

Clinical efficacy of *Vamana Karma* with *Ikshwaaku Beeja Yoga* followed by *Shatapushpadi Ghanavati* in the management of *Artava Kshaya w. s. r* to polycystic ovarian syndrome

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Abstract

Background: Due to sedentary lifestyle and stress, the incidence of metabolic disorders are increasing day by day. Among these polycystic ovarian syndrome (PCOS) is an intricate disorder affecting 4%–8% women in their reproductive age and related to ovarian dysfunction characterized by obesity, oligomenorrhea, anovulation and hyperandrogenism. In modern system of medicine, the available allopathic regimen has its own limitations, so it is need of time to find a safe and effective alternative therapy for such type of condition. The most common symptom in 85%–90% of PCOS patients is oligomenorrhea which can be correlated to *Artava Kshaya* (loss of menstrual fluid) in Ayurveda. Hence, in the present clinical study, *Vamana Karma* (therapeutic vomiting) with *Ikshwaaku* seed formulation followed by *Shatapushpadi Ghanavati* was planned. **Aims:** To evaluate the efficacy of *Vamana Karma* (therapeutic vomiting) followed by *Shatapushpadi Ghanavati* in the management of *Artava Kshaya* (loss of menstrual fluid) w. s. r to PCOS. **Materials and Methods:** A total of 15 patients of PCOS were clinically diagnosed and treated by *Vamana Karma* (therapeutic vomiting) procedure with *Ikshwaaku* seed formulation. After completion of *Vamana Karma* (therapeutic vomiting) and *Samsarjana Krama*, (post therapy dietary regimen for revival) *Shatapushpadi Ghanavati 2 Vati* (each 500 mg) twice in a day with lukewarm water was given for 45 days. After completion of 2-month trial, assessment of therapy was estimated by subjective and objective parameters. **Results:** Statistically extremely significant ($P < 0.0001$) results were found in menstrual irregularities, obesity, and body mass index. The significant result in reduction of nondominant follicles ($P = 0.01$ and 0.03 for right and left ovary, respectively), lowering the fasting blood sugar level ($P = 0.02$) and hirsutism ($P = 0.03$) was found. **Conclusion:** *Vamana Karma* (therapeutic vomiting) followed by *Shatapushpadi Ghanavati* is very effective in the management of obese PCOS patients and increasing chances of conception.

Keywords: *Artava Kshaya*, polycystic ovarian syndrome, *Shatapushpadi Ghanavati*, *Vamana Karma*

Introduction

Polycystic ovarian syndrome (PCOS) is a most prevalent endocrinopathy which affects 4%–8% of women of reproductive age.^[1] Forty percent of women have anovulatory infertility due to PCOS.^[2] In this condition, hormonal imbalance affects follicular growth during the ovarian cycle causing the affected follicles to remain in immature form, leading to multiple ovarian cysts associated with obesity, oligomenorrhea, etc. Incidence of this disease is increasing nowadays because of sedentary lifestyle, pollution and excessive intake of junk food.^[3]

In Ayurveda, such type of condition can be correlated under the broad heading of *Artava Kshaya*, as oligomenorrhea is the most common symptom affecting 85%–90% of PCOS

patients.^[4] The treatment advised for *Artava Kshaya* includes *Samshodhana* (bio purification) followed by *Agneya* drug and is the line of treatment according to *Acharya Sushruta*.^[5] In further commentary on *Sushruta Samhita*, *Dalhana* describes *Vamana Chikitsa* (therapeutic emesis) for the same. For this purpose, *Ikshwaaku* seed formulation was specifically selected for *Vamana Karma* (therapeutic vomiting) as it is advised for *Kapha* and *Granthi Vikara* (cystic swellings).

