

ROLE OF LAVANBHASKAR CHURNA, SAJJI KSHARA AND NAVSADAR IN THE MANAGEMENT OF (BEEJKOTH) GRANTHI WITH SPECIAL REFERENCE TO PCOS

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ABSTRACT

PCOS is a relatively common endocrine disorder affecting women of reproductive age group; insulin resistance and hyperinsulinemia being one of important causes. It has also been studied that PCOS consequently results in infertility and the only treatment is Surgery and Hormone replacement therapy. There is no direct reference involving the detail clinical spectrum of PCOD in our ancient texts of Ayurveda; instead the symptoms have been explained as a part of various diseased conditions. The present study was carried out with a plan to clinically evaluate efficacy of Ayurvedic treatment regimen on PCOS. In the present study total 60 patients were registered in two groups. In the first group, a combination of three drugs namely *Lavanbhaskar churna*, *Sajji kshara* and *Navsadar* were given where as the second group was administered a placebo drug. Of 60 patients registered, only 36 completed the research study (30 patients in Group A and 06 patients in Group B). All the patients were assessed before and after treatment based on subjective parameters like Interval and Duration of menstruation, Dysmenorrhea, Obesity and Objective parameters like Follicular size, Hormonal profile. The results were statistically evaluated using unpaired T test. Comparatively, trial drug of group A has a beneficial effect on the symptoms of PCOS and showed significant results than group B. Thus it can be concluded that Combination of *Lavan Bhaskar Churna*, *Sajjikshar* and *Navsadar* can be used in the management of PCOS.

Keywords: *Ayurvedic*, Dysmenorrhea ,Hormone replacement therapy.

INTRODUCTION

Female being the root cause of progeny, utmost care should be given to protect her from any ailments that affect her motherhood but PCOS is one of the conditions affecting this unique capacity of woman. The disorder is probably the most common hormonal abnormality in women of reproductive age

and certainly a leading cause of infertility. PCOS- Poly Cystic Ovarian Syndrome also known as Poly Cystic Ovarian Disease -as the name suggest, is a collection of signs and symptoms related to ovarian dysfunction. It was originally described by Stien and Levental in 1935, so called as “Stien-Levental

Syndrome". It is a heterogeneous disorder characterized by menstrual irregularities, clinical and biochemical Hyperandrogenism and hyperinsulinemia, which ultimately leads to infertility¹. PCOD is a common cause of infrequent & irregular periods affecting as many as 10% of woman in their reproductive age². The disorder accounts for 30 % of all infertility cases with 73 % of women suffering from PCOS. PCOS is a familial condition and appears to have its origin during adolescence mainly associated with increased weight gain during puberty. In Ayurvedic classics there is not a complete description of such disease menstrual irregularities are described under the broad heading of *Ashtoartavadushti*³, while the description of infertility due to anovulation is scattered as *Pushpopaghata*⁴ and *Abeejatva*⁵. *Pushpaghni Jataharini* is mentioned in *Kashyapa Samhita*, *Revati Kalpadhyaya* bears similitude to the symptom of Hyperandrogenism. But features of metabolic dysfunction and polycystic ovarian morphology are not evident from any depiction. PCOS is not a completely curable disease. In modern science, PCOS is treated by hormonal therapy along with symptomatic treatment which in long term is associated with many side effects. Moreover it may also fail in preventing the long term consequences of PCOS. The last alternative is surgery; Partial oophorectomy or drilling of the ovaries. In Ayurvedic literature, so far no standard Ayurvedic drug has been established for the management of PCOS. Thus, it is necessary to modulate a well accepted Ayurvedic approach towards the disease and formulate the principles of management. If the treatment is planned well by means of scientific research and applying the *doshic* status, it can make wonders in the curability of complex symptoms of PCOS. As this disease is manifested due to mixed etiological factors and presents with complex symptomatology, the treatment should also be broad spectrum. In view of this, *Lavanbhaskar churna*⁶, *Sajji Kshara* and *Navsadar* were selected as a trial

drugs. As trial drugs have not been established as standard drugs for PCOS, the effect of it should only be assessed by comparing it with no drug group that is a Placebo. So in order to find out a therapeutically efficacious, safer, cost effective and an easily available drug for the management of PCOS an attempt has been made to evaluate the efficacy of these drugs by means of a comparative study with a placebo drug.

