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Exploring the role of *Kantavallabha rasa* in Polycystic ovarian syndrome management: A pilot Study

Research Article

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Abstract

Polycystic Ovary Syndrome (PCOS) is a complex hormonal disorder affecting the reproductive system, metabolism, and skin. Since modern treatments often focus on individual symptoms, there is a need for a more holistic approach. *Kantavallabha rasa*, a classical Ayurvedic medicine traditionally indicated in the conditions like *Mandagni, Gulma,moola roga* and *bhagandara* , was studied for its potential role in managing PCOS. A pilot study was conducted with 10 women of PCOS, diagnosed using the Rotterdam criteria. Symptoms such as irregular periods (amenorrhoea/oligomenorrhoea), pain in menstruation, hair fall, oily skin, acne, hirsutism (excess facial hair), acanthosis nigricans (dark skin patches), and BMI were monitored. Hormone levels (especially AMH) and ultrasound findings (ovarian volume and follicle count) were also assessed. Statistical analysis was done using paired t-test to evaluate the outcomes. The results showed notable improvements. Women, who had been suffering from PCOS for 3 to 20 years, experienced a significant reduction in the gap between menstrual cycles, pain during menstruation, and ovarian size. There was also clear improvement in hirsutism (unwanted hair growth), acanthosis nigricans, and the number of ovarian follicles. Remarkably, even participants, who had not menstruated for over a year, saw the return of their periods before the treatment ended. This suggests that *Kantavallabha rasa* may be a promising Ayurvedic solution for managing PCOS.

Keywords: Hormonal disorder, *Gulma,* Amenorrhea, Hirsutism, Acanthosis, AMH.

Introduction

The polycystic ovary syndrome (PCOS) is a heterogeneous combination of different signs and symptoms that gathered together to form a spectrum of a disorder with a mild presentation in some, while in others a severe disturbance of reproductive, endocrine and metabolic function. The pathophysiology of the PCOS appears to be multifactorial and polygenic. There are many extra-ovarian aspects to the pathophysiology of PCOS, yet ovarian dysfunction is central (1). The pathophysiology includes the involvement of hormones of Hypothalamus- pituitary- ovary- adrenal- thyroid glands, insulin and many enzymes. PCOS affects 4%–20% of women of reproductive age, worldwide (2). The key features of PCOS include menstrual cycle disturbance, hyperandrogenism and obesity. Though, the definition of PCOS is debatable, a refined definition of the PCOS considered now a days is as follows: the presence of two out of the following three criteria:1. Oligo- and/or anovulation, 2. Hyperandrogenism (clinical and/or biochemical), 3. Polycystic appearance of ovaries (3). As the disease is more complicated due to the involvement of multiple factors, multiple glands and multiple organs, its health hazards are also highly dangerous.

For PCOS, though there are no direct references in *Ayurveda*, the variable clinical features of PCOS are mentioned in various contexts of descriptions of gynecological and other disorders. *Ayurveda* is a practice of medicine which is based on certain principles of management. By utilizing these principles, management of PCOS can be established. As per *Ayurveda*, it can be considered that PCOS is a condition where multiple *doshas (tridoshas*) and multiple *dushyas* like *rasa, rakta, meda, asthi, shukra dhatus* are involved and the pathology is *avarana* variety, in which some times, *anya dosha avarana* and sometimes *anyonya avarana* takes place which is very tough to manage, as there remains *ekadesha vriddhi* and *anya desha kshaya*. As the disease consists complex pathology including *avarana*, it requires the *dravyas* like *naimittika rasayanas* which can palliate all the doshas, eventually restoring the deranged *dhatus* and can resolve *avarana*. Though, number of studies were conducted on the topic PCOS, no specific holistic drug is available as such. During the last five years, there have been over 3,172 articles published related to PCOS, with an increasing number of articles published each year. Of these articles, the topics of insulin resistance (IR) and metabolic abnormalities associated

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with PCOS were the most researched. One of the most challenging aspects of this syndrome is its ambiguous diagnostic criteria and vast complexity of characteristics and so needs lot of research in understanding and managing the disease. (4) *Kantavallabha rasa* is one of the *Kupi-pakwa rasayanas*, which consists mainly of *lauha* varieties and *parada*. The drug when is given with *shatapushpa churna anupana* may have synergistic effect in target organs. The present study is one such attempt which is aimed to utilize the properties of *Kantavallabha rasa* in the management of PCOS.