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Table 1: Contents of *Shatapushpadi Ghanavati*

Sanskrit (Botanical) name	Family	Part used
<i>Shatapushpa</i> (<i>Anethum sowa</i> Linn.)	Umbelliferae	Fruit
<i>Hingu</i> (<i>Ferula foetida</i> Regel)	Apiaceae	Resin
<i>Sahachara</i> (<i>Barleria cristata</i> Linn.)	Acanthaceae	Whole plant
<i>Krishna Jeeraka</i> (<i>Carum carvi</i> Linn.)	Umbelliferae	Fruit
<i>Ajamoda</i> (<i>Carum roxburghianum</i> Benth. (Radhuni))	Araceae	Fruit
<i>Eranda</i> (<i>Ricinus communis</i> Linn.)	Euphorbiaceae	Root
<i>Kantakari</i> (<i>Solanum xanthocarpum</i> Schrad.)	Solanaceae	Whole plant
<i>Kumari</i> (<i>Aloe vera</i> (L.) Burm.f.)	Liliaceae	Leaf pulp
<i>Karanja</i> (<i>Pongamia pinnata</i> Linn.)	Fabaceae	Stem bark
<i>Guduchi</i> (<i>Tinospora cordifolia</i> Willd.)	Menispermaceae	Stem
<i>Meshashringi</i> (<i>Gymnema sylvestre</i> R.Br.)	Asclepiadaceae	Leaf

**Figure 1:** *Ikshwaaku* fruit

Shatapushpadi Ghanavati [Table 1] contains *Agni Mahabhuta* (fire element) predominant drugs, which corrects the residual pathology in the context of PCOS.

Aims and objectives

- To evaluate the efficacy of *Vamana* (therapeutic vomiting) followed by *Shatapushpadi Ghanavati* on *Artava Kshaya* (loss of menstrual fluid) in relation to PCOS and to assess the findings based on ultrasonography (USG), obesity (body weight, body mass index [BMI], waist-hip ratio [WHR]) and blood sugar level in relation to PCOS.

Materials and Methods

A total of 15 female patients fulfilling the criteria for diagnosis of *Artava Kshaya* and PCOS were selected from the Outpatient and Inpatient Department of Panchakarma, National Institute of Ayurveda, Jaipur. Ethical clearance was obtained from Institutional Ethics Committee, dated November 7, 2014 (Approval number F10 (5)/EC/2014/7218), before

commencement of the study. Informed consent was taken from each registered patient before starting the treatment. The trial is also registered in the Clinical Trial Registry of India (trial no: CTRI/2017/02/007825).

Study protocol

- Study type: Interventional
- Purpose: Treatment
- Masking: Open label
- Timing: Prospective
- Endpoint: Efficacy and safety
- Number of groups: One
- Number of patients: 15 patients.

Drugs used in the trial

All the medicines were procured from NIA Pharmacy, Jaipur, except *Ikshwaaku* fruit [Figure 1], which was collected from post Aagadgaon, district Ahmednagar, Maharashtra (authenticated by the Department of Botany, Rajasthan University, Jaipur, with authentication number RUBL211524 dated April 11, 2015).

Total duration of trial

The trial duration was 2 months.

Diagnostic criteria

Patients fulfilling the revised Rotterdam criteria (2003) were included.

The criteria state that two out of the following three criteria should be present in the diagnosis of PCOS:

- Oligo-anovulation
- Clinical and/or biochemical hyperandrogenism
- Polycystic ovaries in USG (antral follicle count ≥ 12 and/or ovarian volume > 10 ml).

Inclusion criteria

- Age group 20–40 years (unmarried and married patients)
- Diagnosed cases of PCOS
- Irregular menses/scanty menses due to anovulatory cycle
- Patient fit for *Vamana Karma*.

Exclusion criteria

- Cervical tumor, polyp, carcinoma cervix
- Uterine fibroid
- Congenital anomalies of female genital tract
- Tuberculous endometritis
- Congenital adrenal hyperplasia
- HIV/venereal disease research laboratory/HbsAg positive
- Malignant disease and patients on cytotoxic drugs
- Patient not fit for *Vamana Karma*.

Laboratory investigations

Following investigations were carried out before and after treatment.

- Fasting blood sugar (FBS) level
- Postprandial blood sugar (PPBS) level
- USG (abdomen and pelvis)

4. Physical parameters such as body weight, BMI and WHR were also assessed.

Methodology

Procedure

Vamana Karma (therapeutic emesis)

Vamana Karma was administered in the following steps.