Aim and objectives

1. To find out the aetiopathogenesis of PCOS in Ayurveda parlances.
2. To evaluate the efficacy of both the selected drugs on menstrual irregularities & anovulation caused by PCOD.

Materials and methods

The whole study was carried out in the following manner.

Conceptual study

In this phase, a critical review of Ayurvedic and Modern literatures regarding the subject was carried out. Different Ayurvedic and modern texts, research papers and journals were consulted for the conceptual part for latest information.

Clinical study

Patients attending the OPD of Stri Roga & Prasooti Tantra of Post graduate institute of V.Y. D. S Ayurvedic Mahavidyalaya Khurja fulfilling the criteria for the selection were selected. A detailed history regarding menstrual history, obstetric history, family history, past medication, clinical findings pertaining to *Dosha*, *Dushya*, *Agni*, *Srotas* etc. along with vaginal and speculum examination to assess any sign of infection or any disease related to menstrual irregularity or infertility were filled up in specially prepared Performa.

1. Study design

Present study was designed as a randomized clinical trial.

2. Sample size:

Total 60 patients (30 in each Group) were registered fulfilling all the inclusion criteria.

3. Selection Criteria

A. Inclusion criteria: Patients fulfilling at least two of following three criteria⁷:

- Oligomenorrhoea / or Anovulation
- Hyperandrogenism (clinical /or bio-chemical)
- Bilateral or unilateral PCO - diagnosed by USG.

B. Exclusion criteria:

- Patients having any other disease causing Oligomenorrhoea and Anovulation.
- Any organic lesions of reproductive tract like TB, carcinoma and congenital deformities or any other pelvic pathology.
- Patients suffering from adrenal hyperplasia, severe insulin resistance, androgen secreting neoplasm, thyroid abnormalities, Cushing syndrome, and cardiac diseases were excluded.

4. Criteria for diagnosis:

Patients were selected on the basis of their clinical presentation particularly related to menstruation and hirsutism and on the basis of Ultrasonography (USG) with the report of unilateral or bilateral PCO and or anovulation. Hormonal assessment was carried out only to support the diagnosis, not as diagnostic criteria.

To assess the effects of therapies, a special scoring and gradation method based on subjective and objective parameters was adopted as follows:

Subjective Parameters

- Interval of menstruation.
- Duration of menstruation.
- Pain associated with menstruation.
- Obesity (on the basis of BMI).

Objective Parameters

- Follicular size.
- Hormonal profile including S. FSH and S.LH.
- C.B.C.

4. Selection of drug

- Group A: Lavanbhaskar Churna, Sajji kshara and Navsadar orally were given.

- Group B: Patients were treated with Placebo drug.

5. Posology

Group A:

- *Lavanbhaskar churna* orally 2g B.D for two months.
- *Sajjikshar* orally 1.5 g B.D for two months.
- *Navsadar churna* orally 1.5 gm B.D for two months.

Group B:

- Roasted wheat orally 500 mg B.D. after meals for 2 months.

6. Follow up

After completion of the treatment the patients of both the groups had been examined for follow up at the interval of one cycle to record whether the improvement provided by the therapy is sustained or otherwise, depending upon cooperation from patients after completion of treatment. Any new complaint or complication emerged during follow up related to study was also noted.

Results

The present study entitled 'Role of *Lavanbhaskar churna*, *Sajji kshara* and *Navsadar* in the management of *Beejkoth granthi* with special reference to PCOS' was conducted in Post graduate institute of Vaidya Yagya Dutt Sharma Ayurvedic Mahavidyalaya Khurja, Bulandshshar, U P. The study was designed with an aim to evaluate the effect of these three drugs mainly on menstrual irregularities and anovulation caused by PCOS. Of 60 patients registered in two groups only 36 completed the study (30 in group A and 6 in group B). In group A, improvement in irregular (delayed) menses was highly significant while insignificant result was observed in duration of menses, significant growth was found in follicular size while ovulation was found only in 2 patients. Also in this group, reduction in weight was highly significant. In group B (placebo), no any significant or marked effect was found in any of the symptoms of PCOS. Comparatively both A & B group showed mostly

similar effect on menstrual irregularities and follicular growth.

