E-ISSN:2456-3110

Research Article

Polycystic Ovarian Disease (PCOD)

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Journal of Ayurveda and Integrated Medical Sciences

2025 Volume 10 Number 6 JUNE

Publisher

Maharshi Charaka Ayurveda

www.maharshicharaka.in

Effect of Kanashatahwadi Kashaya Orally and Asanadi Niruha Basti in management of Polycystic Ovarian Disease (PCOD)

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DOI:10.21760/jaims.10.6.6

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Polycystic ovarian syndrome is a heterogeneous, multisystem endocrinopathy in women of reproductive age with the ovarian expression of various metabolic disturbances and a wide spectrum of clinical features such as obesity, menstrual abnormalities, and Hyperandrogenism. This disease was described by and named as Stein-Leventhal syndrome in 1935. This condition is fairly common affecting 5%-15% of adolescent girls.[1]

Materials and Methods: In this study, (n=45) eligible patients were selected randomly for this study on the basis of inclusion and exclusion criteria. All selected patients were treated with Kanashatahwdi Kashaya/decoction orally for 3 months along with one cycle of Yoga Basti. Asanadi Niruha Basti and Murchhita Tila-Taila Matra Basti).

Result: After the treatment, some patients experienced only symptomatic improvements. Out of a total maximum patients had only mild improvement in symptoms, out of (n=45) only 4 Patients had no improvement, (n=4) had moderate improvement, and another (n=4) had marked improvement.

Conclusion: Application of Basti therapy i.e., Asanadi Niruha Basti with oral administration of Kanashatahwadi Kashaya had a beneficial effect on Polycystic ovarian syndrome.

Keywords: Asanadi Niruha Basti, Kanashatahwadi Kashaya, Basti, Niruha Basti, Yoga Basti, Polycystic Ovarian Disease

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How to Cite this Article

Mishra V, Vishwesh BN, Lakra A, Effect of Kanashatahwadi Kashaya Orally and Asanadi Niruha Basti in management of Polycystic Ovarian Disease (PCOD). J Ayu Int Med Sci. 2025;10(6):38-44.

Available From

https://jaims.in/jaims/article/view/4419/

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2025-05-11	2025-05-21	2025-06-05	2025-06-13	2025-06-25

Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
None	Nil	Yes	11.32	

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Introduction

Polycystic ovary syndrome/disease (PCOS/ PCOD) is a heterogeneous endocrine disorder that impacts many women of reproductive age worldwide.**[2]** This syndrome is often associated with enlarged and dysfunctional ovaries, excess androgen levels, resistance to insulin, etc.**[3]**

One in ten women are thought to have PCOS before to menopause and deal with its after effects.**[4]**

The most common features usually include excessive weight gain, Oligomenorrhea /Amenorrhea, increased triglyceride (Hypertriglyceridemia) and insulin levels in the blood (Hyperinsulinemia), Acne, Hirsutism, Hyper menorrhoea, and infertility due to chronic Anovulation. Women of all ages, from youth to menopause, are increasingly affected by polycystic ovarian disease.**[5]**

In Ayurveda, there are many clinical conditions where the cardinal features of polycystic ovarian syndrome, i.e., Oligo/Anovulation, Cystic ovaries, and Androgen Excess.

In condition Similar *Artavakshaya (*Hypomenorrhoea*), Nastaartava (*Amenorrhoea*) Kshinaartava (*Hypomenorrhoea*) Pushpaghni Vikutajataharini* and *Bandhya* (Infertility) the mixed features of PCOS/PCOD can be seen.

As the name PCOS suggests it is a group of many disorders hence a single *Yoni-Vyapada* Or a disease condition cannot be correlated with manifestations of PCOS.

Aim of the study

To evaluate of the efficacy of *Kanashatahwadi Kashaya* (medicated decoction. Internal use /external oral route or another route mentioned) and *Asanadi Niruha Basti* (medicated decoction. Internal use /external oral route or other route mentioned) in Polycystic ovarian syndrome.

Objectives

1. Evaluate the therapeutic efficacy of *Kanashatahwadi Kashaya* and *Asanadi Niruha Basti* in the management of Polycystic Ovarian Disease.
2. To explore and understand *Ayurvedic* theories, treatment, and practices on polycystic ovarian syndrome.

