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Effect of *Shatapushpa Taila Matra Basti* and *Pathadi Kwatha* on Poly Cystic Ovarian Disease

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Abstract

Poly Cystic Ovarian Disease (PCOD) is a complex disorder affecting 5-15% women in their reproductive age and related to ovarian dysfunction, characterized by menstrual irregularities, hyperandrogonism, obesity, and infertility. In Ayurveda, these symptoms are found under various conditions, caused by vitiated *Vata* and *Kapha*. *Pathadi Kwatha* and *Shatapushpa Taila Matra Basti* were studied in the current attempt to evaluate their comparative efficacy in cases of PCOD. Total 34 patients of PCOD were registered among which, 32 had completed the treatment of 2 months. They were randomly divided in to three groups. In group A *Pathadi Kwatha* (10 g, bid) and *Shatapushpa Taila Matra Basti* (60 ml for 7 days after cessation of menses for 2 consecutive cycles) were administered. In group B only *Basti*, whereas in group C capsules of roosted wheat flour were administered. Better results were obtained in group A especially in menstrual irregularities, achieving follicular growth and in weight reduction.

Key words: *Artavavaha Srotas, Matra Basti,* ovarian functions, *Pathadi Kwatha,* PCOD, *Shatapushpa Taila*

Introduction

Poly Cystic Ovarian Disease (PCOD) is a common cause of infrequent and irregular periods and affects as many as 5-15% of woman in their reproductive age.[1] This disease is characterized by menstrual irregularities, clinical, and/or bio-chemical hyperandrogonism and hyperinsulinemia, which ultimately leads to infertility. Apart from infertility, some of the other symptoms associated with Poly Cystic Ovarian Syndrome (like hirsutism, obesity, and android fat patterning)[1] may interfere with female self perception and are in contradiction to culture-dependent beauty ideals.

Symptoms of PCOD direct the way of involvement of *Kapha* and *Vata Dushti* causing *Avarodha* or *Avarana* in *Artavavaha Srotas*. Thus for the treatment, *Pathadi Kwatha* mentioned by Sushruta in *Vatakaphaja Artavadushti*[2] was selected. This drug contains *Patha* (*Cissampelos pareira* Linn.), *Shunthi* (*Zingibar officinalis* Roxb.), *Maricha* (*Piper nigrum* Linn.), *Pippali* (*Piper longum* Linn.), and *Kutaja* (*Holarrhena antidysenterica* Roxb.ex. Fleming) in equal proporation. *Shatapushpa* (*Anethum sowa* Kurz.) is the drug of choice in any disease related to *Artava*[3] in any form so *Shatapushpa Taila Matra Basti* (STMB) was selected.

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Materials and Methods

Patients

Patients attending the OPD of Stree Roga and Prasooti Tantra, I. P. G. T. and R. A., Jamnagar, fulfilling the criteria for the selection were selected into the study irrespective of their religion, caste, etc.

Inclusion criteria

Patients, fulfilling at least two of the following three criteria[4] (ESHRE/ASRM – Rotterdam revised criteria for PCOD, 2003):

1. Oligomenorrhea and/or anovulation.
2. Hyperandrogonism (clinical and/or bio-chemical).
3. PCO-diagnosed by Trans Vaginal Sonography (TVS).

Exclusion criteria

- Patients having any other disease causing oligomenorrhea and anovulation excluding PCOD on the above criteria.
- Any organic lesions of reproductive tract like tuberculosis, carcinoma and congenital deformities, or any other pelvic pathology.
- Patients suffering from adrenal hyperplasia, severe insulin resistance, androgen secreting neoplasm, thyroid

abnormalities, Cushing's syndrome, cardiac diseases will be excluded.

Drugs
The drug *Patha* was collected from Sanjivani Pharmaceuticals, Baroda in raw form. *Shatapushpa* was purchased from the market of Jamnagar. Other drugs, (*Trikatu*, *Kutaja*, and *Tila Taila*) were obtained from the Pharmacy of Gujarat Ayurved University, Jamnagar. All drugs were identified in the Pharmacognosy laboratory, IPGT and RA. *Pathadi Kwatha*, *Shatapushpa Taila*, and roasted wheat flour capsules as placebo drug were prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar.

Investigations
Hematological investigations like Hb%, TC, DC, ESR, and routine urine investigations were done. serum Lutinizing Hormone (LH), serum Follicular Stimulating Hormone (FSH) were done on 2nd or 3rd day of menses. USG was done on 2nd or 3rd day of menses for diagnosis of PCO and it was also done in between 12th to 20th day of menses for follicular growth and ovulation.