Comparative Statistical results

Table 1: Effect of therapy on Menstrual cycle Interval

Group	N	Mean		X (BT-AT)	%	S.D	S.E	T	P
		B.T	A.T						
A	30	2.40	1.86	0.53	32.43	0.73	0.13	4	<0.001
B	06	0.83	1.00	-0.16	120.00	0.40	0.16	1	<0.363

After treatment in group A, interval of menstruation decreased up to ≤ 35 days in 20.00% of patients; up to 36-45 days in 20.00% of patients; up to 46-55 days in 13.33 patients while it was found same (≥ 56 days) in 46.66% patients. While in group B, it

decreased up to ≤ 35 days in 50% of patients; up to 36-45 days, up to 46-55 days and remained same (≥ 56 days) in 16.66% patients respectively.

In group A result is statistically highly significant, while in group B result is statistically insignificant.

Table 2: Effect of therapy on Duration of Menses

Group	N	Mean		X (BT-AT)	%	S.D	S.E	T	P
		B.T	A.T						
A	14	1.00	0.83	0.16	12.50	0.46	0.08	1.9	<0.05
B	06	1.00	0.833	0.16	25	0.46	0.08	1.9	<0.05

In group A, though normal duration of 3-5 days was found in maximum patients (88.88%), after treatment the duration of menses increased upto 5 days in maximum (70%) of patients while in group B it remains almost same. Statistically the effect of

therapy on duration of menses is insignificant in two groups. This result was found because most of the patients in all two groups were having duration of 5 days.

Table 3: Effect of therapy on Pain associated with Menses

Group	N	Mean		X (BT-AT)	%	S.D	S.E	T	P
		B.T	A.T						
A	30	0.60	0.00	0.60	62.50	0.85	0.15	3.84	<0.001
B	06	0.33	0.33	0.00	00.00	0	0	-	-

In group A, bearable pain during menstruation was found in 04 patients while need of oral analgesics was found in 07patients. After treatment 100.00% had no pain and 0% patients had bearable pain during menses. In group B, bearable pain during

menses was found in 02 patients. After treatment it remained same. Effect of therapy on pain associated with menstruation is statistically highly significant in group A (<0.001); while no change was found in group B.

Table 4: Effect of therapy on Obesity

Group	N	Mean		X (BT-AT)	%	S.D	S.E	T	P
		B.T	A.T						
A	30	0.40	0.50	-0.10	10.00	0.30	0.05	1.7	<0.08
B	06	0.00	0.00	-	-	-	-	-	-

Effect of therapy on obesity particularly on the basis of BMI shows that there is no marked reduction in obesity in any patient of the two groups. Result is statistically insignificant in group A while it remains same or even reduced in group B.

In Group A the initial mean score of follicular size was 0.10 which was 0.46 after the treatment. This improvement was statistically significant ($P < 0.001$). While in group B, no any change was found after treatment.

Table 5: Effect of therapy on follicular size & ovulation

Group	N	Mean		X (BT-AT)	%	S.D	S.E	T	P
		B.T	A.T						
A	14	0.10	0.46	-0.36	100	0.55	0.10	3.61	<0.001
B	06	0.16	0.16	0.00	00.00	0	0	-	-

Effect of therapy on Hematological parameters.

The Hb% result was found to be statistically significant after comparing before and after treatment. In group A, Statistically TLC result is insignificant while it is statistically significant in Neutrophils, Lymphocytes and Eosinophils. In case of Monocyte, result is statistically significant

whereas result is statistically insignificant in Basophil and in ESR.

In group B changes of all the hematological parameters before and after treatment were insignificant.

Comparative effect of therapy

For the data analysis of parameters, the un-paired “t-test” is applied for inter group comparison.

Table 6: Comparative Total Effect of Therapy between Group A & B

Symptom	Group	N	Mean	SD+/-	SE+/-	DF	T+/-	P
Interval of menstruation	A	30	1.87	1.22	0.22	34	1.5751	<0.1245
	B	06	1.00	1.26	0.52			
Duration of menstruation	A	30	0.83	0.53	0.10	34	0.0000	<1.0000
	B	06	0.83	0.75	0.31			
Obesity	A	30	0.50	0.78	0.14	34	1.5584	<0.1284
	B	06	0.00	0.00	0.00			
Pain with menstruation	A	30	0.47	0.82	0.15	34	0.8682	<0.3914
	B	06	0.17	0.41	0.17			
Follicular growth	A	30	0.00	0.00	0.00	34	3.7639	<0.0006
	B	06	0.33	0.52	0.21			

