptoms include amenorrhea or infrequent menstruation, irregular bleeding, infrequent or no ovulation, hirsutism, acne, acanthosis nigricans, chronic pelvic pain, increased weight or obesity, diabetes, lipid abnormalities and high blood pressure.⁶ Increasing prevalence, common cause of infertility and no satisfactory treatment in any other system of medicine are main

reasons that stress on the need of research on management of PCOS through *Ayurveda*.

There are evidences that lifestyle change with as little as 5–10% weight loss has significant clinical benefits, that improves psychological outcomes,⁷ reproductive features i.e. menstrual cyclicality, ovulation, fertility and metabolic features insulin resistance and risk factors for Coronary vessel Disease and Type 2 Diabetes Mellitus. This study compares the effect of lifestyle intervention in terms of *Pathyaahara*, *yoga* practice and a commonly practiced medicine *Kanchanar Tvaka Kashaya* in PCOS.

AIMS AND OBJECTIVES

1. To Understand the *Nidana* and *Samprapti* of PCOS in *Ayurveda*.
2. To evaluate the role of lifestyle modification through *Pathyahahara* and *Yogasana* in management of PCOS .
3. To evaluate the role of *Kanchanara Tvaka Kashaya* in the management of PCOS.
4. To compare the efficacy of above two interventions in management of PCOS.

MATERIALS & METHODS

STUDY DESIGN

Present study was designed as a controlled clinical trial. Thirty female patients



belonging age group of **15 to 40** years were selected for the study and were divided into two groups of 15 patients each. Ethical clearance was obtained from IEC, reference F/10(5)/EC/2014/337 and written consent was obtained from the patients. Raw drugs were procured from Pharmacy of NIA and dietary preparations i.e. *Yavagu*, *Yoosha* were prepared by patients themselves. Instruction leaflets were provided to the patients containing information regarding method of preparation of *Yavagu & Yoosha*.

Criteria for selection of patients

Patients attending the OPD of *Swasthavritta*, *Prasooti & Stree Roga* of NIA and SSBH, Jaipur were screened on the basis of following criteria's:

Inclusion criteria

Patients suffering from two or more of the following symptoms were selected for study: (Rotterdam revised criteria for PCOS, 2003)⁸

1. Oligomenorrhoea and / or Anovulation
2. Hyperandrogenism (Clinical and/or Bio-chemical)
3. Polycystic Ovary- diagnosed by USG.

Exclusion criteria

Patients falling in various categories mentioned below were excluded from the trial:

1. Patients having any other disease causing oligomenorrhoea and anovulation excluding PCOS on above criteria.

2. Any organic lesions of reproductive tract like TB, carcinoma and congenital deformities or any other pelvic pathology.
3. Patients suffering from adrenal hyperplasia, severe insulin resistance, androgen secreting neoplasm, thyroid abnormalities, Cushing's syndrome, cardiac diseases.

Investigations

Routine pathological investigations of blood were carried out in the pathology laboratory of NIA Hospital. Complete Blood Count, Thyroid Stimulating Hormone, Pelvic Ultrasonography were carried out for confirmation of diagnosis of PCOS and to compare the results in both groups.

Grouping of patients

In the present study thirty clinically diagnosed patients of PCOS were selected and divided into two groups i.e. Group A and Group B.

Duration of study

Both the groups received treatment for a period of three months with follow-up on every 15th day.

* **Group A:** 15 Patients were counselled to follow dietary and yoga Module.

Dietary Module: One meal on every alternate day comprising of *Dashamoola Yavagu and Kulattha Yoosha* as per Agni of patient as mentioned in Table 1.

Duration – 3 months



Table I Treatment Protocol

Group	No. of Patients	Clinical Intervention for a duration of 3 months
A	15	Pathyaahara- Dashamoola Yavagu* & Kulattha Yoosha** Yoga Aasana- Surya Namaskara & Shavasana
B	15	Kanchanara Tvaka Kashaya 30ml bd

• **Method of Preparation of Dashamoola Yavagu**

100 gms of Dashamoola Kashaya Choorna was boiled with 800 ml of water and reduced to 1/4th of original. After straining this 200 ml of Kashaya was used to prepare 50-60 gms of Puraana Shaali (one year aged rice).