Study design
Placebo controlled randomized clinical study was carried out. Informed consent was taken from the patient before including them in the clinical trial.

Management of the Patients

Drug dosage, duration, and method of administration

Grouping
Selected patients were randomly divided into three groups.

Group A
Patients were given 10 g of *Pathadi Kwatha Churna*, 2 times/day. They were advised to make decoction from it. Along with the oral drug, patients were also given STMB in the dose of 60 ml for 7 days after cessation of menses in two consecutive cycles. In this group, 14 patients completed the treatment and 1 discontinued.

Group B
Patients of this group were treated with only STMB in the dose of 60 ml for 7 days after cessation of menses in two consecutive cycles. In this group, 12 patients completed the treatment and 1 discontinued.

Group C
Patients were given Placebo capsules in the dose of 2 capsules of 500 mg each 2 times/day. In total, six patients were registered and have completed the treatment in Group C.

Duration
2 months.

Pathya-Apathya
Patients were advised to take less amount of diet than required, correct their dietary habits, and avoid unhygienic and junk food. Mild to moderate exercise especially inclusion of *Suryanamaskara* as per their capacity was suggested. They were also advised for intercourse during *rutukala* (from 12th to 20th day of menses) and not to take much of stress.

Follow up
Follow-up was carried out for one month.

Criteria for assessment
Assessment was made on change in clinical features before and after treatment. Special scoring pattern was given to each symptom ranging from 0 to 3. Total effect of therapy in each patient was evaluated after completion of the treatment.

The obtained results were measured according to the grades given below:
Completely cured: 100% relief
Marked improvement: >75% to <100% relief
Moderate improvement: >50–75% relief
Mild improvement: >25–50% relief
Unchanged: up to 25% relief

Statistical analysis
The obtained data on the basis of observations was subjected to statistical analysis. $P < 0.001$ is considered as highly significant, $P < 0.01$ as significant, and $P < 0.05$ as insignificant.

Observations and Results

In the present study, majority (55.88%) of patients belonged to age group of 25-35 years, 94.12% were married, 76.47% were housewives, 50% had taken allopathic medicines, 38.24% had chronicity of >5 years, 94.11% were having the dietetic habits of *Vishamasana*, 20.59% had dyspareunia, 79.41% were suffering from *Chinta* (worry), 67.65% had *Vatakapha Prakriti*, 73.53% had *Mandagni*. Maximum (64.71%) patients had irregular delayed menses (oligomenorrhoea), 29.41% had painful menses, 61.76% had primary infertility, 52.94% had Ferriman Gellway score[5] ≥8, 23.52% were obese, 100% patients were having *Artavavaha Srotodushti*, 88.24% had bilateral PCO on USG finding, 90.63% had the follicular size between 0->12 mm and LH:FSH ratio >2 in 32.35% of the patients.

In group A, statistically significant results were found in delayed menses (32.43%), painful menses (62.50%), and achieving follicular growth (100%). In this group statistically highly significant results were found in reduction of body weight (4.31%). In group B, statistically significant results were found in delayed menses (50%), painful menses (100%), and achieving follicular growth (66.67%). No change was found in any symptoms in group C. Though weight reduction was found in group A but, no change was found in the BMI score, whereas in groups B and C, there was increase in weight instead of decrease [Tables 1-3]. At the same time no improvement was found in hirsutism and LH:FSH ratio in any group. Changes in hematological parameters were within normal limits.

On overall assessment in group A, 7.14% patients showed complete remission, 14.29% showed marked improvement, 28.57% showed mild improvement, whereas 50% remained unchanged. In group B, 33.33% patients showed complete remission, 8.33% showed moderate improvement, 16.67% showed mild improvement, whereas 41.68% remained unchanged. In group C, only 16.67% patients showed mild improvement, whereas 83.33% remained unchanged [Figure 1].

Discussion

Effect on menstrual irregularities

Amapachana, *Srotoshodhana*, and *Vatakaphashamaka* properties of both *Pathadi Kwatha* and STMB may be responsible for the efficacy.[6] *Ushna*, *Tikshna*, *Lekhana*, *Pachana*, etc., properties of contents of *Pathadi Kwatha* are similar to *Pitta* increases *Agneya Guna* of *Pitta*, which is responsible for decreasing interval. This effect is also supported by *Vatanulomana* property of *Matra Basti*. Looking to the result, it can be said that the combination of *Kwatha* and *Matra Basti* may decrease the level of androgen, which allows estrogen to work on endometrium.

