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Effect of *satapushpa* churnam with *tila tailam* in oligomenorrhea associated with polycystic ovarian syndromeJyothi Jacob ^a, N. Vijayakumar ^a, Jeby Jose Olickal ^{b,*}^a Govt. Ayurveda College, Trivandrum, Kerala, India^b Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India

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ABSTRACT

Background: Current medical intervention of Polycystic Ovarian Syndrome (PCOS) mainly includes hormonal therapies which have long-term health consequences.

Objective: This study aimed to evaluate the effect of natural drug *satapushpa* (*Anethum sowa* Kurz.) powder with *tilatailam* (sesame oil) as *anupanam* (vehicle) in oligomenorrhoea associated with PCOS.

Materials and methods: A single-group, before and after intervention study in the outpatient department and inpatient department of Government Ayurveda teaching hospital for women and children was done among women aged 18–35 years. Individuals diagnosed with oligomenorrhoea for more than three consecutive menstrual cycles and fulfilling Rotterdam's criteria of PCOS were included. Six grams of powder was given morning and evening along with 12 ml of *tilatailam* for three months. Effectiveness was assessed at 3rd and 6th months.

Results: A total of 30 patients were recruited; the mean (SD) age was 22.6 (3.9) years. Majority were students (86.7%), residing in urban areas (60%), and unmarried (80%). Almost one-third of the participants had *kapha-vata prakriti*. There was no significant change in menstrual duration and amount of bleeding. However, a significant reduction in the menstrual interval was observed after three months of treatment ($p = <0.001$). Similarly, the median interquartile range (IQR) volume of the right ovary was reduced from 10 (7.2–14.8) to 5.3 (4.7–7.6) cm^3 ($p = <0.001$), and the median (IQR) volume of the left ovary reduced from 9.1 (6.7–11.9) to 5.1 (4.6–7.1) cm^3 ($p = <0.001$).

Conclusion: Treating PCOS using *satapushpa* powder and *tilatailam* for three months effectively regularizes the menstrual interval and reduces ovarian volume.

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1. Introduction

The lifestyle changes of modern society, such as sedentary lifestyle, altering food habits, and intolerable stress, make women more vulnerable to diseases. Polycystic Ovarian Syndrome (PCOS) is one of those diseases caused by an altered lifestyle, affecting the capacity to give birth to children [1]. Globally, the prevalence of PCOS is generally thought to be between 3–10% [2]. The estimated prevalence in India ranged from 3.7 to 22.5 percent [3,4]. PCOS is often described as a condition of hormone imbalances and is believed to have a genetic basis. Despite the high prevalence of

PCOS, the diagnosis and differential diagnosis remains confusing. Once the diagnosis is made, the management options can seem daunting at first. However, if approached from the standpoint of what the patient or medical provider is concerned about at any given time, the options seem more manageable.

The medical intervention of PCOS mainly includes hormonal therapies which have long-term health consequences [5]. Hence, researchers are looking for herbal medicines to treat PCOS in alternative medicine, which does not cause any side-effects. Ayurveda understands a disease based on the *doshas* and *dushyas* involved in disease manifestation [6]. Hence, the specific nomenclature of the diseases is not much essential. This indicates a description of the emerging disorders in Ayurveda, which are explained under various contexts that need to be analyzed based on the symptoms. There is no direct reference to PCOS in Ayurveda, but the symptoms can be seen in conditions mentioned in Ayurveda

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literature [7]. Based on the clinical features, it resembles 'pushpaghni jathaharini', described by Acharya Kasyapa in *Revathi Kalpa adhyaya* [8]. A disease condition called 'nashtarhava' described by Acharya Susrutha, is the basic pathology involved in PCOS [9]. Though conventional medicines are found to be effective in inducing and regularizing menstruation to a certain extent, untoward effects of the synthetic drugs, mainly in the form of hormones, cannot be ignored. Hence, in this study, we aimed to evaluate the effect of natural drug *satapushpa* (*Anethum sowa* Kurz.) powder with *tilatailam* (sesame oil) as *anupanam* (vehicle) in oligomenorrhoea associated with PCOS.

