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

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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 hara*, *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 *ghritha bharjitha hingu*; 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 *Kaumarabhritya*, which deals with the management of a pregnant lady, care after delivery, and man-

agement of diseases of new born and defects of breast milk.

According to *Shabda kalpa druma*, *Stree* 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 described by Acharva *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. Nashtarthava² described by Acharya Sushrutha to *vata-kapha* mentions that due arthavanasa occurs in females, which can be correlated with amenorrhea associated with PCOS. In vandhya yoni vyapat³, artava is destroyed. This can be considered as secondary amenorrhoea 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 Kashaya⁴ and Kanasatahwadi Kashaya⁵ 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

- 2. 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) added with 400ml of water and boiled up to 50 ml and filtered. Patient has to take in luke warm stage twice daily along with *guda* (3 grams) 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 pa-

tients 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* is boiled in 400 ml of water upto to 50 ml and filtered. *Ghritha bharjitha hingu* will be powdered and a pinch (approximately equal to 250mg) 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.

ASSESMENT 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:

- a). The result on criteria duration of bleeding in group A showing statistically highly significant result with P value = <0.001 and Group B showing statistically significant result with P value = 0.005 which indicates that both the Group A and Group B are effective
- b). The comparative study proved to be having statistically significant difference between the effect of treatments on duration of bleeding in Group A and Group B.

- c). If we see the percentage of relief, it is evident that in Group A, percentage of relief is 29.4% and for group B is 25%.
- d). These may be due to Ama pachana, dipana, srothoshodhana,,vata kapha samaka properties of Saptasaram kashaya and Kanasatahwadi kwatha. Guda which is the anupana in Saptasaram Kashaya is raktha vardhaka. Shunti, Sahachara and Eranda in Saptasaram Kashaya are ushna veerya and possess vata anulomana property which helps in removing the shrothorodha and removes the avarana of kapha, thus helps to improve the duration of bleeding. Agnimantha and shunti are known for its ama pachana properties which also help to improve the days of bleeding within its normal limits.

EFFECT ON AMOUNT 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, bilwa 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.

EFFECT OF TREATMENT ON INTENSITY OF PAIN:

a) The result on criteria of intensity of pain in both groups showing statistically highly significant results with P value =< 0.001 which indicates both the groups 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 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, rakta 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 *vilwa* and *eranda* are proved to have antispasmodic 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 individu-

- ally with P value < 0.001 which indicates that both Group A and Group B are effective
- b) The comparative study proved to be having statistically significant difference between two groups.
- c) If we see the percentage of relief, it is evident that in Group B which is 63.15% is high as compared to Group A (36.34%)
- d) The drugs which are used in *Kanasatahwadi* and *Saptasaram Kashaya* are having the properties of *deepana pachana* and drugs like *Tila* is having *varnya* property.

Also, the drugs are *dipana- pachana* which corrects the metabolism by correcting the function of *dhathwagni* and by promoting the *poshana* of *raktha dhathu* which aids in reduction of *mughadushika* and also acting on patho-physiological aspect bringing about ovulation and thereby correcting the hormonal imbalance.

Karanja and *devadaru* are *vibandhahara* which acts upon the clogged pores of the skin, reduce *kapha* i.e excess sebum and hence cures the acne.

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 ASSESMENT:

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 SYMPTOMS MEAN DIFFERENCE % of relief T Value P Value A В A В 0.95 0.15 37.2% 68% Interval between cycles 2.702 0.010 0.35 29.2% Duration of bleeding 0.60 25% 8.786 < 0.001 Amount of bleeding 2.10 0.60 45.5% 28% 9.971 < 0.001 1.40 0.45 75.6% 40% 9.810 < 0.001 Pain 0.05 0.30 3.03% 16.2% 0.007 **BMI** 2.584 0 Hirsutism 0 0 0 0 0 0 0 0 0 0 0 Acanthosis nigricans 0.40 0.10 33.3% 84.6% 0.048 Acne 2.042 Rt.Ovarian volume 3.95 6.85 24.3% 38.4% 4.243 < 0.001

4.25 27.2% 33.5% < 0.001 Lt.Ovarian volume 4.95 1.198

100.00% 80.00% 60.00% 40.00% 20.00% 0.00% ■ Group A ■ Group B 🎾

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 mentioned 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.

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