Hence, the present study is aimed to evaluate the efficacy of *Kantavallabha rasa* in the management of PCOS particularly in the improvement of Subjective parameters like irregular menstrual cycles and their associated features, objective parameters like hirsutism, acne, acanthosis, BMI and USG findings like ovarian volume and no. of follicles.

Materials and Methods:

Drug review:

Kantavallabha rasa(5) consists of *kanta Bhasma* (Magnetite) 16 parts, *lauha Bhasma* (Iron) 14 parts, *mandoora bhasma* (Old iron rust) 12 parts, *Shuddha tankana* (Borax)10 parts, *shuddha manahshila* (Realgar) 8 parts, *shuddha shilajatu* (Black Bitumen) – 6 parts, *shuddha parada* (mercury)and *Shuddha gandhaka* (sulpher)- each equal to mixture of above all (each 66 parts); It is a *kupi pakwa* preparation. The drug is purchased from Sri Venkateshwara Ayurveda Nilayam, Chintaluru. The *sahapana Dravya Shatapushpa churna* is purchased from Manphar Ayurvedic pharmacy, Vijayawada.

Table 1: Posology of drug

Dose of *Kantavallabha rasa*	*Sahapana*	*Anupaana*	*Aushadha sevana Kala*	Duration of drug intake	Follow up	*Pathya- apathya*
125mg twice daily	*Shatapushpa churna* 1gm	Warm water	*Abhakta kala* -twice a day (*pratah- sayam)*	45 days	2 months followed by completion of therapy	*Pathya – apathya* mentioned as per individual drug of *Kantavallabha rasa.*

Study type: This pilot study is an open labeled, single group clinical trial, involving 10 patients.

Selection criteria

Inclusion criteria

Patients with diagnostic criterion of any two of three features of anovulation or oligo-ovulation, clinical and/or biochemical hyperandrogenism, and polycystic ovarian morphology (PCOM) seen on ultrasound were taken for study. Patients of reproductive age group (18-45) only were considered for the study. Patients suffering from diabetes mellitus, obesity, hypothyroidism etc. along with PCOS also were considered for the study. Patients having other pelvic pathology like uterine fibroids, adenomyosis, functional ovarian cysts in addition to PCOS also were considered for the study.

Exclusion criteria

Patients having congenital anomalies were not considered for the study. Patients who had malignancies either of reproductive system or anywhere were not taken for the study. Patients, having hyperandrogenemia due to other causes like adrenal hyperplasia, Cushing's syndrome etc., were not taken. Patients, having cardiac diseases, neurological diseases and severe respiratory diseases, were not taken. Patients, suffering from STDs, AIDS, other acute infections and chronic infections like Tuberculosis etc., were not considered for the study. Patients with any critical illness, those are not mentioned in inclusion criteria were excluded from the study.

Table 2: Subjective parameters:

1.Interval between menstrual cycles*note1: 0- 28-35 days/ 10-12 times per year 1- 35-40 days/ 9 times per year 2- 40-45 days/ 8times per year 3- 45-52 days/ 7 times per year 4- 52-60 days /6 times per year 5- 60-73 days / 5times per year 6- 73-91 days / 4times per year 7- 91-122 days / 3times per year 8- 122-183 days / 2 times per year 9- Once per anum 10- More than a year
2a. Duration of menstruation*note2. In case of hypo menorrhoea: 0- 3-5 days 1- 2 days 2- 1 day 3- Only spotting appears
2b. Duration of menstruation*note2. In case of poly-menorrhoea: 0- 3-5 days 1- 5-10 days 2- 10-15 days 3- 15-20 days 4- 20-25 days 5- 25-30 days 6- More than 30 days
3. Quantity of menstrual bleeding: 0- 2-3 pads/day 1- 1-2 pad/day 2- <1 pad/day 3- Only spotting

