

## **A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHADUSHNA KWATHA AND KANASATAHWATI KWATHA IN PCOS**

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### **ABSTRACT**

PCOS is considered as a hyperglycemic condition. Although exact etiology of PCOS is not known, it is a condition with several hormonal disturbances including hyperandrogenemia, insulin resistance and hyperinsulinemia. We do not find description of PCOS in Ayurvedic classical texts, but considering the symptoms, it can be correlated with *Granti Bhootha Aartava* or *Pushpaghni Jataharini*. In this study, an effort is made to evaluate and statistically analyze the efficacy of *Shadushna kwatha* and *Kanasatahwati kwatha* in PCOS. These drugs are known to have *Kapha Vata Shamaka* and *Deepana Pachana* properties. **Objectives of Study** 1. A Comprehensive study of PCOS and its congruence in *Ayurveda*. 2. To study the efficacy of *Kanasatahwati Kwatha* and *Shadushna kwatha* 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 will be taken. Diagnostic criteria were randomly placed in two equal groups. **The Group A** *Kanasathwati kwatha* in the dose of 50ml orally twice daily before food with luke warm water as *anupana* for a period of 3 cycles. **The Group B** *Shadushna kwatha* in the dose of 50ml orally twice daily before food with luke warm water as *anupana* for a period of 3 cycles. **Results and Interpretations:** Clinical parameters were assessed statistically and results will be concluded. The significance between both the groups will be observed. **Conclusion:** *Kanasatahwati kwatha* is having a better result than *Shadushna Kwatha* in PCOS.

**Keywords:** PCOS; *Kanasatahwati Kwatha*; *Shadushna Kwatha*

### **INTRODUCTION**

Menstrual cycle or menstruation in women is a natural physiological process. Modern women live a stressful life which is affecting their mental and physical well being adversely. One of the most common menstrual disorders being observed in women is PCOS (Poly Cystic Ovarian Syndrome).

PCOS is a heterogeneous endocrine disorder leading to several health complications including menstrual dysfunction, infertility, hirsutism, acne, obesity and metabolic syndrome. PCOS is considered to be the most common life style disorder, and the world wide prevalence of PCOS is 6.5-6.8% according to NIH

criteria.<sup>1</sup> It occurs among all the races and nationalities. It is an endocrine disorder affecting women in their reproductive life. It is an ovarian cause of secondary amenorrhoea which not only hampers the normal menstrual cycle but also has significant affliction on the fertility of the lady.

The exact pathophysiology of PCOS is not clearly understood but it can be assumed that PCOS occurred due to excess of production of the androgen by the ovaries<sup>2</sup>. Considering the contemporary science, it is known to feature several hormonal disturbances including hyperandrogenemia, insulin resistance and hyperinsulinemia<sup>3</sup> and accordingly the treatment is given like hormonal therapy, anti diabetic drugs and surgical ovarian drilling techniques etc. Administration of this hormonal therapy may lead to adverse effects. Hence it is necessary to modulate an alternative medical support, which is of cost effective and cause no adverse effects.

The strength of Ayurveda is the principle of bringing about balance in the *Shareera* and *Manas*. There is no direct reference about this disease in Ayurvedic texts, which indicates that this symptomatology was comparatively less prevalent in the ancient times. Considering the symptoms of PCOS, it can be inferred that, in this *avastha*, there is *Avarodha* of *Pushpa* and *Vata* by the *dushita Kapha* and *Medas* where *Anavasthitachittatva* is a major *nidana*. *Pushpaghni Jaataharini*<sup>4</sup> mentioned by *Kashyapa* bears some resemblance with symptoms of PCOS. From this one can assume that the main dosha which involved in PCOS is the *Kapha* and *Vata*. And our *Acharya's* has been mentioned many good drugs which are having *Kaphavata shamaka* properties. So there is a wide scope of research in *Ayurveda* to find out the best medicine which is safe and potent remedy to reduce the symptoms, the size of the cyst and to normalize the ovulation. *Kanashatahwati kwatha*<sup>5</sup> and *Shadushna kwatha*<sup>6,7</sup> are the *yogas* which contains drugs having *Kaphavata shamana* and *dipana pachana* properties.

Hence in this study, an effort is made to evaluate and statistically analyze the efficacy of *Shadushna kwatha* and *Kanasatahwadi kwatha* in PCOS.

## Materials and Methods

### Source of Data

- **Literary Source**

All the Classical, Modern literature, Journals and Websites about the disease and the medicine has been reviewed and documented for the planned study.

