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 Aartava Kshaya, as oligomenorrhea is the most common symptom affecting 85%-90% of PCOS patients. Materials and Methods: A total of 15 patients of PCOS were clinically diagnosed and treated by Vamana Karma (therapeutic vomiting) followed by Ikshwaaku seed formulation procedure with Ikshwaaku seed formulation. After completion of Vamana Karma (therapeutic vomiting) and Samarasjana 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  |
|----------------------------------|--------------|------------|
| Shatapushpa (Anethum sowa Linn.) | Umbellifera  | Fruit      |
| Hingu (Ferula foetida Regel)     | Apiaceae     | Resin      |
| Sahachara (Barleria cristata Linn.) | Acanthaceae | Whole plant|
| Krishna Jeeraka (Curcuma carvi Linn.) | Umbellifera | Fruit      |
| Ajamoda (Curcuma roxburghianum Benth. (Radhuni)) | Araceae | Fruit      |
| Eranda (Ricinus communis Linn.)  | Euphorbiaceae| Root       |
| Kantakari (Solanium xanthocarpum Schrad.) | Solanaceae | Whole plant|
| Kumari (Aloe vera (L.) Burn.f.)  | Liliaceae    | Leaf pulp  |
| Karanja (Pongamia pinnata Linn.) | Fabaceae     | Stem bark  |
| Guduchi (Tinospora cordifolia Willd.) | Menispermaceae | Stem      |
| Meshashringi (Gynmema sylvestre R.Br.) | Asclepiadaceae | Leaf      |

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:
1. Oligo-anovulation
2. Clinical and/or biochemical hyperandrogenism
3. 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.
1. Fasting blood sugar (FBS) level
2. Postprandial blood sugar (PPBS) level
3. 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 (bowl 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-Ikshwaku* seed powder in the dosage of 5–7 g with other conventional drugs such as Yashtrimadhu (Glycyrrhiza glabra Linn.), Vachra (Acorus calamus Linn.), rock salt and honey.

**Samsarjana Karma**

The specific diet plan was advised to the patient according to Avara, Madhyma 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 \(\frac{1}{2}\) 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* (vitiates 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 5.65% 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. Shatapurshadi Ghanavati has Deepana (Stomachic), Pachana (Digestant), Agni Deepana (increases digestive procedures) and Artava Janana (regularize menstruation) properties. Hence, Vamana followed by Shatapurshadi Ghanavati removes the obstruction of flow of Vata and increases the Artava Dhatu (female reproductive tissues) qualitatively as well as quantitatively which help in menstrual irregularities.

The Vamana drug Ikhswaku 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 Ikhswaku has testosterone-lowering effect. 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 Shatapurshadi 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 Shatapurshadi 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 Ikhswaku has lipid-lowering, hypoglycemic effect. ES \( (P < 0.0001) \) results were found in obesity and BMI after completion of therapy. Sthauliya (obesity) is the Rasapradoshaja Vikara (disease caused due to vitiation of plasma and lymphatic tissues). As Vamana Karma cleanses microchannels of body, further Shatapurshadi 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 (vitiated Dosha). As far as Dosha is concerned based...
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Table 3: Effect of therapy on subjective parameters

| Criteria                  | n  | Mean Difference | Percentage of relief | SD | SE | W | Number of pairs | P   | Result |
|---------------------------|----|----------------|----------------------|----|----|----|-----------------|-----|--------|
| 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 |
|------------------------------------|----|------------|-----------------|----------------------|----|----|------|--------|--------|
| Endometrial thickness              | 15 | Right      | 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 |
| Mean NDF                           | 15 | 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|
| Ovarian volume                     | 15 | 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 |
|-----------------|----|-----------------|----------------------|----|----|------|-------|--------|
| Fasting sugar   | 15 | 90.06 83.13     | 6.93                 | 8.33 | 9.99 | 2.58 | 2.68  | 0.02 S |
| Postprandial sugar | 15 | 109.6 116.5     | 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 |
|-----------------|----|-----------------|----------------------|----|----|------|-------|--------|
| 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-Vata* 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). 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 Lekhana (scraping) properties of the ingredients of Shatapushpadi Ghanavati normalizes Kapha vitiation and Vatavaigunya (vitiated 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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Conflicts of interest
There are no conflicts of interest.

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