

## A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF RAJAPRAVARTAKA CHURNA AND HINGUVACHADI CHURNA IN PCOS

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### ABSTRACT

Polycystic Ovarian Syndrome (PCOS) is the most common health problem caused by a disproportion of reproductive hormones with the ovarian expression of various metabolic disorders and a wide range of clinical features such as obesity, menstrual abnormalities and hyperandrogenism. In this modern era, the erratic lifestyle, high-calorie diet and deskbound jobs have resultantly expanded the spread of hormonal disparities and menstrual disorders have led to an increased prevalence of PCOS up to 20-30 %. There are similar conditions explained in the classics under the context of *Pushpaghni jataharini*. The treatment should be *Kapha-Vata hara, vatanulomana, dipana, pittavardhaka* along with avoidance of causative factors. Considering the above facts, *Rajapravartaka churna* and *Hinguvachadi churna* were selected for the study. The present study was aimed to bring out the effect of *Ayurveda* in PCOS, which is safe and non-hormonal. **Objectives of the study:** 1) A comprehensive study of PCOS and its congruence in *Ayurveda*. 2) To study the efficacy of *Rajapravartaka churna* and *Hinguvachadi churna* in PCOS and to compare its efficacy. **Materials and Methods:** A randomized comparative clinical study of two groups, consisting of 20 patients in each group. Group A - *Rajapravartaka churna* orally in the dose of 3gm twice daily along with *tila kwata* as an *anupana* 50ml; before food for a period of two consecutive cycles. Group B was given *Hinguvachadi churna* orally in the dose of 250mg twice daily along with water; before food for a period of two consecutive cycles. **Results and Interpretation:** The study has shown a statistically significant difference between each group in its efficacy. **Conclusion:** *Rajapravartaka churna* showed better results than

Hinguvachadi churna while taking the account of the percentage of each criterion.

**Keywords:** Polycystic ovarian syndrome, Pushpaghni Jataharini, Rajapravartaka Churna, Hinguvachadi Churna.

## INTRODUCTION

Ayurveda is anticipated in the contemporary world as a special, important branch of medicine that helps preserve health by holding the body, mind and spirit of the person in perfect equilibrium with nature. The *Ashtanga Ayurveda* has eight branches, but there is no direct connection to the *Prasuti Tantra* and the *Sthree Roga*. Instead, *Kaumarabhritya* by *Acharya Haritha*, which deals with the management of a pregnant lady, treatment after delivery and management of newborn diseases and breast milk defects. *Stree* is said to be the root cause of progeny, as per *Shabda kalpa druma*:

“*Sthrayathi Garbho Yasyamithi Sthree*”

Therefore, to protect her from any illnesses that affect motherhood, women should be given special care. To safeguard the health of the woman, *Ayurveda* provides primary care as she is considered the vital cause of the coming generation. As privilege is reserved exclusively for women is the act of giving birth to a child, the only time when both joy and pain function in tandem.

Polycystic ovarian syndrome is the most prevalent endocrinopathy. The incidence of this disease is increasing nowadays because of a sedentary lifestyle, excessive intake of junk foods.

The condition was first described in 1935 by American Gynecologist F. Stein. and L. Leventhal so it is also called Stein –Leventhal syndrome.<sup>1</sup> PCOS is a heterogeneous disorder that affects at least 7% of adult women. Research suggests that 5-10% of females are affected by PCOS making it the most common endocrine abnormality.<sup>2</sup> Women with PCOS have Irregular Menstrual Cycle, excess of Androgens, Insulin Resistance, Anovulation, Acne, Hirsutism and Infertility.

As per Rotterdam criteria, diagnosis of PCOS require the presence of any two of the following: Oligo/Anovulation, Hyperandrogenism and Polycystic

Ovaries<sup>3</sup>. Modern management of PCOS is targeted for weight reduction in obese patients, hormonal pills and invasive techniques, which gives only symptomatic relief.

