A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SAPTASARAM KASHAYA AND KANASATAHWADI KASHAYA IN PCOS

Hafsa. P. Ahamed¹, Satish Jalihal²

¹P. G Scholar, Dept. of. Prasuti Tantra and Stree Roga, Alvas Ayurveda Medical College, Moodbidri, Karnataka, India
²Associate Professor, Dept of Prasuti Tantra and Stree Roga, SVM Ayurvedic Medical College, Ilkal, Karnataka, India

Email: hafsa1818@gmail.com

ABSTRACT

Polycystic Ovarian Syndrome (PCOS) is the most common health problem with the ovarian expression of various metabolic disorders and a wide range of clinical features such as obesity, menstrual abnormalities and hyperandrogenism. The treatment should be Kapha-Vata hora, vatanulomana, dipana, pittavardhaka along with avoidance of causative factors. Considering the above facts, Saptasaram Kashaya and Kanasatahwadi Kashaya were selected for the study. Objectives of study: To evaluate and compare the efficacy of Saptasaram Kashaya and Kanasatahwadi Kashaya in PCOS. Materials and methods: A randomized comparative clinical study of two groups, consisting of 20 patients in each group. Group A - Saptasaram Kashaya, 50ml twice daily with Guda as Anupana; before food for a period of three consecutive cycles. Group B - Kanasatahwadi Kashaya, 50ml twice daily with ghrittha bharjitha hinga; before food for a period of three consecutive cycles. Results and Interpretation: The study has shown that statistically significant difference between each group in its efficacy. Conclusion: Kanasatahwadi Kashaya showed better results than Saptasaram Kashaya, while taking the account of percentage of each criterion.

Keywords: Polycystic ovarian syndrome, Saptasaram Kashaya, Kanasatahwadi Kashaya.

INTRODUCTION

The contemporary world anticipates Ayurveda as a unique, indispensable branch of medicine that helps to preserve health by keeping the individual’s body, mind and spirit in perfect equipoise with nature. It has eight branches, the Ashtangas of Ayurveda, but there is no direct reference of Prasuti Tantra and Sthree Roga. Instead it is included by Acharya Hareetha under Kaumarabhritiya, which deals with the management of a pregnant lady, care after delivery, and management of diseases of new born and defects of breast milk. According to Shabda kalpa druma, Sthree is said to be the root cause of progeny: “Sthrayathi Garbho Yasyamithi Sthree” Therefore, women should be given to guard her from any ailments that affect motherhood. Ayurveda gives foremost care to safeguard the wellbeing of the woman as she is considered as the essential cause for the
coming generation. The act of giving birth to a child, the only occasion where both pleasure and agony work in unison is an honor reserved exclusively for women. But the erratic lifestyle of modern era – sedentary life, altering food habits and unbearable stress makes the women more exposed to diseases. PCOS is one such ailment that affect the regular function of female reproductive system which affects her sole capacity to give birth to children. It also causes changes to her physical appearance, including weight gain, male pattern hair growth and acne.

In Ayurveda there is no direct reference to PCOS but the symptoms can be correlated to a disease called Pushpaghni Jataharini\(^1\) described by Acharya Kashyapa in Revathi Kalpa Adhyaya. In this condition it is described that the patient will be having regular but futile cycles and corpulent cheeks with excessive hair. Nashtarthava\(^2\) described by Acharya Sushrutha mentions that due to vata-kapha avarana, arthavanasa occurs in females, which can be correlated with amenorrhea associated with PCOS. In vandhya yoni vyapat\(^3\), artava is destroyed. This can be considered as secondary amenorrhea or anovulation which ultimately causes infertility.

In PCOS, as it is a metabolic disorder, there is impairment in the functioning of Agni, which leads to the formation of asamyak pachita ahara rasa. Both vitiated kapha and saama rasa causes srothorodha finally leading to vata vaigunya. Psychological state of the woman is also disturbed which causes stress, anxiety, depression etc that causes vitiation of vata. Vitiated vata and kapha causes avarana of artavavaha srotas leading to arthavanaasha and vandhyathva.