2. Methods

2.1. Study design and setting

We conducted a single-group, before and after intervention study in the outpatient and inpatient department of Government Ayurveda teaching hospital for women and children, Kerala, South India. Individuals aged 18–35 years, diagnosed with oligomenorrhoea for more than three consecutive menstrual cycles and fulfilling Rotterdam's PCOS criteria were included. Ultrasonography of the abdomen and pelvis was done to confirm the diagnosis. Patients with acromegaly, Cushing's syndrome, primary amenorrhoea, menorrhagia, concurrent or previous use of oral contraceptive pills within the last three months, patients with androgen-producing adrenal tumor or other neoplastic growth, and those with other systemic and chronic illnesses, including thyroid disorders, were excluded. The patient's status After Treatment (AT) and After Follow up (AF) was compared with the status Before Treatment (BT).

2.2. Sample size

Assuming a mean difference of 20 days for a menstrual interval with standard deviation (SD) for mean as 35 and 15; 95% confidence interval, 80% power, the calculated sample size was 30. Consecutive patients satisfying inclusion and exclusion criteria were recruited till attaining the sample size.

2.3. Study procedure and data collection

The qualitative data related to the clinical condition were collected as per the case proforma. Sociodemographic details such as age, education, occupation, domicile, presenting complaints with duration, history of presenting complaints, associated symptoms, personal history, family history, and treatment history were collected using direct interview. General, local, and systemic examinations were done to know the intensity of the disease or any other associated diseases. Ayurvedic clinical examinations like *dasavidha pareeksha* (ten-fold examination), *ashta sthaana pareeksha* (eight-fold examination), and *prakruti pareeksha* (body nature examination) [10] were also undertaken for understanding the etiopathogenesis from an Ayurvedic point of view.

2.4. Preparation of drugs

Certified, standardized samples of *satapushpa* powder in packets of 6 gm each were prepared for distribution. Similarly, genuine sesame seeds were collected, and oil was extracted by using traditional mechanized wooden mortar. This was given to the patients in bottles suitable for dispensing medicine. Methods of administration were explained to the patients along with written advice in their local language. *satapushpa* powder was given in the

dose of 6 gm twice daily, morning and evening, along with 12 ml of *tilatailam* as *anupana* (vehicle), 1 h before food.

2.5. Data collection

The patients were advised to report every month to assess changes in the menstrual interval, duration, amount of bleeding, etc. During each visit, the required medicines were given. The study drug was administered for three months continuously. Following this, the next three months were considered as a follow-up period, and the clinical changes in the patients were assessed. A menstrual interval of 21–35 days and 3–7 days bleeding were considered normal. The numbers of sanitary pads used were counted to assess the amount of bleeding.

2.6. Ethics

This study was approved by the institutional ethics committee of Government Ayurveda College Trivandrum, Kerala, and assigned the approval number IEC 111/28.04.2015, and informed consent was obtained from the patients before the enrolment. They were allowed to withdraw from the study at any time as per their will. *Satapushpa* and *tilatailam* are mentioned in Ayurvedic literature and used by eminent medical practitioners for a long time; no side-effects were reported or known.

2.7. Statistical analysis

Data were entered into Microsoft Excel sheets and analyzed using Stata version 14. Categorical variables such as education, occupation, and marital status were summarized as proportions. Continuous variables such as age, body mass index (BMI), and menstrual interval days were summarized as mean with SD or median with interquartile range (IQR). The significant effect of treatment on selected variables was assessed based on the non-parametric Friedman test, followed by Post hoc Wilcoxon's signed-rank test. A p-value less than 0.05 was considered to be statistically significant.

3. Results

The study was conducted among 30 participants, and the mean (SD) age was 22.6 (3.9) years. [Table 1](#) shows the sociodemographic distribution of the study participants. Majority of the participants were students (86.7%), residing in urban areas (60%), unmarried (80%), Hindus (86.7%), and college-educated (70%). Most of the participants (43.3%) belonged to the lower socioeconomic class.