According to *Ayurveda* these symptoms are found in *Pushpaghanijataharini*<sup>4</sup>, identified in *Revathi Kalpa Adhyaya* by *Acharya Kashyapa*. It is mentioned in this situation that the patient will have periodic but futile cycles and corpulent cheeks with excessive hair. *Artavakhaya*<sup>5</sup>, *Nashtartava* mentioned by *Acharya Sushruta*, mentions that *arthavanasa* occurs in females due to *vata-kapha avarana*, which can be associated with PCOS-associated amenorrhea. *Artava*<sup>6</sup> and *Granthi bhuta Artavadhusti*<sup>7,8</sup> and it is caused by vitiated *vata* and *kapha* and *Rasa-Meda- mamsa-rakta dhatu dushti*. So, the treatment should be *Kapha vata hara*, *Vatanulomana*, *Dipana*, *Pittavardhka* along with *Nidana Parivajana*.

Considering the above factors *Rajapravartaka churna*<sup>9</sup> mentioned in *Rasaratna sara va Siddaprayoga Sangraha* processes *Kapahavatahara*, *Dipana Pachana* and *Srotoshodhana* properties and *Hinguvachadi churna*<sup>10,11</sup> mentioned in *Ashtanga Hridaya* having *Kapha Vata hara*, *Tikshna guna*, *Ushna virya*, *Katu Vipaka*, *Lekhana* and *Srotodhodana properties* are selected for the present study. The dissertation is entitled "A comparative clinical study to evaluate the efficacy of *Rajapravartaka churna* and *Hinguvachadi churna* in PCOS"

## MATERIALS AND METHODS: SOURCE OF DATA:

### Literary Source:

All the classical, Modern literature, Journals and Websites about the disease and the medicine were reviewed and documented for the planned study.

### Sample Source:

40 patients diagnosed with PCOS, fulfilling the diagnostic and inclusion criteria, attending O.P.D of AI-

va's Ayurveda Medical College and Hospital, Moodbidri and other available sources were selected for the study

**Drug Source:** Raw drugs have been identified and collected from the available local market under the supervision of *Dravyaguna* experts and *choorna* was prepared at Alva's pharmacy, Mijar.

**METHOD OF COLLECTION OF DATA:**

The qualitative data related to clinical conditions was collected as per the case proforma. The information included in the case proforma was complete history, physical signs and symptoms, necessary lab investigations and ultra-sonography (Abdomen and pelvis). The parameters of signs and symptoms have been scored on basis of standard methods and have been analyzed statistically.

**Design of Study:** A randomized comparative clinical study of two groups, consisting of 20 patients in each group has been taken.

**Diagnostic Criteria:**

The diagnosis was based upon the presence of any two of the following three criteria:

1. Oligo and/ anovulation
2. Clinical Hyperandrogenism
3. Polycystic Ovaries (diagnosed with USG)

**Inclusion Criteria:**

1. The age group of 18 to 35 years
2. Patients fulfilling the diagnostic criteria
3. Both married and unmarried

**Exclusion Criteria:**

1. Patients with primary amenorrhea
2. Endocrinological disorders like Diabetes Mellitus, Thyroid abnormalities, Congenital Adrenal Hyperplasia and Hyperprolactinemia.
3. Malignancy and chronic systemic diseases
4. Concurrent or previous use of oral contraceptive pills within last 3 months
5. Hypoplastic uterus and ovaries.
6. Those having gross structural abnormalities of the uterus and appendages.
7. Streaky ovaries and surgical removal of ovary, Congenital Adrenal Hyperplasia

**INTERVENTIONS:**

**Group A:** was given *rajapravartaka churna* orally in the dose of 3gm twice daily along with *tila kwata* as an *anupana* 50ml; before food for a period of two consecutive cycles.

**Method of Preparation:** The dry drugs are made into a fine powder using a pulverizer, sieved, mixed and collected in an airtight container. **Anupana-** Drugs of *Tila and Brahmi* was purchased and was prepared in the form of *kashaya choorna* as coarse powder. 25 grams of *kashaya choorna* were packed and patients were advised to prepare fresh *kashaya* every time. Mode of preparation and administration were also explained to the patients 25 grams of *kashaya choorna*

**Tila Kwatha preparation** -One packet *kashaya choorna* (25 grams) was added with 400ml of water and boiled up to 50 ml and filtered. Patient had taken in lukewarm stage twice daily along with 3gm of *Rajapravartaka churna before food*.

**Group B:** was given *Hinguvachadi churna* orally in the dose of 250mg twice daily along with water; before food for a period of two consecutive cycles.

**Method of preparation:** The dry drugs are made into a fine powder using a pulverizer, sieved, mixed and collected in an airtight container The menstrual phase of the menstrual period has been excluded in both groups.