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4.Pain associated with menstruation:
- 0- No pain
- 1- Bearable pain
- 2- Needs oral analgesics
- 3- Needs injectable analgesics

5.Hair fall:
- 0- No hair fall
- 1- Mild hair fall
- 2- severe hair fall

*Note1: If menstruation doesn't appear within due course of time duration(3 ½ months), the patient will be observed till she gets menstruation (to the maximum extent of 1 year). If in any case of non -appearance of menstruation and follow up beyond 3 ½ months is not possible, there the grade will be mentioned as the previous grade i.e. grade of before treatment

*Note2: As it is observed in PCOS cases that either there may be very scanty bleeding with short duration or may be prolonged bleeding in scanty/ excess quantity, both kinds of duration of menstruation were taken for study as both are abnormal.

Table 3: Objective parameters

1. Hirsutism (Ferriman Gallwey score) (6)
- 0- Complete lack of terminal hairs
- 1- Minimal presence of terminal hairs
- 2- More than minimal terminal hairs
- 3- Not too large hairs
- 4- Presence of terminal hairs (male pattern)

Scoring is considered at 11 areas- Upper lip, sub burn area, Chin, Lower jaw and neck, Chest, Upper back, Lower back, Upper abdomen, Lower abdomen, Upper arms, Thighs (>8 hirsutism)- total score 44

2. *Acne scoring is mentioned below separately.

3. Oily skin

Time of occurrence of oiliness after wash is considered and gradation is done.
- 0- never
- 1- 5 or more hours after washing,
- 2- 2-4 hours after washing,
- 3- 1hour after washing,
- 4- All the day

4. **Baldness**

Basing on the spread, gradation is given. As the abnormality is not found in the cases of present study, gradation is not mentioned here.

5. Acanthosis Nigricans
- 0- Normal skin texture appearance without skin thickening
- 1- Slightly pronounced skin markings without skin thickening
- 2- Moderately pronounced skin markings with slight skin thickening
- 3- Exaggeration of skin markings with moderate skin thickening
- 4- Velvety plaque with marked skin thickening
- 5- Bark-like skin with marked skin thickening

6. Obesity (BMI)
- 0- 20-25 kg/m^2
- 1- 25-30 kg/m^2
- 2- 30-40 kg/m^2
- 3- >40 kg/m^2

***2. Acne: Global Acne Grading System (GAGS) (7)**

Location factor	Score	Type of lesion	Score
Forehead	2	No lesion	0
Right cheek	2	Comedo	1
Left cheek	2	Papules	2
Nose	1	Pustules	3
Chin	1	Nodules	4
Chest and upper back	3		

The score for each area (Local score) was calculated using the formula: **Local score = Factor × Grade (0-4)**

The global score is the sum of local scores, and acne severity was graded using the global score. Mild -1-18, Moderate 19-30, Severe-31-38, Very severe >39.

Table 4: Parameters basing on investigations

1. **Serum. AMH (Anti mullerian hormone)** 0 - Up to 4ng/dl 1- > 4-7 ng/dl 2- > 7-10 ng/dl 3- > 10-13 ng/dl 4- > 13-16 ng/dl 5- > 16-19 ng/dl 6- > 19-22 ng/dl 7- > 22 ng/dl	**2. Serum Testosterone** Scoring is given basing on CLIA method and ECLIA methods) As there is only one case of elevated s. testosterone levels gradation is not shown here.
3. **Serum.HbA$_1$C** (8) 0- < 5.7 1- > 5.7 - 6.4 2- > 6.4 - 6.5 3- > 6.5 - 7 4- > 7 - 7.5 5- > 7.5- 8 6- > 8 - 8.5 7- > 8.5 - 9 8- > 9 - 9.5 9- > 9.5 - 10 10- > 10	4. **Serum FSH (Follicle stimulating hormone) & LH (Luteinizing hormone) ratio** As the ratio of these two was found normal in all the taken cases, the ratios are not mentioned here.