• **Method of preparation of Kulattha Yoosha**

Kulattha (*Dolichos biflorus*) is soaked in water overnight so that it becomes soft. This Yoosha is Krita Yoosha. Initially 40 Grams of Kulattha is boiled with approximately 750 ml of water till Kulattha becomes soft.⁹ After boiling it is to be processed with one tsf Go Ghrita and 3-6 Grams powder of Prakshepaka Dravyas.

Prakshepaka Dravyas used, were powdered combination of Pippali, Pippalimoola, Maricha, Chitrak, Ajamoda, Hingu, Shunthi, Jeeraka, Dhaanyaka. Saindhav lavana was added as per taste.

Maatra (Dose) of Yavagu and Yoosha

Aahara Maatra is dependent upon Agni of person and it varies even among the same

individual based on Kaala and other factors. Hence it is not possible to standardise Maatra of Aahara for any individual.

Patients daily practiced Yoga as mentioned in Table II.

Table 2 Yoga Module

S.No	Regime	Approx. Duration
1.	Prayer	2 min
2.	Surya Namaskara	15-25 min
3.	Shavaasana	5 min
Total		20-30 min

Group B: 15 patients of PCOS were administered 30 ml Kanchanara Tvaka Kashaya orally b.d. before food for three months.

Method of Preparation :

Kanchanara Tvaka Yavakoota Choornam (Bark of *Bauhimia variegata*) 40 Grams is boiled with approximately 350 Milliliters(ml) of water and quantity is reduced to 1/4th of original i.e. 60 ml. Then the decoction is strained and divided into 2 equal doses of 30 ml each with equal warm water and taken before food.

Assessment criteria:

1. Subjective criteria:

1. Interval of menstruation
2. Duration of menstruation
3. Pain associated with menstruation
4. BMI
5. Acne
6. Hirsutism (Ferriman Gallaway Score)
7. Depression
8. Sleep Disturbance



2. Objective criteria- Pelvic USG

A. Based on size, volume and stroma of bilateral ovaries, number and size of dominant and non dominant follicles.

SCORRING PATTERN:-

1. Interval of menstruation

Interval of menstruation	Grade	Score
< 35 days	Nil	0
36-45 days	Mild	1
46-55 Days	Moderate	2
>56 days	Severe	3

2. Duration of menstruation

Days of menstruation	Grade	Score
3-5 days	Nil	0
1-2/6-7 days	Mild	1
1/8-9 days	Moderate	2
Spotting / > 9 days	Severe	3

3. Pain associated with menstruation

Pain associated with menstruation	Grade	Score
No pain	Nil	0
Bearable Pain	Mild	1
Need of oral analgesics	Moderate	2
Need of injectables	Severe	3

6. Hirsutism**

Pattern of hair growth	Grading	Score
No body hair in male distribution area	Nil	0
Body hair seen in upper lip	Mild	1
Body hair seen in upper lip, chin	Moderate	2
Body hair seen in upper lip, chin, around the breast nipples linea alba of the lower abdomen	Severe	3

**The distribution and severity of the hirsutism can be quantified using the Ferriman and Gallaway score; a score of 8 or greater is deemed as significant hair growth .

7. Depression

Depression	Grade	Score
No depression	Nil	0
Occasional depression	Mild	1
Mild presence of depressed mood every day everyday but able to carry out routine work	Moderate	2

4. Body Mass Index

BMI	Grade	Score
18.5-25 kg/m ²	Nil	0
25.1 - 30 kg/m ²	Mild	1
30.1 - 40 kg/m ²	Moderate	2
More than 40 kg/m ²	Severe	3

5. Acne

ACNE	Grade	Score
No lesions	Nil	0
Comedones*	Mild	1
Papules	Moderate	2
Pustules, Nodules	Severe	3

*Comedones are skin-coloured, small papules frequently found on the chin, forehead of those with acne. A single lesion is a comedone. Open comedones are blackheads; black because of surface pigment (melanin), rather than dirt. Closed comedones are whiteheads; the follicle is completely blocked.