Materials and Methods

This study was approved by Institutional Ethical Committee (IEC) of Institute of medical sciences Banaras Hindu University, Varanasi vide IEC code Dean/2022/EC/4014on 15/04/23 and CTRI registration was also done (CTRI/2023/08/055939 with reference number REF/2023/06/068479).

All 45 Patients were selected from OPD of Prasuti Tantra department of BHU. The method adopted in present study was an open labelled, single arm, interventional clinical trial. The Study period was 4 months. (3 months with medication and one month without medication) A detailed consent of all patients was filled with history, sign and symptoms, examinations and investigations. Evaluation was done before and after treatment and results were analyzed symptomatically & statistically.

Inclusion Criteria

1. Female patients of age group 18-40 yrs.
2. Diagnosed with PCOS as defined by Rotterdam criteria.
3. Patients who are having irregular menses / scanty menses due to PCOD.
4. Elevated LH and altered ratio of LH: FSH ratio.
5. Clinical or biochemical evidence of Hyperandrogenism.
6. Both married and unmarried patients.

Exclusion Criteria

1. Age exceeds or less then Criteria
2. Diagnosed cases of congenital malformation
3. Benign and malignant lesion of reproductive organ.
4. Other endocrinal dysfunction like Thyroid dysfunction and adrenal hyperplasia, Diabetes Mellitus etc.
5. Patient with Anorectal diseases.
6. Patient with HIV/VDRL/HBsAg positive.
7. Pelvic Inflammatory Disease.

Method of preparation of drugs

***1. Kanashatahwadi Kashayam* (Decoction)**

For the preparation of Kashaya all the drugs (*Kana*, *Shatahwa*, *Karanj*a, *Latakaranj*, *Daruharidra, Bharangi, Kulattha, Tila* and *Rasona*) will be taken in equal proportions and crushed into coarse powder (*Yavakuta*). One *Pala* (48gms) of coarse powder will be added to 16 times water.

It will boil on medium flame and reduced to 1/8th part and after filtering will be used in lukewarm state with *Hinguniryasa* as form of *Prakshepadravya* (As per *Kashaya Kalpana*) (Mentioned in Sh.Sa.Ma.Kh. 2/1) and taken after intake of food in a dose of 40 ml twice daily for 90 days.

***2. Asanadi Niruha Basti* (Medicated Enema)**

In present study these drug formulations are used with modification based on easy availability and authenticity of drugs and ingredients are *Asan, Khadir, Manjistha, Sariva, Usheer, Ashwagandha, Haritaki, Vibhitaki, Amalki, Punarnva, Haridra, Gokshur, Saptachakra* used as *Kashaya Dravya, Triphlachurna* for *Kalkadravya* and *Murchita Tila Tail* as *Snehadravya* along with *Madhu* and *Saindhav-lavana*.

Approximately 240ml of *Asanadi Kashaya*, 80 ml of *Murchhita Tila Taila*, 40 gm of *Triphalakalka*, 120ml of *Madhu* along with 5 gm of *Saindhav Lavana* taken one by one in a wide notched sterile container and triturated with a wooden spatula until complete homogenous mixture was formed.

Method of administration of drugs

- Orally *Kanashatahwadi Kashaya* (40 ml) was administered after taking food in BD dose for 90 days. Four (4) follow-ups were done at every one month.
- First three (3) follow-ups were done with medication and 4thfollow-up was done without medication after one month.
- After clearance of Menses**,** *Matra Basti* was given after taking meal, per rectum with 60ml of *Murchhita Tila Taila*, on 1st, 3rd, 5th, 7th, 8th day of course of *Basti*. *Niruha Basti* was given in empty stomach at morning, per rectally with 480ml of *Asanadi Niruha Basti* on 2nd, 4th, 6th day of course of Basti.