The behavioral and physiological characteristics ([Table 2](#)) show that majority of the cases (66.7%) had sedentary nature of work. Almost 10 (33.3%) had irregular food habits. Most of the cases had normal appetite (83.3%), bowel pattern (70%), and sound sleep (86.7%). One-third (33.3%) of participants were anxious, and about the same were stressed. One-fourth (23.3%) were overweight, and 13.3% were obese. Almost one-third of the participants had *kaphavata prakriti*, and most were '*madyam satwa*' (56.7%). Around 70% had a family history of either hypertension, dyslipidemia, fibroid, or endometrial hyperplasia. The mean (SD) age of attaining menarche was 12.7 (1.3) years.

The distribution of menstrual symptoms and clinical characteristics were summarized in [Table 3](#). Around one-third (36.7%) cases reported blackish menstrual blood colour, 18 (60%) patients reported painful menstruation, and twenty-two patients noted the presence of clots associated with menstruation. Exactly half of the participants had acne, and 46.7% of the cases had complained about hirsutism.

Table 1
Sociodemographic details (N = 30).

Variable	n	%
Age in years		
18–21	12	40
22–25	13	43.3
Above 25	5	16.7
Occupation		
Student	26	86.7
Office work	4	13.3
Domicile		
Rural	12	40
Urban	18	60
Marital status		
Married	6	20
Unmarried	24	80
Socio-economic class^a		
Class I (Above INR 7053)	7	23.3
Class II (INR 3527 - INR 7052)	3	10
Class III (INR 2116 - INR 3526)	6	20
Class IV (INR 1058 - INR 2115)	1	3.3
Class V (Below INR 1057)	13	43.3
Education		
Pre-degree/Plus two	9	30
Graduate	15	50
Post graduate	6	20
Religion		
Christian	3	10
Hindu	26	86.7
Muslim	1	3.3

^a Updated BG Prasad's social classification as per January 2017 for Kerala (Quilon).

Table 4 shows the effect of treatment on the menstrual interval, duration, and amount of bleeding. Before treatment, out of the 30 patients, 13 (43.3%) had menstrual intervals between 35 and 60 days, 61–90 days menstrual interval for 10 (33.3%), and rest had more than 90 days. After three months of treatment, 23 (76.7%) had menstrual intervals less than 35, and 5 (16.7%) had a menstrual interval of 35–60 days. However, it was observed that after follow-up, a statistically significant change in the menstrual interval compared to after treatment ($p = 0.44$) was not elicited. Before treatment, out of 30 patients, one had menstrual duration of less than three days, and twenty-six patients (86.7%) had normal menstrual duration. Three patients had menstrual duration of more than seven days. After treatment, most of the patients' menstrual duration was almost the same as before treatment (93.3%). A similar observation was found AF also (96.7%). The duration AT vs. BT was statistically not significant ($Z = 0$, $p = 1$), and a similar observation was found BT vs. AF ($p = 0.56$). The change in the amount of menstrual bleeding BT and AT was not found to be significant.

After three months of treatment, a considerable reduction in the mean menstrual interval days was noticed (from 90 days to 33.5 days, $p < 0.001$) (Table 5). The median (IQR) volume of the right ovary was 10 (7.2–14.8) cm³ BT which reduced to 5.3 (4.7–7.6) cm³ after the treatment period of three months. Similarly, before treatment, the median (IQR) volume of the left ovary was 9.1 (6.7–11.9) cm³ and reduced to 5.1 (4.6–7.1) cm³. Wilcoxon signed-rank test shown a significant ($p < 0.001$) difference between BT and AT. There was a statistically significant difference in BMI, BT, and AT ($z = -3.3$, $p \leq 0.001$).

4. Discussion

This study aimed to find the efficacy of Ayurveda drugs in treating oligomenorrhoea associated with PCOS as a safe, non-hormonal, and effective treatment against the associated symptoms. The conventional methods mainly depended upon hormonal

Table 2
Behavioural and physiological characteristics (N = 30).