Table 5: Parameters basing on USG findings

1.**Ovarian volume:**	2.**FNPO (No. of follicles per ovary)**
5. <10cc	0- <6 in no.
6. 10-14 cc	1- 6-8 in no.
7. 14-18 cc	2- 8-10 in no.
8. 18 -22 cc	3- 10-12 in no.
9. >22 cc	4- >12 in no.

Table 6: Assessment of overall effect

Excellent Improvement	75-100% relief in subjective parameters, objective parameters, investigations and USG findings / achievement of pregnancy in associated infertility case
Significant Improvement	50-75% in subjective parameters, objective parameters, investigations and USG findings
Moderate Improvement	26-50% in subjective parameters, objective parameters, investigations and USG findings or improvement either only in subjective& objective parameters/ Investigations& USG findings
Mild Improvement	1-25% in subjective parameters, objective parameters, investigations and USG findings or improvement either only in subjective/ objective/ Investigations/ USG parameters
No Change	0% relief in any of the parameters

Age wise distribution of 10 patients of PCOS- 80% (8) patients of the study belonged to the age of 18-28 and remaining 20% (2) patients belonged to the age of 28-38.

Marital status wise distribution of 10 patients of PCOS- 70% (7) patients of the study were unmarried.

Chronicity wise distribution of 10 patients of PCOS- All the patients of the present study had the history of long chronicity. Among them, 50% (5) patients had 3-6 years of chronicity, 40% (4) patients had 6-10 years of chronicity and 10% (1) had 20 yrs of chronicity of the disease.

Chief complaint wise distribution of the patients- All the patients (100%) had the feature of oligomenorrhea with grade ≥ 6, 30% (3) patients had hypomenorrhoea as per duration of menstruation, 20% (2) patients had bleeding for prolonged days, 50% (5) patients had hypomenorrhoea as per quantity of blood loss and remaining had normal quantity of blood loss during menstruation, 70% (7) patients had the presence of hirsutism, out of which 10% (1) had the familial history of hirsutism. 50% (5) patients had the presence of acne with mild (80%- 4 patients) to moderate (20%- 1 patient) degree. 70% patients (7) had the complaint of oiliness of the body. Only 20% patients (2) had complained about the male pattern baldness, but 90% (9) patients had complained the hair fall of different degrees. 10% (1) patients had high level of mood swings before menstruation and another 10% (1) patients had minimal degree of mood swings. Among 10 patients, 4 patients (40% were obese, one (10%) was of morbid obese and remaining were of moderate weight.

Diet wise distribution of 10 patients: 80% (8) patients were of non-vegetarians, and all of these had history of intake of chicken or eggs very frequently. 40% (4) patients had history of habitual intake of bakery foods, 40% (4) patients had history of habitual intake of frozen foods particularly ice creams, 80% (8) patients had the habit of regular curd usage, 40% (4) patients had the history of high usage of oily foods and 60% (6) patients used to consume pickles much.

Agni, koshtha, asana (Diet) wise distribution of 10 patients: 60 % patients had samagni, 30 % (3) had vishamagni and 10 % (1) patients had teekshnagni. Except 1 patient (10%), all(90%) had Madhyama koshtha. 8 patients (80%) had the history of samasana and 2 patients (20%) had the habit of adhyasana.

Personal history wise distribution of 10 patients: Among 10 patients, 3 (30%) patients had the history of constipation and the remaining 70% had regular bowel movements. One patient among the sufferers of constipation had the habit of mala vegadharana. 3 patients (30%) had the habit of mutra vegadharana. Except 1 (10%), all had the history of sufficient sleep. 3 patients (30%) had the habit of ratri jagarana, 20 % patients had the habit of divaswapna and 30 % (3) had the habit of late wakening. 50% patients (5) had sedentary life style, where as 30 % patients (3) had stressful lifestyle. Only 1 patient (10%) had the habbit of regular exercise, that was also for last 1 year. Among 10 patients, only 2 (20%) had normal psychological state, remaining all (80%) had been suffering from some kind of psychological disturbances.