Table 1: Parameters and Scoring Criteria for the Conducted Study

Parameters	Sub Parameter	Scoring	Grading
Menstrual	Menstrual bleeding	0	Spotting
		1	Scanty
		2	Moderate
		3	Excessive
	Interval Menstrual cycle	0	≥3 days
		1	2-3 days
		2	1 day
	Duration Menstruation	0	≥3 days
		1	2-3 days
		2	1 day
	Interval of Menstrual cycle	0	20-28 days
		1	29-45 days
		2	46-60 days
		3	>60 days
	Before and After treatment criteria were followed for next observation.		
Ovarian volume	Left ovary	Before treatment	After treatment
	Right ovary	Before treatment	After treatment
Hormone	Serum FSH	Before treatment	After treatment
	Serum LH	Before treatment	After treatment
	Serum PRL	Before treatment	After treatment
	Serum TSH	Before treatment	After treatment
	Serum Testosterone	Before treatment	After treatment
	LH:FSH Ratio	Before treatment	After treatment
Associated Criteria	Acanthosis Nigricans	Before treatment	After treatment
	Acne	Before treatment	After treatment
	Hirsutism	Before treatment	After treatment
	BMI	Before treatment	After treatment

Follow-Ups:

A total four (4) follow-ups were done at regular intervals of one month to see the changes in signs and symptoms of PCOS. Three follow-ups were done with medication and a fourth follow-up was done without medication. Above mentioned parameter checked and noted every time for keen observation.

Table 2: Parameters related Criteria of result for the Conducted Study

SN	Status of patient	Criteria
1.	Marked improvement	Patients get 100% relief in signs and symptoms
2.	Moderate improvement	Patients get 50-< 100% % relief in signs and symptoms
3.	Mild improvement	Patients get up to 50% relief in signs and symptoms
4.	No improvement	Patients get no relief in signs and symptoms

***The p value is calculated for significant data.**

Observations and Results

In this present study, (n=45)the maximum number of patients (40%) belonged to the age group of 20-25 years, 43n (95.6%) patients belonged to the Hindu religion, 21 (46.7 %) patients belonged to semi-urban areas,30 (66.6%)patients were graduates, 30 (66.7%), patients were students, 43 (95.6%) patients belonged to middle-class families, 22 (48.9%) patients had normal psychological status but 19 (42.2%) women were anxious, maximum i.e. 28 (62.2%) patients had good appetite,14 (31.1 %) had average, and only 3 (6.7%) had poor appetite. It was observed that mainly 36 (80%) patients were unmarried whereas only 9 (20%) patients were married.

In present study 28 (62.2%), patients had scanty bleeding, 11 (24.4%) had moderate, 3 (6.7%) had spotting and 3(6.7%) had excessive bleeding. Duration of menstruation was only for one day in 8.9% of patients, and for 2 to 3 days in 31.1% of patients whereas normal duration (i.e. more than 3 days) was present in 60% of patients.

Interval of the menstrual cycle was more than 60 days in 73.3% of patients; 46-60 days in 15.6%; 29-45 days in 4.4% whereas the normal interval (i.e., 20 to 28 days) was present in 6.7% of patients. Colour of menstrual blood was bright red in a maximum of 27(60%) patients, dull red in 17 (37.8%) and blackish in only 1 (2.2%) patient.

Blood clots during menstruation were absent in a maximum of 39 (86.7%) patients whereas it was present in 6 (13.3%) patients. Maximum of 30 (66.7%) patients had mild pain (mild discomfort) during menstruation, 11(24.4%) had moderate pain (interfere with most daily activity), and only 4(8.9%) patients had severe pain (unable to perform daily living activities).

Out of 45n patients, 10n patients had a history of taking OCPs as a previous treatment for PCOS in the study group. No one had a history of any ovulation induction drugs.

It has been observed that maximum i.e., 26n (57.8%) patients had normal weight or BMI, 17n (37.8%) patients were pre-obese, 1 (2.2%) were under weight and other 1 (2.2%) were in Obese class 1 state.

In this present study maximum patients i.e., 31n (68.9%) had moderate Waist-Hip-ratio 9n patients had low and other 5n (11.1%) had High Waist-Hip-ratio.

Out of 45 patients, 21 (46.7%) patients had striae on the breast, flanks, and thigh region. It was revealed that 9 patients had Acanthosis Nigricans, 7 (15.6%) patients had Acne on their faces. In this study, maximum of 19 (42.2%) patients were without Hirsutism, 17 (37.8%) with mild Hirsutism, 7 (15.6%) had moderate Hirsutism, and only 2 (4.4%) patients had severe Hirsutism.