Marked depression whole day, lost interest in most things and carry out the routine work and personal activities(like bathing, combing) without any interest	Severe	3
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8. Sleep Disturbance

Normal satisfying sleep	Nil	0
Occasional delayed sleep without waking episodes	Mild	1
Frequent delayed sleep with 1-2 waking episodes	Moderate	2
Daily delayed sleep with frequent waking episode followed by delayed re-appearance of sleep	Severe	3

Objective Criteria:

Pelvic sonography of ovary:

Both ovaries are normal in size shape and echo texture	Nil	0
One ovary is normal in size and echo pattern & another is having thin walled unilocular small cyst	Mild	1
Both ovaries are slightly enlarged in size with multiple small follicles	Moderate	2
Bilaterally multicystic ovaries	Severe	3

Statistical analysis:

The obtained information's were analysed statistically in terms of mean score (X), Standard deviation (S.D.), Standard Error (S.E.). Paired't' test was carried out at the level of 0.1, 0.05, 0.02, 0.01, & 0.001 of P levels. The result were interpreted as –

P < 0.1 Non-significant (N.S.)

P < 0.05 Mild significant

P < 0.02 Moderate significant

P < 0.01 Significant (S.)

P < 0.001 Highly significant (H.S.)

Overall effect of therapy

The overall effect of therapy was grouped into 5 types.

1 – Complete Cured (100% relief)

2 – Marked Improvement (> 75 % to <100 % relief)

3 – Moderate Improvement (> 50 % - 75 % relief)

4 – Mild improvement (> 25 % - 50 % relief)

5 – Unchanged (up to 25% relief)

Follow up

Follow-up was taken after duration of 15 days for 3 months. After completion of the

treatment the patients of both the groups was followed up every month for three months to see whether the improvement provided by the therapy is sustained or otherwise, depending upon cooperation from patients after completion of treatment. Any new complaint or complication emerged during follow up was also recorded.

Observations

Maximum patients were of the age group 26-35 years(53.33 %), educational status graduates(46.66%), occupation students(36.66 %), unmarried (53.33 %) negative history of PCOS, BMI 25-30 kg/m² (73 %), main complaint of delayed menses(30%), history of less than 1 year(66 %), *Vatakaphaja Prakruti* (73.53 %), habit of *Vishamashana*(63 %),*Sthoola Akriti* (73 %),sedentary lifestyle (80%) habit of *Divasvapna* (53.33 %), *Nidra* less than 8 hrs a day (53 %), *Avyayama* (73 %), *Mandagni*(46 %), *Chinta* (73.33 %)*Artava Vaha Sroto Dushti* (100 %), B/L ovarian cyst (80 %), follicular size 0-12 mm (66 %).

RESULTS & DISCUSSION

Table III Effect of therapy on subjective and objective parameters



Criteria	Group	Mean			% Relief	SD		t	p value	Interpretation
		BT	AT	X		SE	SE			
Interval of menstruation	A	2.26	1.13	1.13	50	0.51	1.13	8.5	<0.001	HS
	B	2.33	1.46	0.86	37.14	0.51	3.87	6.5	<0.001	HS
Duration of menses	A	2.33	1.33	1.00	42.85	0.75	0.19	5.1	<0.001	HS
	B	2.33	1.73	0.60	25.71	0.50	0.13	4.5	<0.001	HS
Dysmenorrhoea	A	1.06	0.13	0.93	87.50	0.59	0.15	6.08	<0.001	HS
	B	1.60	0.93	0.66	41.60	0.48	0.12	5.29	<0.001	HS
BMI	A	1.2	0.73	0.46	38.88	0.51	0.13	3.50	<0.01	Sig.
	B	1.2	1.20	0	0	0	0	0	0	NS
Acne	A	1.13	0.26	0.86	76.47	0.83	0.21	4.02	<0.01	Sig.
	B	1.53	1.06	0.46	30.43	0.51	0.13	3.50	<0.01	Sig.
Hirsutism	A	1.66	1.66	0	-	-	-	-	-	NS
	B	1.66	1.66	0	-	-	-	-	-	NS
Depression	A	1.86	0.60	1.26	67.85	0.45	0.11	10.71	<0.001	HS
	B	1.80	1.46	0.33	18.51	0.48	0.12	2.64	<0.02	Mod. Sig.
Sleep Disturbance	A	1.53	0.53	1	65.21	0.75	0.19	5.12	<0.001	HS
	B	1.46	1.26	0.2	13.63	0.41	0.10	1.87	<0.10	NS
Pelvic USG Findings	A	2.53	1.66	0.86	34.21	0.51	0.13	6.5	<0.001	HS
	B	2.53	1.73	0.80	31.57	0.56	0.14	5.5	<0.01	Mod Sig.