Dasha vidha & sroto pareeksha wise distribution of 10 patients: 60 % patients (6) belonged to vata kapha prakruti and remaining 40% (4) patients belonged to pitta kapha prakruti. Vikruti wise examination revealed that 5 patients (50%) had vata kapha dushti, 30% patients (3) had anyonya vata dushti, one patient (10%) had sannipataja dushti and another one (10%) had medo avruta vata dushti. 70%(7) patients had Madhyama sara, 60% (6) patients had Madhyama samhanana, 70% (7) patients had madhyama Pramana, 70% (7) patients had Madhyama satmya, 80% (8) patients had Madhyama satva, 50% (5) patients were of Madhyama vayas and remaining (50% were of pravara vayah.70% (7) patients belonged to jangala desha (pravara desha) and remaining (30%) belonged to sadharana desha (Madhyama desha). All patients (100%) had Madhyama vyayama shakti. 50% (5) patients had Madhyama abhyavaharana shakti, 30 % (3) had pravara abhyavaharana shakti and remaining 20 % (2) had avara abhyavaharana shakti. 60% (6) patients had Madhyama jarana shakti, 40% (4) patients had pravara jarana shakti.

Srotovikriti wise distribution of 10 patients: 20% (2) patients had pranavaha sroto vikriti,40 % (4) patients had anna vaha sroto vikriti, 50% (5) patients had rasavaha sroto vikriti, 40 % (4) patients had rakta vaha sroto vikriti, 20% (2) had medo vaha sroto vikruti, 40 % (4) patients had asthivaha sroto vikriti, 20% (2) patients had pureeshavaha sroto dushti, 40 % (4) patients had swedovaha sroto dushti and all the patients (100%) had shukravaha sroto dushti.

Investigations wise distribution of 10 patients: Except one (10%), all patients (90%) had normal Hb percentage. All (100%) had normal TC, DC, ESR, blood sugar reports. Only one patient (10%) had slightly elevated lipid profile, 50% patients (5) had enhanced AMH levels, all (100%) patients had normal (≤ 1:2) FSH and LH ratio. Only one (10%) had elevated testosterone level (biochemical), only one patient (10%) had elevated Hb A^1C. All (100%) had normal thyroid profile and normal urine reports.

USG wise distribution of 10 patients: All patients (100%) had bilateral PCO and increased size and volume of ovaries and multiple cysts in ovaries in USG findings. Other USG findings revealed that 2 patients (20%) had grade 1 fatty liver, one patient (10%) had chronic cervicitis, one (10%) had ovarian cyst.

Statistical Analysis

Various observations made, and results obtained were computed statistically using Paired 't-test' to find out the significance of the values obtained. All the results were calculated by using Online T test calculator software.

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Results And Discussion

Table 7: Result in major symptoms (subjective features) of the 10 patients of PCOS

Parameter	N	Mean		SD		SEM		T	P	Result
		BT	AT	BT	AT	BT	AT			
Interval between menstrual cycles	10	7.7	0.4	1.64	0.7	0.52	0.22	16.2781	< 0.0001	Extremely significant
Quantity of menstruation (low)	5	1.6	0.6	0.89	0.55	0.4	0.24	1.5811	0.189	Not significant
Dysmenorrhea	6	2	0.17	0.63	0.41	0.26	0.17	11	<0.0001	Extremely significant
Oiliness of skin	7	1.86	0.57	0.69	0.79	0.26	0.3	3.0571	0.0223	Significant
Hair fall	8	1	0.75	0	0.655	0	0.231	1.0801	0.3159	Not significant

Interval of menstruation

The study revealed that Kantavallabha rasa is extremely significant in reduction of the interval of menstruation in all 10 patients of the sample. The patients of grade 10 (1pt with more than 12 months interval and another one with 3 years of amenorrhoea) also got menstruation during the course or follow up of treatment. In maximum number of clinical studies conducted on PCOS, the maximum interval of menstrual cycles taken was around 120 days (9), whereas in the present study, cases of amenorrhoea of more than 1year also were taken and obtained good results even in those cases.