Amount of Menstruation

Before treatment 6.7% of patients had spotted bleeding during their menstruation, 62.2% of patients had scanty bleeding (≤1pad/day), and 24.4% of patients had moderate bleeding (2-3 pads/day) and only 6.7% patients had excessive bleeding (≥4pad/day).

During 1st follow-up, the number of patients was decreased who had spotted bleeding and the number of patients was increased who had scanty bleeding. But no changes were seen in those patients who had moderate and excessive bleeding.

During 2nd follow-up the result was the same in all patients, there were no changes.

During 3rd follow-up, 71.1% of women had moderate bleeding because some more patients got improvement in amount of menstrual blood loss during menstrual cycle as compared to initial.

Duration of Menstruation **-** Initially, 60% of patients had a normal duration of menstruation during the menstrual cycle i.e., 3 days. Initially, 31.1% of patients had only 1-2 days of menstrual cycle, and 8.9% of patients had only 1 day of the duration of menstruation.

During 1st follow-up, the number of patients was decreased who had only one day of menstruation due to they got mild improvement in the duration of menstruation. During 2nd follow-up, there were no significant changes in any of the patients who got improvement in the duration of menstruation during the menstrual cycle. Subsequently, improvement was observed during the 3rd, and 4th follow-up.

Interval of Menstrual Cycle - Initially maximum of 73.3% of patients had increased interval of menstruation (≥60 days). Initially, 15.6% of patients had 46 to 60 days and 4.4% of patients had 29 to 45 days of the interval of menstrual cycle. During 1st follow-up, the result was almost the same. During the 2nd, 3rd, and 4th follow-ups, improvement in interval of menstrual cycle was observed. Before treatment, 73.3% of patients had an interval of menstrual cycle that was ≥ 60 days after 4th follow up that number reduced to 6.6%.

Dysmenorrhoea (Menstrual Pain) - Before treatment 30 (66.7%) of patients had mild pain during their menstruation, 11(24.2%) of patients had moderate pain, and only 4 (8.9%) patients had severe pain during their menstruation. During the first follow-up, 6 patients who had previously mild pain they got improved to No pain. 2 patients who had severe pain in the initial they got improvement to moderate pain and 3 patients improved from moderately to mild pain. During the second and third follow-up subsequently, improvement was noted. In the fourth follow-up significant improvement was noted in menstrual pain, 13 patients who had mild pain previously they got improved to No menstrual pain, and 4 patients who had severe pain before treatment got significant improvement from severe to moderate pain.

There were no so much changes in the BT mean and AT mean of the mean volume of the left ovary and Right ovary volume. The mean Sr FSH and Sr LH at BT and at AT was slightly change but Sr. LH: Sr.FSH was statistically highly significant. The mean Sr PRL, Sr TSH and Sr Testosterone at and at AT was statistically not significant.

Discussion

In the present study, we have a beneficial effect on the parameters like amount and duration of menstruation. There is also a beneficial effect in the complaint of dysmenorrhoea. However, we got a minimal beneficial effect on the parameter of interval of the menstrual cycle. Also, there is no changes noted in Hirsutism, Acne, striae, Acanthosis Nigricans, and BMI. The correction in these parameters may take a prolonged period of treatment in PCOS.

After treatment, we noticed very minimal regression in the size of Ovaries and hormonal profile. Reversible changes are not seen in the LH/FSH ratio and other hormonal profiles like Sr. PRL, Sr. TSH, and Sr. Testosterone are unchanged. *Kanashatahwadi* Kashaya has drugs like *Kana* (*Pippali*) showed a marked increase in serum gonadotropin and decreased intratesticular testosterone concentration, despite normal serum testosterone titers. It is also used for Anti-inflammatory, Hepatoprotective, and Hypoglycemic activity.**[6]**

Shatahwa which helps in maintaining BMI and correction of help in the HPO axis,**[7]** *Latakaranjahas* an Antiandrogenic effect and it also helps in the regulation of the estrous cycle and restore normal hormonal levels.**[8]** Researches shows that Berberine is found to be effective in ovarian theca cell hormone production (Berberine reduces insulin resistance which is induced by dexamethasone in theca cells in vitro) and it also helps in the improvement of female menstrual pattern.**[9]** *Tila* which blocks excess estrogen during the luteal phase and it also decreases serum dehydroepiandrosteronesulfate (DHEAS) (helps in estrogen production), and increases serum sex hormone-binding globulin (binds excess sex hormones),**[10]** *Rasona* which changes insulin resistance,**[11]** *Hingu* which changes FSH receptors and androgen receptors, etc. may have the capacity to reverse the pathology of PCOS of administered for a prolonged time.**[12]**