Panchakola powder^[6] was used for *Deepana* and *Pachana* in the dosage of 3 g twice in a day before food for 3–7 days with lukewarm water followed by *Snehapana* (administration of oil orally) with *Murchita Tila Taila*^[7] with initial 30 ml dose, increasing day by day according to *Agni* (digestive fire) and *Koshtha* (bowel motion habit) of the patient till *Samyak Snigdha Lakshana* (symptoms of complete oleation on body) were obtained. *Dashamoola Taila* was used for external therapeutic massage of oil to the entire body and *Dashamoola Kwatha* were used for external complete body massage with medicated oil for 2 days prior and on the day of *Vamana*.

Administration of *Vamana Yoga-Ikshwaaku* seed powder in the dosage of 5–7 g with other conventional drugs such as *Yashtimadhu* (*Glycyrrhiza glabra* Linn.), *Vacha* (*Acorus calamus* Linn.), rock salt and honey.

Samsarjana Karma

The specific diet plan was advised to the patient according to *Avara*, *Madhyama* and *Pravara Shuddhi* (low, medium and complete purification level) after classical *Vamana* procedure.

Follow-up

Shatapushpadi Ghanavati (compounded formulation) was given for 45 days in the dose of 1 g (2 tablets each of 500 mg) for 2 times a day 1 or ½ h before food with lukewarm water.

Assessment criteria

Objective parameters

1. Blood sugar (fasting and postprandial)
2. Body weight, BMI, WHR
3. USG (includes endometrial thickness [ET], ovarian volume and number of nondominant follicles [NDF]).

Subjective parameters

1. Menstrual irregularities (includes duration, interval and pain associated with menses)
2. Acne
3. Hirsutism (based on Ferriman–Gallwey score). A special scoring pattern was adopted for assessment of subjective parameters [Table 2].

Statistical analysis

Student's paired *t*-test was applied for objective parameters. Wilcoxon sign-rank test was applied out for analysis of all subjective parameters.

The obtained results were interpreted as follows:

- >0.10 nonsignificant (NS)
- <0.05 significant* (S)
- <0.01 very significant** (VS)

- <0.001 highly significant***
- <0.0001 extremely significant**** (ES).

Statistical software used

GraphPad InStat for Windows version 3.06, La Jolla, CA, USA, was used.

Observations

All patients had chief complaint of menstrual abnormalities, 33.33% patients had positive family history of diabetes, 73.33% patients had chronicity of PCOS >5 years. History of hair fall was noted in 76.66% of patients. Maximum patients 73.33% had hormonal therapy as treatment history, maximum patients (60%) reported consumption of *Madhura Rasa* dominant diet, 46.67% patients were taking *Snigdha Ahara* (fatty foods like milk products, etc.). 66.67% of the patients were addicted to tea, 60% were suffering from stress. All patients were having *Artava Vaha Srotas Dushti* (vitiated channels of female reproductive system) and 80% had history of not doing any physical exercise [Graph 1].

Results

Effect of therapy on subjective parameters

Out of 15 patients statistically extremely significant (ES) results were found in prolonged interval of menses (42.91%), very significant (VS) result in delayed menses (55.68%), significant result in painful menses (52.76%), nonsignificant (NS) changes in acne (85%) and significant changes were observed in hirsutism (4.8%) [Table 3].

Effect of therapy on ultrasonography

Statistically results were found in mean effect of therapy (ET) (8.19%) and ovarian volume (right [32.66%] and left [15.77%] side of ovary). Statistically significant changes were observed in mean NDF of right (26.39%) and left (21.42%) side of the ovary after *Vamana* followed by *Shatapushpadi Ghanavati* [Table 4].

Effect of therapy on other parameters

Effect of therapy on blood sugar

Out of 15 patients, significant change in FBS was noted in 8.33% patients and NS results were observed in PPBS in 5.56% patients [Table 5].