Variable	n	%
Nature of work		
Sedentary	20	66.7
Moderate	10	33.3
Food habit		
Regular	20	66.7
Irregular	10	33.3
Appetite		
Normal	25	83.3
Reduced	3	10
Irregular	2	6.7
Bowel		
Within normal limit	21	70
Constipated	8	26.7
Irregular	1	3.3
Sleep		
Sound	26	86.7
Disturbed	4	13.3
Psychological status		
Depressed	3	10
Normal	7	23.3
Anxious	10	33.3
Stressed	10	33.3
BMI^a		
Under weight (<18.5)	1	3.3
Normal weight (18.5–24.9)	18	60
Overweight (25–29.9)	7	23.3
Obese (30–35)	4	13.3
Paternal history of PCOS	3	10
Maternal history PCOS	4	13.3
Family history of diabetes mellitus	13	43.3
Age at menarche in years		
09–12	9	29.9
13–16	21	70
Prakriti		
Kapha pitta	7	23.3
Kapha vata	9	30
Pitta kapha	2	6.7
Pitta vata	3	10
Vata kapha	2	6.7
Vata pitta	7	23.3
Satwa		
Avaram	13	43.3
Madhyamam	17	56.7

^a Body mass index in Kg/m².

preparations and invasive techniques. These modalities are noted with some side-effects also [11]. In the present study, *sathapushpa* powder with *tilaitalam* was administered to patients with PCOS.

Table 3
Menstrual symptoms and clinical characteristics (N = 30).

Variable	Category	n	%
Menstrual blood colour	Normal	18	60
	Pale	1	3.3
	Blackish	11	36.7
Pain	Painful	6	20
	Mild	12	40
	Painless	12	40
Severity of pain ^a	None	12	40
	Mild	12	40
	Moderate	5	16.7
	Severe	1	3.3
Clots	Present	22	73.3
	Absent	8	26.7
Body weight	Gain	17	56.7
	Loss	1	3.3
	Stagnant	12	40
		15	50
Acne		14	46.7
Hirsutism		18	60
Hyperpigmentation			

^a Verbal rating scale.

Table 4
Effectiveness of treatment on menstrual cycle, duration, and amount of bleeding (N = 30).

Measure	n (%)			Comparison	P value
	BT	AT	AF		
Menstrual cycle					
Grade 0 (<35 days)	0 (0)	23 (76.7)	21 (70)	BT-AT	<0.001
Grade 1 (35–60 days)	13 (43.3)	5 (16.7)	6 (20)	BT-AF	<0.001
Grade 2 (61–90 days)	10 (33.3)	2 (6.7)	3 (10)	AT-AF	0.44
Grade 3 (91–120 days)	2 (6.7)	0 (0)	0 (0)		
Grade 4 (>120 days)	5 (16.7)	0 (0)	0 (0)		
Menstrual duration (days)					
<3	1 (3.3)	0 (0)	0 (0)	BT-AT	1
3–4	26 (86.7)	28 (93.3)	29 (96.7)	BT-AF	0.564
>7	3 (10)	2 (6.7)	1 (3.3)	AT-AF	0.317
Amount of bleeding					
Spotting	3 (10)	2 (6.7)	1 (3.3)	BT-AT	0.157
Scanty	3 (10)	0 (0)	1 (3.3)	BT-AF	0.129
Moderate	23 (76.7)	28 (93.3)	28 (93.3)	AT-AF	0.655
Excessive	1 (3.3)	0 (0)	0 (0)		

The majority of the participants (83.3%) were below 25 years of age. This period of reproductive life is mainly concerned with child-bearing, career development, and an increase in family burden [12]. Hence, the woman cannot concentrate more on her health; it might be a reason for the increased incidence in this age group. A maximum of 60% of patients hailed from the urban shows the relationship of the disease with the lifestyle and food habits where the urban population is more influenced by the sedentary lifestyle and abnormal food habits. The current study also presented a high proportion of PCOS cases in upper or middle-class individuals due to the same reason. The distribution of nature of work shows a relation of the disease with the sedentary lifestyle.