In *Asanadi Kashaya* has *Asana* which has Methanol extract was able to exert its protective effect successfully by restoring all the parameters to normal and diminishing the cysts found in ovaries., improve hormonal imbalance (decrease testosterone and increase estrogen, LH, FSH).**[13]**

Manjistha helps in significantly controlling LH Surge and elevated levels of FSH and thus LH/FSH ratio improved. It also helps in decreasing serum testosterone levels.**[14]**

Sariva has been reported that it decreases serum Prolactin levels and improves the LH/FSH ratio in females.**[15]** *Ashwagandha* Increases the secretions of gonadotropin hormones and improves oogenesis. It also decreased serum LH level, increased FSH level and finally improved folliculogenesis.**[16]** *Gandharva Haritaki* is used along with other treatments that result in the Stimulation of the ovary to Ovulation, ovarian volume decreases thus the size of the ovaries is also reduced. Symptoms of PCOS are relieved with a Remarkable decrease in weight and normalizing hormones.**[17]** *Amalaki* regulates normal gonadotropin hormones and helps in follicular maturity. It also helps in decreasing body weight and reduces the level of lipids, sugar, and insulin in the blood. It is responsible for decreasing free testosterone and leptin levels in the blood and increasing TNF-α. It also helps in decreasing the LH/FSH ratio.**[18]** *Haridra* reduces DHEAS levels and improves menstruation. *Gokshura* reduces DHEAS levels and improves menstruation. **[19]**

Regularisation of the menstrual cycle and improvement in the duration of menstruation will take time as the condition is due to *Santarpana*, *Vatakaphadushti*, *Srotorodha*, and vitiated *Dhatvagni*.

In PCOS *Kapha-Medodosha* and *Gambheer Dhatu* involvement initially so in this treatment, *Vamana* and *Virechana* are preferred, before *Shamana* and *Basti*, but here we are not giving *Tikshanashodhana* like *Vamana/Virechana*. That's why the treatment with *Shamanadravya* will take time to show beneficial effects.

The drugs which are used in *Kanashatahwadi Kashaya* majority are *Vata-Kaphahara* and *Katu - Tikshnaguna*, *Ushnavirya*. They will help in regularizing *Vata Dosha* removal of *Kupitakapha* and normal movement of *Vata* and *Artava*.

Cyclicity of the menstrual cycle is mainly dependent on intact HPO axis, maturation of follicles, and ovulation. The correction of any endocrinal dysfunction is always difficult and many of the time they are irreversible. The conditions like *Astanindita, Sthoulya, Prameha, Anartava, Vandhya* etc.

Having similar *Samprapti* like PCOS which are considered as *Kricchasadhya/Yapyarogas*. As their involvement in *Gambheer Dhatu* and involvement of many *Srotas*. The clearance of *Srotosanga*, and correction of *Agni* and *Dhatvagni* needs *Tikshnashodhna*, *Punahshodhana* and *Kramasha Shodhana* is advised as treatment because of their complexity. This may be the reason for unenthusiastic results in this parameter. Patients found relief in the complaint of dysmenorrhoea. The clinically and statistically significant result after completion of the study period as well as the drug-free follow-up. Basti, the main line of treatment, the correction of *Vatadushti* and the drugs which are used in the study are *Vatahara*, *Anulomana, Dipana, Pachana, Shoolaghna, Vednahara*. Many of the drugs like *Hingu, Rasona, Kulthath, Tila* are having beneficial effect in reducing menstrual pain.

There are no significant changes in cutaneous manifestation like - Acne, Hirsutism, Acanthosis Nigricans, Abnormal Pigmentation, *Striae*. No significant changes were found statistically as well as clinically. It shows that the condition required prolonged treatment and requires vigorous *Shodhana* and *Shamana*, once the cutaneous manifestation develop in advanced phase of disease condition.

The LH: FSH ratio which was altered in PCOS does not change even after the completion of the study period.

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