**Period of Observation:**

Assessed on the fifth day after menstruation of two consecutive cycles.

Follow up: 5<sup>th</sup> day of menstruation after the treatment.

**ASSESSMENT CRITERIA:**

**Subjective Parameters:**

- Irregular periods
- Pain
- Hirsutism
- Acne
- Acanthosis Nigricans

**Objective Parameters:**

- Interval between cycles
- Duration of bleeding
- Amount of bleeding (no of pads used per day)

- Ultra-sonography (abdomen and pelvis) for ovarian volume
- BMI

#### INVESTIGATIONS:

#### OBJECTIVE PARAMETERS:

1. Ultrasonography

#### SCREENING PARAMETERS:

Following investigations are done, if necessary:

1. CBC
2. ESR
3. LFT
4. TFT
5. Diabetic Profile
6. Hormonal assay

## DISCUSSION

In the present study, it was found that clinical features of this disorder differ from patient to patient. As menstrual irregularities were found in all patients, related symptoms like hirsutism, acanthosis nigricans, obesity, acne were not present in all patients. So, the outcome of treatment was mostly evaluated based on improvement on main symptoms first and then on associated symptoms.

The assessment was done after the 2<sup>nd</sup> menstrual cycle and the changes in outcome variables were analyzed statistically.

#### EFFECT ON INTERVAL BETWEEN CYCLES:

- The result on the criteria interval of both groups shows statistically highly significant results with P-value <0.001 individually, which indicates both the groups are effective.
- The comparative study proved to be statistically significant which indicates *Rajapravartaka churna* is having a better result on the interval between cycles
- If we see the percentage of relief, it is evident that in Group A percentage of relief is 34% which is high when compared to Group B which is 25.5%
- These may be due to *dipana, paachana, kapha vata samana* and *Agneya* properties of drugs of *Rajapravartaka churna*. The drugs like *Hingu, Shunti, Tila, Pippali*, due to their *katu tikta rasa, theekshna guna* and *ushna veerya* are *agneya*

*dravyas* and *vata kapha samana* and *artava janaka* properties thus helping in improving the regularity of the menstrual cycle.

#### EFFECT ON DURATION OF BLEEDING:

- The result on the criteria interval of both groups shows statistically highly significant results with P-value <0.001 individually, which indicates both the groups are effective.
- The comparative study proved to be having a statistically significant difference between the effect of treatments on the duration of bleeding in Group A and Group B.
- If we see the percentage of relief, it is evident that in Group A, the percentage of relief is 25.5% and for the group, B is 31.25%.
- These may be due to *Amapachana, Deepana, Srotoshodhaka, Vata- Kapha hara* properties of *churna*. *Hingu* is having *Anuloma* property and most of the drugs are having *Ushna Veerya* which helps in removing *Srotoshodhaka* and removes *Avarana* of *Kapha*, thus helping in improving bleeding.

#### EFFECT ON AMOUNT OF BLEEDING:

- The result on criteria of the amount of bleeding in both groups showed statistically highly significant results with P value= <0.001, which indicates both Group A and Group B are effective.
- The comparative study proved to be a statistically significant difference between the effect of treatments on the amount of bleeding in Group A and Group B.
- If we see the percentage of relief, it is evident that in Group A the percentage of relief is 40.8% which is higher when compared to Group B which is 32.6%.
- *Hingu* and *Tila* is having *Vatanulomana* property which will help in the proper functioning of *Apana Vayu* there by the normal flow of menstruation also occurs.

#### EFFECT OF TREATMENT ON INTENSITY OF PAIN:

- The result on criteria of the intensity of pain in both groups showed statistically highly significant results with P-value =< 0.001 which indi-

cates both the groups are effective.

- The comparative study proved to be having a statistically significant difference between the two groups.
- If we see the percentage of relief, it is evident that in Group A, the percentage of relief is 75% which is high when compared to Group B which is 34.4%.

#### **EFFECT OF TREATMENT ON BMI:**

- The effect of treatment on BMI on two groups is significant statistically individually with the P value of Group A being 0.008 and Group B is 0.021
- The comparative study proved to be having a statistically significant difference between the two groups.
- If we see the percentage of relief, it is evident that in Group A percentage of relief is 29.6 % which is higher when compared to Group B which is 17.8%.
- *Hingu* is having *medohara* property. *Vijaya* and its derivative Tannin have anti-obesity and anti-diabetic activity. By virtue of the above properties, these drugs can correct hyperinsulinemia and weight gain which are the most common presentations in patients with PCOS.