The present study is aimed to bring out the influence of Ayurveda in the management of PCOS, which is safe, non-hormonal and effective against the associated symptoms still remains a challenge. The conventional methods which depends mainly on hormonal preparations and invasive techniques provide only symptomatic relief and are unaffordable too. Saptasaram Kashaya\(^4\) and Kanasatahwadi Kashaya\(^5\) will be highly beneficial in PCOS due to its authentic reference regarding the effectiveness, easy administration and absence of side effects. By this, we can focus Ayurveda into mainstream in management of Polycystic Ovarian Syndrome for the benefit of woman who are considered to be the root cause of offspring. For this purpose, Saptasaram Kashaya and Kanasatahwadi Kashaya mentioned in Sahasrayoga, Rakta gulma prakarana are selected as an oral administration in the clinical study. The dissertation is entitled as “A comparative clinical study to evaluate the efficacy of Saptasaram Kashaya and Kanasatahwadi Kashaya 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 Alva’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 available local market under the supervision of Dravyaguna expert and Kashaya choorna was prepared at Alva’s pharmacy, Mijar.

METHOD OF COLLECTION OF DATA:
The qualitative data related to clinical condition 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 sign and symptoms has been scored on basis of standard methods and is 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:
Diagnosis was based upon the presence of any two of the following three criteria:
1. Oligo and/ anovulation
Clinical Hyperandrogenism
3. Polycystic Ovaries (diagnosed with USG)

Inclusion Criteria:
1. Age group of 16 to 35 years
2. Patients fulfilling the diagnostic criteria
3. Both married and unmarried

Exclusion Criteria:
1. Patients having gross structural abnormalities of uterus and appendages
2. Those having primary amenorrhea
3. Those suffering from malignancies and chronic systemic diseases.
4. Concurrent or previous use of Oral Contraceptive Pills within last three months.
5. Endocrinological disorders like Diabetes Mellitus, thyroid abnormalities, Congenital Adrenal Hyperplasia and Hyperprolactinemia.
6. Androgen secreting tumors and Pituitary dwarfism.
7. Hypoplastic uterus and ovaries

INTERVENTIONS:
The Group A: has been given Saptasaram Kashaya to take orally in the dose of 50 ml twice daily along with Guda as Anupana; before food from day fifth of menstruation for a period of three consecutive cycles.

Method of Preparation: Drugs of Saptasaram Kashaya was purchased and prepared in the form of Kashaya choorna as coarse powder. 25 grams of kashaya choorna separately packed and advised patients to prepare fresh Kashaya every time. Mode of preparation and administration were also explained to the patients. One packet Kashaya choorna (25 grams) along with two cloves of crushed lasuna (25 grams) boiled in 400 ml of water upto 50 ml and filtered. Ghritha bharjitha hingu will be powdered and a pinch (approximately equal to 250 mg) will be added to the Kashaya. It was advised to administer 50 ml twice daily in luke warm stage along with a pinch of hingu choorna, before food.

The Group B: has been advised to take Kanasatahwadi Kashaya orally in the dose of 50 ml twice daily along with ghritha bharjitha hingu; before food from day fifth of menstruation for a period of three consecutive cycles.

Method of preparation: Drugs of Kanasatahwadi Kashaya was purchased and prepared in the form of Kashaya choorna as coarse powder. 25 grams of Kashaya choorna were packed and advised the patients to prepare fresh Kashaya every time. Mode of preparation and administration were also explained to the patients. One packet Kashaya choorna (25 grams) along with two cloves of crushed lasuna (25 grams) boiled in 400 ml of water upto 50 ml and filtered. Ghritha bharjitha hingu will be powdered and a pinch (approximately equal to 250 mg) will be added to the Kashaya. It was advised to administer 50 ml twice daily in luke warm stage along with a pinch of hingu choorna, before food.

The menstrual phase of the menstrual period has been excluded in both groups.

Period of Observation:
Assessed on fifth day after menstruation of three consecutive cycles.

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)
- Ultrasonography (Abdomen and Pelvis) for ovarian volume
- BMI

INVESTIGATIONS:
A). OBJECTIVE PARAMETRES:
1. Ultrasonography

B). SCREENING PARAMETRES:
Following investigations are done, if necessary:
1. CBC
2. ESR
3. Hormonal Assay
4. LFT
5. Lipid Profile
6. Thyroid profile
7. Diabetic Profile
DISCUSSION
In the present study it was found that clinical features of this disorder differ in 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 on the basis of improvement on main symptoms first and then on associated symptoms.