According to Ayurveda, factors like deranged *doshas*, impaired *agni* (~digestive/metabolic fire), *srothorodha* (~obstruction of minute channels of body), improper formation and *parinama* (~transformation) of *dhatus* are involved in the etiopathogenesis of PCOS [13]. Considering the *dosha* vitiation, we can identify *kapha vata avarna* (~obstruction of *vata* due to *kapha*) and qualitative derangement of *pitta* may occur here, resulting in the abnormalities of the menstrual cycle. Ayurvedic literature, especially *Satapushpasatavari Kalpadhyaya* of *Kasyapasamhitha*, narrated *satapushpa* as an effective single drug for curing many gynaecological disorders. It is *vataprasamani* (~pacifies *vatha*) [14], thus helping in alleviating the *vatha*, which is the prime factor involved in the development of all *yoni rogas* (~disorders of female genital tract).

Table 5
Effectiveness of treatment on menstrual cycle intervals, ovarian size, BMI (N = 30).

Observations	Median (IQR)	Comparison	P value
Menstrual cycles intervals (days)			
BT	90.0 (60.0–97.5)	BT-AT	<0.001
AT	33.5 (31.8–34.8)	BT-AF	<0.001
AF	33 (31.0–35.3)	AF-AT	0.38
Right ovarian size (cm³)			
BT	10 (7.2–14.8)	BT-AT	<0.001
AT	5.3 (4.7–7.6)		
Left ovarian size (cm³)			
BT	9.1 (6.7–11.9)	BT-AT	<0.001
AT	5.1 (4.6–7.1)		
Body mass index (Kg/m²)			
BT	24.4 (5.3) ^a	BT-AT	<0.001
AT	23.8 (5.2) ^a		

BT- Before Treatment, AT-After Treatment, AF-After Follow-up.

^a Mean (SD).

While going through the properties of *satapushpa* in classics, we can see that it will be effective in increasing *agni* and helps in attaining proper *dhathu* and *upadhathu* formation, alleviate *kapha dosha*, helps in removal of *ama* (~a form of unmetabolized waste that the body cannot utilize) and *srothoroda*. It shows *agneyatwa* (~properties similar to *agni*) which is essential in *arthavajanana* (~formation of menstruation/ovulation). *Rtupravarthani* (~initiates menstruation or ovulation), *yonisukra visodhini* (~clarifies female reproductive organs and sperm/spermatid fluid), and *putrada* (gives progeny) are its specific properties explained in relation with the reproductive system [14]. *Tilatailam* is *vathakaphahara* (alleviates *vata* and *kapha*) and *pittala* (increases *pitta*) in nature and is directly indicated in the *kapha avrutha vatha chikitsa* (~treatment in obstruction of *vata* by *kapha*) [15]. *Taila* is *yoni visodhana* (~clarifies the female reproductive system) [16] and described as *pathya* (~wholesome) in *yonirogas*.

By virtue of these properties, the drugs we used might correct the oligo or amenorrhoea and anovulation. *Satapushpa*, which is indicated in *anarthava* (~amenorrhoea), *viphala arthava* (~anovulatory cycles) like menstrual disorders [17–19], when used along with *tilatailam*, which is also having similar characteristics, is capable of reversing the pathology in this particular condition [20]. Also, the given treatment may help to maintain normal physiological functions of hormones. A study from Sri Lanka reported that *satapushpa* is effective in PCOS by balancing the excessive amounts of androgens [21]. Similarly, *satapushpa* on reducing ovarian volume seems to confirm the possibility of an interaction between the drug and ovarian morphology [22]. The synergic effect of *satapushpa* and *tilatailam* combination make the choice of the drugs effective in this disease.

In the current study, standard procedures were used to prepared all the drugs and given to patients according to all good clinical practices. This study was conducted as a single group with small sample size, and hence may not be representative of all PCOS patients in community; the generalizability of the finding is limited.

5. Conclusion

Treating PCOS using *satapushpa* powder and *tilatailam* for three months effectively regularizes the menstrual interval and reduces ovarian volume. Further studies such as randomized controlled trials comparing the effectiveness of conventional care with this same drug is required.

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Conflict of interest

None.

Author contributions

Jyothi Jacob: Conceptualization, methodology, data curation, writing - original draft preparation. **N. Vijayakumar:** Conceptualization, Supervision, Investigation. **Jeby Jose Olickal:** Methodology, Writing, Editing, Data analysis, and Reviewing.

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