#### **EFFECT OF TREATMENT ON HIRSUTISM AND ACANTHOSIS NIGRICANS:**

The result in criterion on Hirsutism and Acanthosis nigricans of both groups showed statistically insignificant results individually, which indicates both groups are ineffective. The comparative study proved to be statistically significant too.

#### **EFFECT OF TREATMENT ON ACNE:**

- The result on criteria Acne showing statistically significant result individually with a P value of Group A is 0.010 which is significant whereas Group B is 0.163 which is not significant
- The comparative study proved to be having a statistically significant difference between the two groups.
- If we see the percentage of relief, it is evident that in Group A which is 40% is high as compared to

Group B 14.2%

- *Tila* is having *varnya* properties. Also, the drugs like *bharangi*, *chitraka* and *pushkaramoola* are *dipana- pachana* which corrects the metabolism by correcting the function of *dhathwagni*. It promotes the *poshana* of *rasa* and *raktha dhathu* which helps in the reduction of *mukhadushika*. It also acts on the pathophysiological aspect bringing about ovulation and thereby correcting the hormonal imbalance.

#### **EFFECT ON OVARIAN VOLUME:**

The number of the follicular cyst and the volume of the ovary was assessed using USG. 12 or more follicles at least in one ovary measuring 2-9 mm in diameter or total ovarian volume greater than 10 cm<sup>3</sup> are suggestive of PCOS.

- The result on effect on treatment on Ovarian volume of Group A and Group B showing statistically highly significant with P value < 0.001. This indicates both Group A and B are effective
- The comparative study proved to statistically significant difference groups be having no between two group
- If we see the percentage of relief, it is evident that in Group A which is 30% is high as compared to Group B 21.5%
- This is also due to *Kapha - Vatahara, Deepana, Pachana* and *Rechana* property of the drugs in the *churna*. All drugs are having *ushna veerya* which will also pacify *kapha* and *vata* those are the main doshas in PCOS. Due to the *rechana property*, it will help to reduce the size of the ovary. *Brahmi* and its derivative saponin are having a reduction in cyst size of ovaries and a reduction in ovarian volume.

#### **OVERALL ASSESSMENT:**

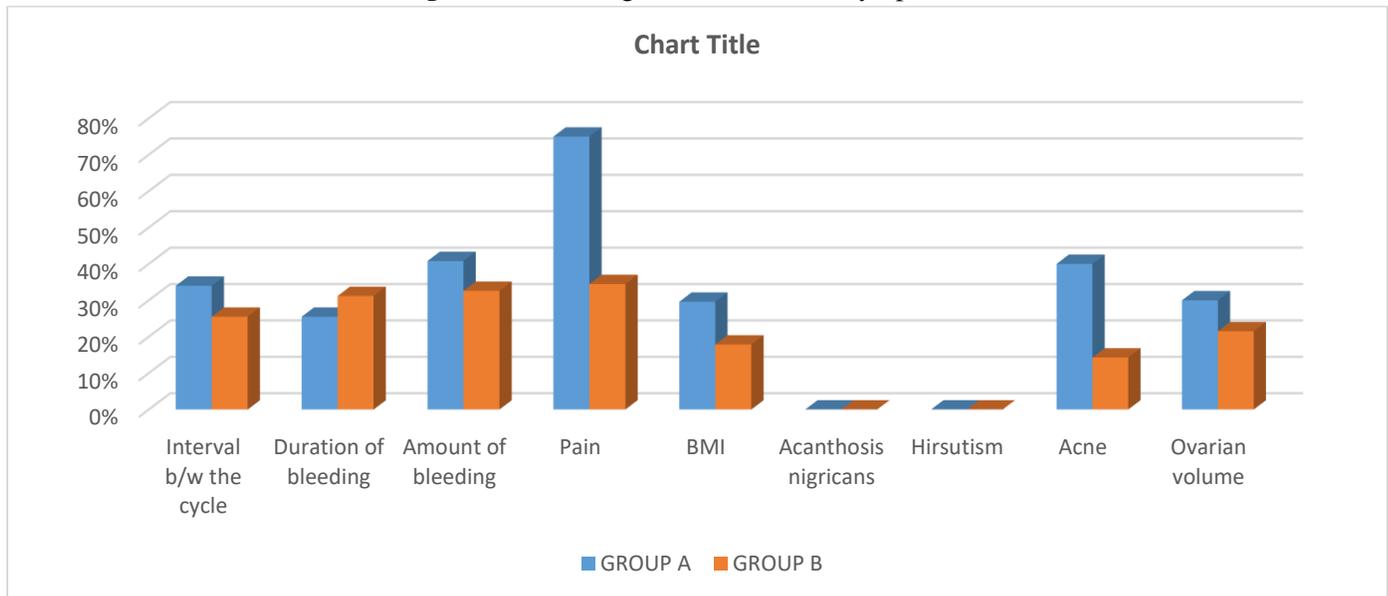
There was moderate improvement in 10% of cases in group A and Group B is 5%