The assessment was done after the third menstrual cycle and the changes in outcome variables were analyzed statistically.

EFFECT ON INTERVAL BETWEEN CYCLES:
1. The result on criteria interval of both groups showing statistically highly significant result with P value <0.001 individually, which indicates both the groups are effective.
2. The comparative study proved to be statistically significant which indicates Kanasatahwadi Kashaya is having better result on interval between cycles.
3. If we see the percentage of relief, it is evident that in Group B percentage of relief is 68% which is high when compared to Group A which is 37.25%.
4. These may be due to dipana, paachana, kapha vata samana and pitta vardhaka properties of drugs of Kanasatahwadi Kashaya. The drugs like Kana, Sathahwa, Tila are having pitta vardhaka and artava janaka properties thus help in improving the regularity of the menstrual cycle.
5. Shathapushpa (sathahwa) mainly by its Phyto estrogenic content helps in bringing down the normal hormonal pattern of H-P-O axis and thus helps in regularizing the menstrual cycle.

EFFECT ON DURATION OF BLEEDING:
- The result on criteria of amount of bleeding in both groups showing 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 statistically significant difference between the effect of treatments in 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 45.45% which is higher when compared to Group B which is 28.57%.
- Drugs like punarnava, bilva in Saptasaram Kashaya are pitta and raktha vardhaka, srothoshodhaka which helps to increase the endometrial thickness and thus helps in the case of hypomenorrhea.
- Studies have proved the action of punarnava root on endometrial histology i.e. it increases the deposition of fibrin and platelets in the blood, hence showing the hematinic effect of the drug.
b) The comparative study proved to be having statistically significant difference between the two groups.

c) If we see the percentage of relief, it is evident that in Group A, percentage of relief is 75.67% which is high when compared to Group B which is 40%.

d) *Saptasaram Kashaya* is having better result in pain as it possesses *vatakapha samana, anulomana, rakra shodhana*. Most of the drugs own fibrinolytic property which reduces the formation of clots during menstruation which in turn reduces the pain. Also, the properties of the drugs may contribute to reduce pelvic congestion thereby reducing intensity of pain.

Drugs like *vilva* and *eranda* are proved to have anti-spasmodic activity thus acts as an analgesic

**EFFECT OF TREATMENT ON BMI:**
- The effect of treatment on BMI on two groups is not significant statistically individually with *P* value = 0.330
- The comparative study proved to be having statistically significant difference between the two groups.
- If we see the percentage of relief, it is evident that in Group B percentage of relief is 16.23% which is higher when compared to Group A which is 3.03%.
- *Kulatha, Lashuna* and *Hingu* of *Kanasatahwadi Kashaya* are having *medohara* property. By virtue of above properties these drugs can correct hyperinsulinemia and resulting 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 result individually, which indicates both groups are ineffective. The comparative study proved to be statistically significant too.

**EFFECT OF TREATMENT ON ACNE:**
a) The result on criteria Acne in both groups showing statistically highly significant result individually with *P* value < 0.001 which indicates that both Group A and Group B are effective

**EFFECT ON OVARIAN VOLUME:**
Number of follicular cyst and volume of ovary was assessed using USG. 12 or more follicles in at least one ovary measuring 2-9mm in diameter or a total ovarian volume greater than 10cm³ are suggestive of PCOS. After the treatment and follow up there was no change in the number of follicular cysts.

A) **Right Ovarian volume**: The result on effect of treatment on Rt. Ovarian volume of Group A and Group B showing statistically highly significant result with *P* value <=0.001. Which indicates both Group A and Group B are effective

B) The comparative study proved to be having statistically significant difference between the two groups

C) If we see the percentage of relief, it is evident that in Group B which is 38.35% is high as compared to Group A (24.45%)

**EFFECT ON OVARIAN VOLUME:**
Number of follicular cyst and volume of ovary was assessed using USG. 12 or more follicles in at least one ovary measuring 2-9mm in diameter or a total ovarian volume greater than 10cm³ are suggestive of PCOS. After the treatment and follow up there was no change in the number of follicular cysts. This shows that both the medicine was not effective in reducing the number of follicular cysts.