Duration of menstruation

As only one patient had the complaint of hypomenorrhea, statistical analysis could not be done, but there was good improvement (reduced to grade 1 from grade 2) in the bleeding quantity. Similarly, only 2 patients had the complaint of menorrhagia. In these, there was no difference before and after treatment in the prolonged days of menstruation. In 1 patient, menstruation was started after taking medicine for 13 days which was continued for more than 1 month (which was present previously too) and stopped with other medication only (not stopped naturally, which was seen in her previous cycles too). After cessation of menstruation, whenever she started the medication, she used to get the menstruation, so the medicine was stopped for few months and again after few months of amenorrhoea, the medicine was started with which she got menstruation.

Quantity of menstruation

Though the duration of menstruation was less in only one patient, the quantity of menstruation was low in 5 patients. Though, the p-value of the study showed non-significant values, the mean of the study was reduced from 1.6 to 0.6 and the patients had satisfactory quantity of menstruation.

Dysmenorrhea

In the symptom dysmenorrhea, the study showed extremely significant results. All the patients had got relief in pain in abdomen after taking medicine.

In the feature, Oiliness of skin (which is a feature of hyperandrogenemia), the study showed significant improvement and in patients of hair fall (again a feature of hyperandrogenemia), the study showed non-significant result. Similarly, in feature mood swings (only 2 patients), only slight improvement was observed.

Table 8: Result observed in signs (objective features/parameters) of the 10 patients of PCOS

Parameter	**N**	**Mean**		**SD**		**SEM**		**T**	**P**	**Result**
		BT	**AT**	**BT**	**AT**	**BT**	**AT**			
Hirsutism	7	8.14	5.14	5.24	4.1	1.98	1.55	4.1451	-0.0060	Very significant
Acne	5	9.8	2.6	5.4	2.79	2.42	1.25	2.3815	0.0759	Not significant
Baldness	3	1.33	1.33	0.58	0.58	0.33	0.33	0	1	Not significant
Acanthosis	9	2	0.78	1	0.83	0.33	0.28	3.773	0.0054	Very significant
BMI	7	2	1.86	1	1.21	0.38	0.48	0.2402	0.8142	Not significant
Weight (Kg)	10	75.8	74.1	20.61	20.66	6.52	6.53	1.4249	0.1879	Not significant

Hirsutism

It is one of the important clinical features of PCOS which was observed in 7 patients of present study. Though the result showed statistically very significant improvement, patients didn't feel much satisfaction in reduction of unwanted hair growth as again hair growth was continued during follow up.

Acne

In acne, which is again a sign of hyperandrogenemia, though the results had shown non-significant improvement, the patients felt much satisfaction in reduction of acne. The mean was reduced to 2.6 from 9.8. Because of the correction of *sroto avarodha*, the issue might be cleared.

Acanthosis nigricans

In this feature, which is a sign of hyperinsulinemia, the result had shown very significant result. *Kantavallabha rasa* which is mainly consisting of *Kanta Bhasma* is a good drug in correction of

prameha (10). The present study result also strengthens this statement.

BMI & weight reduction

Though, there was a satisfactory weight loss (on an average, there was a reduction of 1.7kg/ pt (except in one case, in whom weight gain took place), as per statistics, no significant results were observed. Though there was good weight reduction in many no. of patients, as the reduced weight also fell under same grade of BMI, statistically significant results couldn't be obtained. Obesity and metabolic abnormalities are recognized risk factors for the development of ischaemic heart disease (IHD). There have been a large number of studies demonstrating the presence of insulin resistance and corresponding hyperinsulinaemia in both obese and non-obese women with PCOS(11). As all the ingredients of *Kantavallabha rasa* have the property of *agni deepana, aama paachana ,lekhana* etc., weight reduction might have taken place and as many ingredients are individually indicated in *medo roga*, getting good results in overweight with *Kantavallabha rasa* is quite expected.

Table 9: Study of Investigation results in 10 patients

Parameter	N	Mean		SD		SEM		T	P	Result
		BT	AT	BT	AT	BT	AT			
S.AMH	6	2.33	1	1.97	0.63	0.8	0.26	2.1693	0.0822	Not significant

Serum AMH renders the developing follicles less sensitive to follicle stimulating hormone (FSH). It, when elevated, also interferes with the normal functioning of the ovaries and the enzyme aromatase; therefore, inhibiting the initiation of the primordial follicle (12). Hence, elevated S. AMH is one of the important investigations in PCOS, now a days. Hence, in the present study, it is specifically investigated. Though, the result showed statistically non-significant improvement, there was good mean wise improvement (2.33 before treatment was reduced to 1). Due to the *vrishya, rasayana karma* of *Kantavallabha rasa*, the *avarana of srotus* might be rectified, which resulted in the reduction of S. AMH levels.