There was mild improvement in 50% in group A and 25% of cases in group B. There was minimal improvement in 40% of cases in group A whereas 70% of cases in group B.

**Table 1:** Comparative Effect of Groups

SYMPTOMS	MEAN OF BT-AT		MEAN DIFFERENCE	% Of relief		T Value	P-Value
	A	B		A	B		
Interval between cycles	0.850	0.600	0.400	34%	25.5%	2.260	0.030
Duration of bleeding	0.600	0.50	0.150	25.5%	31.2%	0.737	0.466
Amount of bleeding	1.000	0.75	0.200	40.8%	32.6%	0.940	0.353
Pain	1.200	0.50	0.700	75%	34.48%	3.621	<0.001
BMI	0.400	0.25	0.050	29.62%	17.85%	0.330	0.744
Hirsutism	0.000	0.000	0.000	0.00%	0.00%	0.00	1.000
Acanthosis nigricans	0.000	0.000	0.000	0.00%	0.00%	0.00	1.000
Acne	0.300	0.10	0.150	40%	14.28%	0.125	0.163
Ovarian volume	4.950	3.35	1.100	30%	21.5%	1.198	0.037

**Figure 1:** Percentage of relief in each symptom



## CONCLUSION

A sedentary and stress dominated lifestyle of young women today has led to the increased incidence of PCOS. In women of reproductive age with the ovarian presentation of different metabolic disorders and a broad range of clinical characteristics such as menstrual irregularities, obesity and hyperandrogenism, PCOS is a complex multisystem endocrinopathy. PCOS is not and completely curable condition, but the symptoms can be cured by effective drugs, including diet and exercise, along with lifestyle improvements. *Kashyapa's Pushpahni Jathaharini* bears some similarity to PCOS, as it does not have any clear con-

nection. It does not include the disease to a specific illness or syndrome, according to *Ayurveda* the symptoms are like *Nashtarhava*, *Arthavakshaya*, *Granthibhuta Artava Dushti's*, and *VandyaYoni Vyapat*. Successful PCOS treatment therapy eliminates infertility using safe, non-invasive and non-chemical remedies. *Dosha-Vaigunyatha* in this condition is *Kaphavidhi* and *Vataprakopa*. *Kapha-Vata Avarana* to the *Artavavaha Srotas* can cause *Nashtarhava* or *Arthavakshaya* which is high up in PCOS. *Agneya* property of *Pitta* is reduced in PCOS which is essential for normal *Artava Pravrutthi*. *Dosha Vaigunyata*, *Vishamasana*, and *Vihara* lead to im-

proper functioning of *Agni*, and which leads to *Srotoavarana* and causes *Ama*. Because of this, there occur hormonal imbalance that causes hyperinsulinemia and hyperandrogenism causing Anovulation, menstrual irregularities and ovarian abnormalities like PCOS. The line of treatment should be *Kapha-Vatahara* and *Pitta Vardhaka*. The study has shown a statistically significant difference between each group in its efficacy when comparing. The study has shown Rajapravartaka *churna* is having better action in restoring the normal menstrual cycle, duration of bleeding, Amount of bleeding and reducing acne, reducing pain during menstruation, reducing BMI; and reducing the volume of ovaries. while *Hinguvachadi churna* also shows better results in the interval between cycle, Duration of bleeding, and in reducing the volume of right and left ovaries. Both drugs showed no effect in Hirsutism and Acanthosis nigricans. Hence null hypothesis is rejected; the Alternative hypothesis (H3) is accepted. ie., *Rajapravartaka churna* is more effective than *Hinguvachadi churna* in PCOS.

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