Effect of therapy on body weight, body mass index, and waist-hip ratio

In the present clinical study, statistically ES result was found in body weight (5.54%) and BMI (5.55%). Non-significant change was observed in WHR (0.83%) [Table 6].

Overall effect of therapy on subjective parameter

On menstrual disorder

Of 15 patients, 3 (20%) patients got complete remission, 2 (13.33%) patients got moderate improvement, 5 (33.33%) patients got mild improvement and 4 (26.66%) patients had no improvement at all.

Table 2: Scoring pattern of subjective parameters

No	Parameters	Score
Duration of menses (days)		
1	5	0
2	3-5	1
3	1-2	2
4	Spotting for 1	3
Interval of menses (days)		
1	≤35	0
2	36-45	1
3	46-55	2
4	≥56	3
Pain associated with menses		
1	No pain	0
2	Bearable pain	1
3	Requirement of oral analgesics	2
4	Requirement of injectable analgesics	3
Acne		
1	Mild black head and white head (stage 0)	0
2	Stage 0 + mild inflammation, frequent breakout (stage 1)	1
3	Stage 1 + papule	2
4	Nodule/pustule/cyst	3
Hirsutism (depend on hair distribution pattern on different body part)		
1	Mild coverage	0
2	Moderate coverage	1
3	Complete light coverage	2
4	Heavy coverage	3

Acne

Of 15 patients, 3 (20%) patients got complete remission, 1 (6.66%) patient had mild improvement and 11 (73.33%) patients remain unchanged.

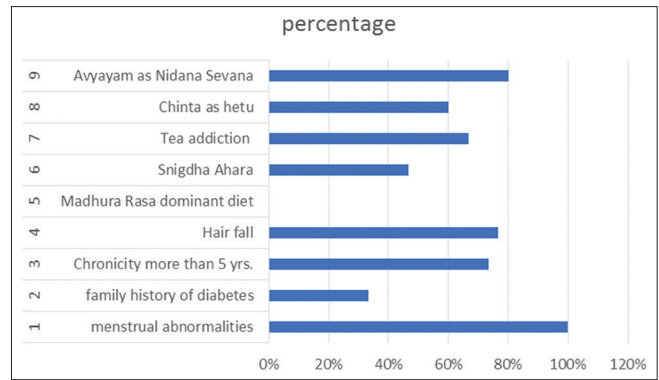
Hirsutism

Of 15 patients, all remained unchanged [Graph 2].

Discussion

Effect of therapy on primary outcome measures

The primary outcome of therapy is regularization of menstrual cycle in relation to interval, duration and pain associated with it. ES results ($P = 0.0010$) were found in interval of menses, VS ($P = 0.004$) in duration of menses, and significant result ($P = 0.015$) in pain associated with menses. *Artava Kshaya* results due to vitiation of *Rasa Dhatu* (plasma and lymphatic tissues) and involvement of *Kapha* and *Vata*. *Vamana* is *Srotoshodhaka* (clearing micro-channels in the body) in nature. *Shatapushpadi Ghanavati* has *Deepana* (Stomachic), *Pachana* (Digestant), *Agni Deepana* (increases digestive procedures) and *Artava Janana* (regularize menstruation) properties. Hence, *Vamana* followed by *Shatapushpadi Ghanavati* removes the obstruction of flow of *Vata* and increases the *Artava Dhatu* (female reproductive tissues) qualitatively as



Graph 1: Observations related to PCOS

well as quantitatively which help in menstrual irregularities.

The *Vamana* drug *Ikshwaku* has testosterone-lowering effect which may decrease the androgen level of body. Hence, after *Vamana*, significant relief in hirsutism ($P = 0.03$) was observed.

Effect of therapy on secondary outcome measures

Significant result ($P = 0.01$ for right ovary and $P = 0.03$ for left ovary) was found in decreasing number of NDFs. *Vamana* with *Ikshwaku* has testosterone-lowering effect.^[8] The decrease level of luteinizing hormone stimulates follicle-stimulating hormone level, which is helpful in maturation of follicles. Further *Aam Pachana* (detoxification of metabolic toxins), *Agni Deepana* (increases digestion) properties of *Shatapushpadi Ghanavati* help in reducing the NDFs directly.