DISCUSSION

Today, PCOS commonly occurs during reproductive age of woman and accounts for being a major cause of infertility. The disorder is associated with a wide spectrum of presenting features including menstrual irregularities, anovulation, infertility, obesity, hirsutism and insulin resistance. Not all people who suffer from polycystic ovary syndrome will have all of these symptoms. Symptoms differ from woman to

woman depending upon the level of severity. In PCOS, hormonal imbalance affects the development of follicular growth at various stages of maturation causing an arrest and atresia of the follicle. The retained follicle forms into a cyst and with each ovarian cycle a new cyst is formed leading to multiple ovarian cysts. PCOS can also be understood well on the basis of Ayurvedic concepts .PCOS occurs primarily due to the imbalance state of

doshas especially *vata* and *kapha*⁸. This *dosha vaishmya* is linked to the symptoms of PCOS. The deranged *vata* vitiates the *mamsa*, *shonita* and *meda* mixed with *kapha*; they produce a circular, raised and knotted inflammatory swelling called *granthi*⁹ which can be compared with a cyst. Due to *Srotorodha* and suppression of *Agneya Guna* of *pitta* by the vitiated *Kapha*, the process of *Beejanirmana* cannot be completed (arrested maturation of follicles). *Apana Vata*, could not function normally for *Beejotsarga* and *Artava Pravritti*. This pathology is responsible for *Anartava* as well as *Vandhyatva* due to anovulation.

Role of *Ama* along with *Dhatvagnimandya* in the *Samprapti* has also been found. Here, multiple small cysts found in the periphery of ovaries can be taken as *Ama*. When production of androgens from these undeveloped or immature cysts becomes high and they circulate as free or unbound in the blood circulation, they produce all the symptoms. When *Dhatvagni* of a particular *Dhatu* is diminished, the formation and utilization of that *Dhatu* becomes incomplete and *Ama* is produced. This type of pathology can be seen in PCOD i.e. formation of *Beeja* is not been completed, hence the process of *Beeja Nirmana* renders at the level of follicular stage and becomes cysts. These cysts can be taken as *Ama* produced in *Artavavaha Srotas* due to *Dhatvagnimandya*. These cysts produce androgens which are not converted into estrogens and thus prevent ovulation. So, this *Ama* is responsible for all symptoms of PCOD.

Mode of action of drugs

The approach towards Ayurvedic treatment for PCOS includes *vata kaphara chikitsa*, *Sroto shodhan*, *ama pachan* along with management of *agnimandya* at both *dhatvagni* and *jatharagni* levels.

In this disease, Because of *Vata kapha dosha vriddhi* and *Pitta Kshaya* the physiological process of menstruation gets disturbed resulting in *Anartava*.

So *Vata kaphahara dravya* along with property with *kshara* may be effective for treatment.

Lavanbhaskar churna is *Vata*, *Kapha nashak*, *Gulma niharaka* and *Vata shool nashak*¹⁰. It aids in digestion and help in *Sroto Shuddhi*. The properties of *Dipana* and *Pachana* elevate the *jatharagni*, *dhatvagni* as well as *artvagni*. *Sajjikshar* is indicated in *Vata-Kaphaja Artava Dushti*. *Sajjikshar* and *Navsadar* are *tikshan ushna guna pradhana kshara* and will help in *vimplapan* of *Granthi*¹¹. *Navsadar* is *tridosha shamak* especially *Kapha dosha hara*. It is *Ushna virya*, *Snigdha*, *laghu*, *Pachaka* and *Jatharagni Pradeepak* Where as *Sajji kshara* is *Tikshan*, *Katu*, *Ushna*, *Pachaka* and *Vayu nashak* and *Udara roga nashak*¹².

The given treatment may work to improve hormone utilization and regulates overall hormone balance.

CONCLUSION

The world of medical science is climbing new steps day by day but this newer disease like AIDS, Malignancies, PCOS etc. are arising every day for which there is no direct correlation in Ayurvedic classics. It is a health problem that affects a woman's menstrual cycle, fertility, sex hormones production, insulin production, and physical appearance. Likewise the etiology and diagnosis remains controversial. No direct correlating condition was found in classical text books. It is found only under the broad heading of "*Yoni Vyapada*". So, it is the need of time to postulate management of the disease by Ayurvedic norms. It is proved statistically to be effective in regularizing menstruation, achieving considerable reduction in body weight, substantial growth of follicles and thus ovulation and through these achievements it may prevent long term consequences of PCOS. No doubt, the above treatment protocol may be helpful but there is need for further study in management of PCOS in future.

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