BT- Before treatment, AT- After treatment, SD- Standard deviation, SE-Standard error, p value- probability HS-Highly Significant, NS-Not significant, Sig.-Significant, Mod. Sig.- Moderately significant

There cannot be any *Yonivyapada* without the involvement of *Vata Dosha*. Menstrual abnormality in the form of oligo or amenorrhoea is main clinical feature of PCOS. *Nidana* like *Mithyahara* i.e. improper dietary intake leads to formation of *Aama* in body and causes *Kapha* and *Medo Dushti* because their nature is same. This *Ama* first affects *Jatharagni* and then *Dhatvaagni*. In the case of PCOS the *Dhatus* that are affected are *Rasa Dhatu*, *Meda Dhatu* (adipose tissue) and *Artava Dhatu* – the female reproductive system. *Artava Dhatu* affected by the *Guru, Snigdha* qualities of *Kapha* and *Ama* creates *Srota Dushti* in *Artavavaha Srotas*. *Apana Vayu* in *Artavavaha Srotas* becomes stagnant – *Sanga*, due to excessive *Kapha* and *Ama* accumulation blocking the

channel impeding the flow of *Vata* in the ovarian cycle. *Pratiloma gati* of *Apana Vata* cause hinderance to normal flow of menstruation hence leading to *Anaartava*, *Heenaartava* or *Atyaartava*. *Pratiloma Apaana Vata* is also main cause of recurrent miscarriages and bad obstetric history in PCOS sufferers.

There is nothing else except diet for sustaining the life of living beings. One is capable to make man disease-free only with the congenial diet. *Aahara* plays an important role in healthy, diseased and convalescent states. *Pathyahara* forms an important aspect of *Ayurvedic* management and is basic to normal functioning of the human body. *Pathyahara* is more important than the medicine itself.



Probable Mode of Action of *Dashamoola Yavagu*

Dashamoola is the drug of choice for *Apana vata dushti*. *Dashamoola* acts on *Pratiloma Gati of Vata* and does *Vata Anulomana*. *Dashamoola Yavagu* has all the *Gunas* of *Dashamoola*, in addition to this, it is *Laghu* and *Supachya*. *Dashamoola* is not just *Vata Hara* but it is *Vata Kaphakara*, by virtue of this action it also acts in *Aavarana Samprapti* also where *Apaana Vata* is *Kaphaavritta* or *Medaavritta*. *Brihat Panchamoola* are having *Ushna Vipaka* hence they are having *Agni Deepana* property, by virtue of which it is *Aama-hara*. *Aama* is responsible for *Sanga* or obstruction in *Artavavaha Srotas*. *Dashamoola* is the drug of choice in *Vataja* disorders and is most commonly preferred in all type of *Vatavyadhis*. All *Yonivyapada* arises due to *Vata-vaigunya* hence *Dashamoola* is right choice of drug for PCOS. *Gokshura* is *Vrishya*, *Garbhasthaapaka* thus helpful in infertility and miscarriages associated with PCOS. *Shali* are cold in potency & sweet in taste as well as *Vipaka*. It do not produces much *Vayu* & bowel bindings. It alleviates all the three *Doshas*. *Dashamoola Yavagu* improved interval and duration of menses with p value <0.001 as shown in Table III.

Probable Mode of Action of *Kulattha Yoosha*

Being *Ushna*, *Ruksha* and by virtue of *Shukra-Doshahara* property *Kulattha* is suitable in condition of oligomenorrhoea and hyperandrogenism which are the cardinal symptoms of PCOS. *Ushna*, *Tikshna*, *Lekhana*, *Pachana* etc. properties of contents of *Prakshepaka Dravyas of Yoosha* i.e. *Pippali*, *Maricha*, *Shunthi* etc are similar to *Pitta*, increases *Agneya Guna* of *Pitta* and *Artava* is also *Aagneya* which is responsible for *Artava Janana*. As *Kulattha* is *Shukra Doshahara* it may reduce the androgens and thus reduced Acne. Due to the high soluble-fibre content, legumes are believed to help reduce blood cholesterol.

Kulattha has a very low glycemic index hence it is absorbed relatively slowly into the blood stream and do not cause sudden surge in blood glucose levels thus is beneficial in PCOS associated with Diabetes Mellitus.