Effect of therapy on associated factors

The significant result ($P = 0.02$) was obtained in decrease in FBS level after completion of therapy. *Vamana Karma* along with *Shatapushpadi Ghanavati* has *Agni Deepana* (increases digestion), *Sroto Shodhaka* (clearing micro-channels in the body) properties, which indirectly increase the metabolism of liver which is the prime site of glucose metabolism. In support to this, advanced researches show that *Ikshwaku* has lipid-lowering, hypoglycemic effect.^[9]

ES ($P < 0.0001$) results were found in obesity and BMI after completion of therapy. *Sthaulya* (obesity) is the *Rasapradoshaja Vikara* (disease caused due to vitiation of plasma and lymphatic tissues). As *Vamana Karma* cleanses microchannels of body, further *Shatapushpadi Ghanavati* has *Sroto Shodhaka* (clearing micro-channels in the body), *Agni Deepana* (increases digestion) and *Lekhana* (scraping) properties which scrap excess *Meda* (fat) from body and help in reducing body weight in general and BMI specifically.

Probable mode of *Vamana Karma*

Vamana Karma is the best therapy for the elimination of *Kapha Dosha*. According to Ayurveda, PCOS may be considered as *Agni Vaishamyajanya Vikara* (disease caused due to vitiation of metabolism) in general and *Rasagni* (metabolism at *Rasa Dhatu* level) and *Medodhatvagni* (metabolism at *Meda Dhatu* level) *Mandya* deficient in particular with *Bahu Dosha Avastha* (vitiating *Dosha*). As far as *Dosha* is concerned based

Table 3: Effect of therapy on subjective parameters

Criteria	n	Mean		Difference	Percentage of relief	±SD	±SE	Sum of all pairs W	Number of pairs	P	Result
		BT	AT								
Interval of menstruation	15	2.33	1.33	1	42.91	0.85	0.22	66	11	0.0010	ES
Duration of menstruation	15	1.67	0.73	0.93	55.68	0.96	0.25	45	9	0.004	VS
Pain associated with menses	15	1.27	0.60	0.67	52.76	0.82	0.21	28	7	0.015	S
Acne	15	0.47	0.067	0.40	85	0.83	0.21	10	4	0.12	NS
Hirsutism	15	16.67	15.86	0.80	4.8	1.20	0.31	21	6	0.03	S

SD: Standard deviation, SE: Standard error, ES: Extremely significant, VS: Very significant, S: Significant, NS: Nonsignificant, BT: Before treatment, AT: After treatment

Table 4: Effect of therapy on ultrasonographical parameter

Parameter	n	Ovary side	Mean		Difference	Percentage of change	±SD	±SE	t	P	Result
			BT	AT							
Endometrial thickness	15		9.88	10.69	-0.81	8.19	3.08	0.80	1.02	0.32	NS
Mean NDF	15	Right	11.86	8.73	3.13	26.39	4.08	1.05	2.97	0.01	S
		Left	11.20	8.80	2.40	21.42	3.83	0.99	2.43	0.03	S
Ovarian volume	15	Right	17.39	11.52	5.86	32.66	14.94	3.85	1.52	0.15	NS
		Left	12.68	10.68	2.00	15.77	5.42	1.40	1.43	0.17	NS

SD: Standard deviation, SE: Standard error, NDF: Nondominant follicle, S: Significant, NS: Nonsignificant, BT: Before treatment, AT: After treatment