Effect on follicular growth and ovulation

Group A shows significant ($P < 0.01$) result on follicular growth, group B shows insignificant ($P < 0.05$) result, whereas no change was found in group C. Follicular size increased after treatment in maximum patients in group A. Patients with no follicular growth reported increase in follicular size after therapy. This may because of removal of *Sanga* by *Kapha-Vata Shamaka Srotoshodhana*, *Aama Pachana*, etc. properties of both the drugs. After removal of *Sanga* created by vitiated *Kapha* and *Ama* in *Artavavaha Srotas*, *Apana Vata* functions well leading to normal *Rajah Pravritti* and *Beeja Nirmana*. It may be hypothesized that both the treatment modalities may decreases LH level thus preventing premature lutinization. Thus normal FSH level stimulates growth and development of follicle.

Effect on other symptoms

Group A shows highly significant ($P < 0.001$) result in reduction of weight, whereas group B and group C show statistically insignificant ($P < 0.05$) result. In groups B and C, weight increased instead of decrease. In group A, additional properties like *Lekhana*, *Rruksha*, *Tikshana*, *Deepana*, *Pachana*, etc., of *Pathadi Kwatha* adds this effect of reduction in body weight[7] by regulating *Jatharagni*. Thus, it checks the excessive growth and accumulation of *Medodhatu* and thereby causing *Lakshana Upashamana* of disease PCOD. These properties are lacking in groups B and C although strict *Pathya Palana* was administered in all three groups. Overall, Group A shows 62.50% result, whereas group B shows 100% result in pain associated with menses. Group C shows insignificant result. Effect of therapy on LH:FSH ratio shows statistically insignificant ($P < 0.05$) in all groups.

Comparing the total effect of therapy with the placebo group, group A and B shows statistically significant ($P < 0.01$) results [Tables 1 and 2] whereas there is insignificant difference in group A compared with group B [Table 3]. Hence, it can be said that both trial drugs have similar effect.

Probable Mode of Action of Drugs

Basti works on whole body after entering into *Pakvashaya* or *Guda*. *Guda* is said as *Sharira Mula* having *Shiras* and *Dhamanies*, which spreads all over the body.[8] It exerts local as well as systemic effect. *Basti Dravyas* normalize *Apana Vata* making it to function normal. It also enhances the function of *Purisha*.[9] One of the function of *Purisha* is '*Anila Anala Dharana*', thus *Basti* leads to correction of *Agni Dushti*. At the end, *Basti* normalize the function of *Apana Vata* leading to normal *Rajah Pravritti* and normal *Beeja Nirmana*. Here,

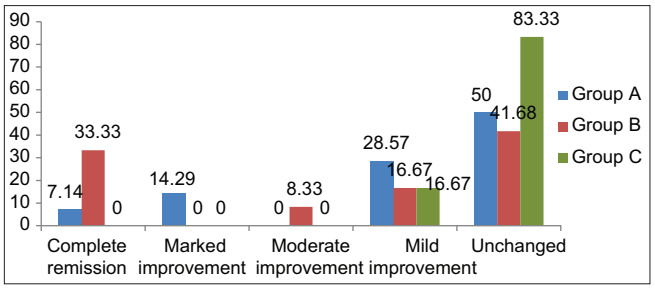

Figure 1: Overall effect of therapy

Table 1: Effect of therapy in Group A

Symptoms	B.T.	A.T.	%	S.D.	S.E.	*t*	*P*
Interval of menses	2.85	1.92	32.43	1.04	0.29	3.21	<0.001
Follicular size and ovulation	0.00	0.57	100.0	0.85	0.23	2.51	<0.01
Obesity (BMI)	1.43	1.29	10.00	0.38	0.14	1.00	<0.05
Obesity (kg)	63.00	60.29	4.31	1.20	0.32	8.43	<0.001
Pain during menses	1.60	0.60	62.50	0.71	0.32	3.16	<0.001

BMI: Body mass index

Table 2: Effect of therapy in Group B

Symptoms	B.T.	A.T.	%	S.D.	S.E.	*t*	*P*
Interval of menses	1.00	0.67	33.33	0.52	0.21	1.58	<0.05
Follicular size and ovulation	0.30	0.90	66.67	1.07	0.34	1.77	<0.05
Obesity (BMI)	0.00	1.00	-	0.00	0.00	-	-
Obesity (kg)	46.17	46.75	↓1.26	1.31	0.38	1.54	<0.05
Pain during menses	1.00	0.00	100.0	0	0	-	-