Probable Mode of action of *Surya Namaskara & Shavasana*

Surya Namaskara help to stretch the pelvic area and *Pranayama* calms the mind. *Yoga* helps to balance hormones by reducing the androgens and encourages egg production. Regular yoga practice relaxes the mind and reduces the stress of weight gain which in turn helps in regularizing the menstrual cycle. Weight gain is associated with a worsening of symptoms while weight loss



improves the endocrine, metabolic profile and symptomatology¹⁰. Evidence shows that lifestyle change leading to weight loss as little as 5–10% has significant clinical benefits in improving the psychological outcomes,¹¹ reproductive features (menstrual cyclicity, ovulation and fertility) and metabolic features (insulin resistance and risk factors for Coronary vascular disease and Type 2 Diabetes Mellitus). *Surya Namaskara* burns about 3.79 calories per minute, according to a study by the Defence Institute of Physiology and Allied Science in India published in the Indian Journal of Physiology and Pharmacology¹².

Practicing *Shavaasana* for a duration of 3 months significantly lowered the stress, depression, loss of confidence and sleeplessness in PCOS patients. *Shavasana* lowers blood pressure and heart rate. Most significant findings is reduction in plasma catecholamines. This indicates that the *Shavaasana* type of relaxation posture considerably reduces the sympathetic nervous activity. Thus, it can be used as a treatment for hypertension associated with PCOS in which sympathetic nervous system becomes overactive.¹³ *Shavasana* and *Mantra* chanting during *Surya Namaskara* calms the nervous system, the byproduct often being improved sleep. This may be due to their ability to enhance

relaxation and induce a balanced mental state. Consistent practice of *Suryanamaskaar* and *Shavaasana* reduces depression as *yoga* lead to significant increase in serotonin levels along with reduction in the levels of monamine oxidase, an enzyme that breaks down neurotransmitters and cortisol.¹⁴ *Yogasana* causes inhibition of the posterior or sympathetic area of the hypothalamus. This inhibition optimizes the body's sympathetic responses to stressful stimuli and restores autonomic regulatory reflex mechanisms associated with stress.

Probable mode of action of *Kanchanara Tvaka Kashaya*

Granthihara and *Bhedana* properties of *Kanchanar* act on reproductive system & improve the functions of ovary and *Artava*. Along with this *Lekhaneeya* property of *Kanchanar* also helps in reducing the size and arrests further growth of cyst. It has chemicals flavonoids with one triterpene caffeate, these compounds showed anti-inflammatory activity. It has proven anti diabetic and anti tumour activity.¹⁵

Follicular size increased after treatment in both the groups significantly. Patients with no follicular growth get the increase in follicular size after therapy. This may be because of removal of *sanga* by properties i.e. *Kapha-vata Shamaka*, *Srotoshodhana*, *Aama-pachana*, etc. of *Dashamoola* and



Kulattha Yoosha. After removal of *Sanga* created by vitiated *Kapha* and *Aama* in *Artavavaha Srotas*, *Apana Vata* functions well leading to normal *Rajah Pravritti* and *Beeja Nirmana*. Few patients could not tolerate *Kanchanar Kashaya* empty stomach, developed nausea. This may be probably due to *Vamanopaga* nature of *Kanchanar*. In such case the medicine was advised after food.

In Group B, *Granthihara* and *Bhedana* properties of *Kanchanar* act on reproductive system & improve the functions of ovary and *Artava*. Both *Antahpushpa* (ovum) and *Bahipushpa* (menstrual blood) are functionally improved with *Kanchanar Tvak Kashaya*. Along with this *Lekhaneeya* property of *Kanchanar* also helps in reducing the size and arrests further growth of cyst.

CONCLUSION

Pathyahara i.e. *Dashamoola Yavagu* and *Kulattha Yoosha* was well tolerated in patients of PCOS and has given good results. Yoga acts on physical, mental & spiritual levels of individual hence it had effect on physical as well as psychological features of PCOS. Results were better in group that was advised *Pathyahara* and *Yogaasana*. It may be because lifestyle modification with *Suryanamskaara*

improves hormonal flow and *Shavaasana* reduces the stress which is usually seen in PCOS patients. Study on large sample size is needed to validate the role of diet & yoga alone in PCOS.

Ethical Approval IEC letter reference F/10(5)/EC/2014/337



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