Though, elevated FSH and LH ratio is an important investigation mentioned in PCOS, in the present study, the ratio was either equal to or less than 1:2. So, this test report statistics were not shown in the study paper.

Serum testosterone and serum HbA1C levels were elevated in only one case each. So statistical analysis could not be done. But, in the patient, in whom, the serum testosterone levels were elevated, the levels were decreased from grade 3 to grade 1. Similarly, in patient, whose serum $HbA^{1}C$ levels were in grade 2 before treatment, were reduced to grade 0, which indicates the efficacy of *Kantavallabha rasa* in both elevated S. testosterone and S. $HbA^{1}C$. Due to *vrishya* and *pramehahara karma*, the *Kanatavallabha rasa* might had shown very good improvement in these two parameters.

Table 10: Study of USG findings in 10 patients

Parameter	N	Mean		SD		SEM		T	P	Result
		BT	AT	BT	AT	BT	AT			
Volume of right ovary	10	2	0.6	1.15	0.7	0.37	0.22	5.25	0.0005	Extremely significant
Volume of left ovary	9	1.89	0.56	1.05	0.73	0.35	0.24	8	0.0001	Extremely significant
No. of follicles in right ovary	9	4.22	1.89	1.86	0.78	0.62	0.26	3.8829	0.0047	Very significant
No. of follicles in left ovary	10	3.8	2	1.48	1.33	0.47	0.42	4.6305	0.0012	Very significant
Endometrial thickness	10	6.07	7.24	3.066	1.922	0.97	0.608	1.1376	0.2847	Not significant

USG findings

The present study revealed that there is extremely significant improvement in reduction in volume of both ovaries and also, there is very significant result in reduction of no. of follicles in both ovaries. This indicates *Kantavallabha rasa* is very effective in improvement of PCO state as per USG findings. As the average endometrial thickness is quite normal before and after treatment, that was not taken into consideration.

Overall assessment

PCOS is a highly complicated condition where multiple systems are involved. In addition to involvement of multiple *doshas, dushyas* and *malas, avarana janya samprapti* is present in PCOS. Hence, it is very difficult to expect complete cure in this disease within less time. Still, *Kantavallabha rasa* has shown excellent relief in 10% cases, significant improvement in 50% cases and moderate improvement in 40% cases. This drug is a *parada's kupi pakwa rasaayana yoga*.

Moreover, it consists all varieties of *lauhas, manahshila, shilajatu, tankana* and also synergized by the *gunas* of *shatapushpa*(13). These drugs have *deepana, amapachana, lekhana, vrishya* and *aartava janaka* actions and *ushna- teekshna- sookshma- vyavayi* properties, because of which the drug alleviates the conditions *anartava/ aniyamitaartava, prameha* (which is seen in the form of reduction in acanthosis and HbA^{1}C levels), *sthoulya* (in the form of weight reduction and feeling of lightness of the body), *gulma* (in the form of reduction in PCO in USG), *yuvana pidaka* etc. and improves the functionality of hypothalamo- pituitary- ovarian axis (in the form of proper maintenance of menstrual cycles etc.), thus correcting the condition PCOS. During the course of medication and follow up, no adverse drug effects were observed.

Conclusion

The present study confirmed that the *ayo yoga i.e. Kantavallabha rasa* with its multifaceted action offered a comprehensive approach in managing PCOS, particularly in the subjective parameters I.e., amenorrhea or oligomenorrhea, objective parameters like acne, acanthosis and weight reduction, investigations like S. AMH, HbA^{1}C and Testosterone and in USG parameters (size of ovaries and no. of follicles). No satisfactory improvement was observed in other features like hair fall and mood swings. Further large-scale studies are warranted to substantiate these findings and elucidate the underlying mechanisms.

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