BMI: Body mass index, ↓ decrease

Table 3: Effect of therapy in Group C

Symptoms	B.T.	A.T.	%	S.D.	S.E.	*t*	*P*
Interval of menses	1.33	1.00	25.00	0.58	0.33	1.00	<0.05
Follicular size and ovulation	0.17	0.17	00.00	0	0	-	-
Obesity (BMI)	0.00	0.00	-	-	-	-	-
Obesity (kg)	47.50	48.17	↓1.40	1.03	0.42	1.58	<0.05
Pain during menses	1.00	1.00	00.00	0	0	-	-

↓ decrease

Shatapushpa Taila was used for the *Basti* and the *Gunas* of *Shatapushpa* are *Balya*, *Deepan*, *Pachan*, *Yonivishodhana*, *Artavajanana*, and *Beejotsarga*.

As per modern appraise, any drug given via rectal route absorbs through mucosal layer of rectum and enters into systemic circulation. Entering into Gastro Intestinal Tract (GIT), *Basti* stimulates Enteric Nervous System (ENS) and generates the stimulatory signals for Central Nervous System (CNS) as ENS resembles CNS.[10,11] These signals stimulate endogenous opioids present in GIT, mainly β-endorphin, which exerts the inhibition of gonadotropin releasing hormone release.[12] Thus, *Basti* given in the patient of PCOD regulates Hypothalamic-Pituitary-Ovary

axis, which results into normalization of ovarian cycle and menstrual cycle too. Parasympathetic activity may be responsible for the function of *Apana Vata*. *Basti* introducing through rectum and may stimulate the parasympathetic nerve supply, which in turn helps for development of follicles and release of ovum from the ovary.

Conclusion

Treatment with the combination of both *Pathadi Kwatha* and STMB has additional effect on the symptoms of PCOD. It is proved statistically to be effective in regularizing menstruation, achieving considerable reduction in body weight, substantial growth of follicles, and thus ovulation. The final outcome of the study is very positive. This treatment protocol may be helpful for management of PCOD in future definitely.

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हिन्दी सारांश

बहुग्रंथितबीजकोष (पॉली सिस्टिक ओवेरियन डिसीस) पर शतपुष्पा तैल मात्रा बस्ति और पाठादि क्वाथ का प्रभाव

कृपा डी. पटेल, लक्ष्मीप्रिया देई, शिल्पा बी. दोंगा, नलिनी आनन्द

पॉली सिस्टिक ओवेरियन डिसीज, जैसा कि नाम संकेत करता है, ओवरी के बाधित कार्य से संबंधित लक्षणों और चिह्नों का समूह है । यह एक अंतःस्त्रावी ग्रंथिओं से संबंधित विषम व्याधि है जिसमें मासिकधर्म की अनियमितता, हाईपर एन्ड्रोजनिज्म, स्थूलता और बंध्यत्व मुख्य रूप से पाये जाते हैं। यह ५%–१५% महिलाओं को उनकी प्रजोत्पादन वय में प्रभावित करता है । आयुर्वेद में इस व्याधि का प्रत्यक्ष वर्णन नहीं मिलता है । जबकि इसके लक्षण कई व्याधि के वर्णन में पाये जाते हैं । अध्ययन में पंजीकृत किए गए कुल ३४ रुग्णाओं को सामान्य वितरण पद्धति से ३ वर्गों में बाँटा गया । वर्ग 'अ'में पाठादि क्वाथ – १० ग्राम, दिन में दो बार तथा शतपुष्पा तैल मात्रा बस्ति–६० मि.ली., मासिक के बंद होने के बाद ७ दिन के लिए दिया गया, जबकि वर्ग 'ब' में केवल बस्ति दी गई । वर्ग 'स'में प्लेसिबो कैप्सुल दी गई । चिकित्सा अवधि २ माह की थी । मुख्यतः मासिक की अनियमितता, स्त्रीबीज का विकास न होना तथा शरीरभार में वृद्धि; इन लक्षणों में वर्ग 'अ'में उत्तम प्रभाव पाया गया । इस चिकित्सकीय अध्ययन से यह निष्कर्ष निकाला जा सकता है कि मंदाग्नि के कारण दुष्ट हुए वात और कफ तथा आम, आर्तववह स्त्रोतस् में अवरोध कर यह रोग उत्पन्न करते हैं ।