A) **Right Ovarian volume**: The result on effect of treatment on Rt. Ovarian volume of Group A and Group B showing statistically highly significant result with *P* value =<0.001. Which indicates both Group A and Group B are effective

B) The comparative study proved to be having statistically significant difference between the two groups

C) If we see the percentage of relief, it is evident that in Group B which is 38.35% is high as compared to Group A (24.45%)

D) **Left Ovarian Volume**: The result on effect on treatment on Lt. Ovarian volume of Group A and Group B showing statistically highly significant
with P value=<0.001. Which indicates both Group A and B are effective

E) The comparative study proved to be having no statistically significant difference between two groups

F) If we see the percentage of relief, it is evident that in Group B which is 32.53% is high as compared to Group A (27.24%)

G) Drugs in Kanasatahwadi Kashaya are having more Ushna veerya and theekshna guna, which promotes Kapha shoshana and hence reduces the ovarian volume

**OVERALL ASSESSMENT:**
There was marked improvement in 10% of cases in group B and no marked improvement results in group A. There was mild improvement in 80% in group B and 30% of cases in group A. There was moderate improvement in 10% of cases in group B whereas 5% of cases in group A and 65% of minimal improvement in group A.

Table 1: COMPARITIVE EFFECT OF GROUPS

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>MEAN DIFFERENCE</th>
<th>% of relief</th>
<th>T Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Interval between cycles</td>
<td>0.95</td>
<td>0.15</td>
<td>37.2%</td>
<td>68%</td>
</tr>
<tr>
<td>Duration of bleeding</td>
<td>0.60</td>
<td>0.35</td>
<td>29.2%</td>
<td>25%</td>
</tr>
<tr>
<td>Amount of bleeding</td>
<td>2.10</td>
<td>0.60</td>
<td>45.5%</td>
<td>28%</td>
</tr>
<tr>
<td>Pain</td>
<td>1.40</td>
<td>0.45</td>
<td>75.6%</td>
<td>40%</td>
</tr>
<tr>
<td>BMI</td>
<td>0.05</td>
<td>0.30</td>
<td>3.03%</td>
<td>16.2%</td>
</tr>
<tr>
<td>Hirsutism</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acanthosis nigricans</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acne</td>
<td>0.40</td>
<td>0.10</td>
<td>33.3%</td>
<td>84.6%</td>
</tr>
<tr>
<td>Rt.Ovarian volume</td>
<td>3.95</td>
<td>6.85</td>
<td>24.3%</td>
<td>38.4%</td>
</tr>
<tr>
<td>Lt.Ovarian volume</td>
<td>4.25</td>
<td>4.95</td>
<td>27.2%</td>
<td>33.5%</td>
</tr>
</tbody>
</table>

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

**CONCLUSION**

PCOS is not a completely curable disease, but the symptoms can be alleviated by proper medications along with lifestyle modifications and daily exercise. No direct correlation of PCOS is found in Ayurvedic classical texts. *Pushpaghni jataharini* men-
tioned by *Kashyapa samhita* bears some resemblance with PCOS. *Dosha vaigunya* in this condition is *Kapha Vridhi* and *Vata prakopa*. Along with *dosha vaigunya*, *vishama ahara* and *vihara* leads to impairment in function of *agni* at various levels which results in *avarana* of *srothas* leading to incomplete metabolism due to *ama* and thus hormonal imbalance that causes hyperinsulinemia and hyperandrogenism causing anovulation, menstrual irregularities and ovarian abnormalities like polycystic ovaries. The study has shown that statistically significant difference between each group in its efficacy when comparing. While taking the account of percentage of relief in each criteria, *Kanasatahwadi Kashaya* showing better results in restoring normal menstrual cycle, BMI, Acne and in reducing the volume of right and left ovaries; while *Saptasaram Kashaya* showing better results in Amount and duration of bleeding and intensity of pain. Both the drugs showed no effect in hirsutism and Acanthosis nigricans. Hence null hypothesis is rejected; Alternate hypothesis (H3) is accepted i.e. *Kanasatahwadi Kashaya* is more effective than *Saptasaram Kashaya* in PCOS.

**REFERENCES**


**Source of Support: Nil**

**Conflict Of Interest: None Declared**