Table 5: Effect of therapy on blood sugar

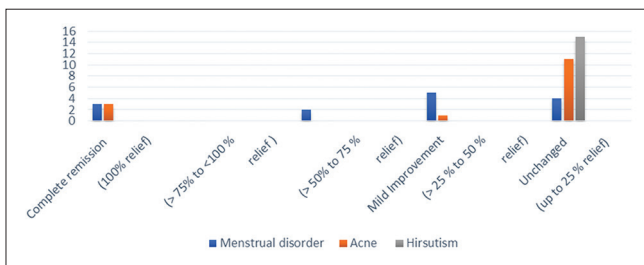
Parameter	n	Mean		Difference	Percentage of change	±SD	±SE	t	P	Result
		BT	AT							
Fasting sugar	15	90.06	83.13	6.93	8.33	9.99	2.58	2.68	0.02	S
Postprandial sugar	15	116	109.6	6.45	5.56	20.34	5.25	1.23	0.23	NS

SD: Standard deviation, SE: Standard error, S: Significant, NS: Nonsignificant, BT: Before treatment, AT: After treatment

Table 6: Effect of therapy on body weight, body mass index, and waist-hip ratio

Parameter	n	Mean		Difference	Percentage of change	±SD	±SE	t	P	Result
		BT	AT							
Body weight	15	65.43	61.80	3.63	5.54	0.61	0.16	23.01	<0.0001	ES
BMI	15	27.53	25.99	1.53	5.55	0.25	0.07	23.26	<0.0001	ES
WHR	15	0.84	0.83	0.007	0.83	0.021		1.34	0.20	NS

SD: Standard deviation, SE: Standard error, BMI: Body mass index, WHR: Waist-hip ratio, ES: Extremely significant, NS: Nonsignificant, BT: Before treatment, AT: After treatment



Graph 2: Total effect of therapy based on subjective assessment criteria

on the pathology and symptom complex, it is *Kapha-Vataja* disorder. Due to increased *Kapha* and *Agnimandya* (deficient metabolism), more number of follicles are produced but not matured, resulting in cyst formation causing obstruction to the

flow of *Vata* in proper direction, which in turn aggravates and results into anovulation and oligomenorrhea as *Prakrita Vata* (balanced *Vata Dosha*) is responsible for proper menstruation. Hence, the treatment should be planned to correct *Agni*, eliminate vitiated excessive *Kapha Dosha* and correct *Vata Dosha* by providing proper movement of *Vata*. To eliminate vitiated *Dosha* and to improve *Agni*, *Samshodhana Chikitsa* (bio purification) is a preferred treatment in Ayurveda.

Further *Ikshwaaku* seed formulation was preferred for *Vamana Karma* as it is specifically mentioned for *Kapha* and *Granthi Vikara* (cystic masses).^[10] As PCOS is metabolic disorder, *Vamana* helps to increase metabolism of body, thereby reducing weight and specifically act on liver metabolism which is the main site of hormone formation. Furthermore, there is

direct relation of estrogen and obesity. Weight loss can improve not thus increased only circulating androgen and glucose levels but also helps for ovulation and thus increases pregnancy rate in obese women with PCOS.^[11]

After *Samshodhana* (bio purification) to correct the residual pathology, *Shatapushpadi Ghanavati* was selected which was prepared using known *Kapha Vatahara* (pacifying *Kapha* and *Vata Dosha*), *Agni Deepana* (increases digestion), *Artava Pravartaka* (regularize menstruation) and *Garbhashaya Shodhaka* (detoxify and improves the function of uterus) drugs.

With respect to the pathology of PCOS, *Ushna* (hot), *Tikshna* (sharp), *Ruksha* (dry) and *Lekhna* (scraping) properties of the ingredients of *Shatapushpadi Ghanavati* normalizes *Kapha* vitiation and *Vatavaigunya* (vitiating *Vata Dosha*), reduces excess *Meda* (fat), removes *Srotorodha/Sanga* (blockage in micro-channels of the body) and creates normal functioning of *Apana Vata* (subtype of *Vata* which responsible for expulsion of waste) thereby regularizing the function of *Aartavavaha Srotas* as *Prakrita Vata* is responsible for proper menstrual flow.

Conclusion

Vamana Karma followed by *Shatapushpadi Ghanavati* is effective in regularizing menstruation, achieving considerable reduction in body weight and BMI, and helpful in lowering FBS level. Thus, this treatment protocol can be useful in the management of obese PCOS patients. Further, a large sample size study may help to support the findings of the study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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