- **Sample Source**

40 Patients diagnosed with PCOS 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 required has been identified and collected from the available local market and the *Kwatha* has been prepared according to the classical reference at Alva Pharmacy, Mijar.

### Method of collection of data

A separate case sheet has been prepared with a complete history, physical signs and symptoms, necessary lab Investigations and Ultra sonography (Abdomen and Pelvis). The parameters of signs 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 is based upon the presence of any two of the following three criteria:

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

### Inclusion Criteria

1. Age group of 18yrs to 35 yrs.
2. Patients fulfilling the Diagnostic criteria.
3. Both married and single.

### **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

### **Interventions**

**The Group A** has been given *Kanasathwati kwatha* in the dose of 50ml orally twice daily before food with luke warm water as *anupana* for a period of 3 cycles.

**The Group B** has been given the *Shadushna kwatha* in the dose of 50ml orally twice daily before food with luke warm water as *anupana* for a period of 3 cycles.

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

### **Period of observation**

A Visit at the end of the menstrual phase of each cycle for a study period of 3 consecutive cycles.

### **Assessment Criteria**

#### **Subjective Parameters**

- Duration of inter-menstrual period
- Duration of menstrual phase
- Amount of bleeding (number of pads)

#### **Objective Parameters**

- BMI
- Hirsutism
- Acne
- Cyst

#### **Investigations**

1. Ultrasonography of abdomen and pelvis.
2. Following investigations are done if necessary
  - Hormonal Essay
  - Lipid profile
  - Thyroid profile
  - Diabetic profile

## **DISCUSSION**

### **Effect of the therapies on subjective and objective criteria:**

In the present study it was found that clinical features of this condition vary in patient to patient. As

menstrual irregularities are found in majority of the patients, associated symptoms like hirsuitism, obesity, acne were not present in all patients. So the effect of therapy was mainly evaluated on the basis of improvement on main symptoms first and then on associated symptoms.

### **Effect on Interval between two menstrual cycles:**

1. The result on the criteria of interval between two menstrual cycle of which Group A shows statistically highly significant result, whereas Group B shows insignificant result.
2. The comparative study proved to be statistically significant which indicates *Kanasatahwati Kwatha* is having better result on interval between two menstrual cycles.
3. If we see the % of relief, it is evident that in Group A (57.14%), the percentage of relief on interval is highly compared to Group B (10.34%)
4. These may be because of *Amapachana*, *Srotosodhana* and *Kapha Vata Samaka* properties of drugs in *Kanasatahwadi Kwatha*. Also the drugs such as *Kana*, *Sathahwa*, *Tila* are having *Pittakara* and *Artavajanaka* properties thus help in inducing the menstrual cycle.

### **Effect on Amount of Bleeding:**

1. The result on criteria amount of bleeding of both groups showing statistically highly significant result individually, which indicates both Group A and Group B are effective
2. The comparative study proved to be statistically significant which indicates *Kanasatahwati Kwatha* is having better result on amount of bleeding.
3. If we see the % of relief, it is evident that in Group A (79.06%), the percentage of relief on amount is highly compared to Group B (47.61%)
4. Some of the drugs in *Kanasathwadi Kwatha* are having *Pittakara* and *Arthavapravartaka* properties and thus helps in the case of oligomennorhoea and hypomennorhoea.

### **Effect on Duration of Bleeding:**

1. i)The result on criteria duration of bleeding in both groups showing statistically highly significant result individually, which indicates both the Group A and Group B are effective
2. (ii)The comparative study proved to be no significant difference in duration of bleeding in the effect of treatment in both the groups
3. (iii) If we see the % of relief, it is evident that in Group A(41.02%), the percentage of relief on interval is highly compared to Group B(22.64%)
4. (iv) These may be because of *Amapachana*, *Srotosodhana* and *Vata Kapha Samaka* properties of both drugs in *Kanasatahwadi Kwatha* and *Shadushna Kwatha*

### **Effect on Intensity of Pain during menstruation**

- (i)The result on criteria duration of bleeding in both groups showing statistically highly significant result individually, which indicates both the Group A and Group B are effective
- (ii)The comparative study proved to be no significant difference in the intensity of pain during menstrual cycle in the effect of treatment in both the groups
- (iii)If we see the % of relief, it is evident that in Group A (86.36%), the percentage of relief on interval is highly compared to Group B(79.92%)
- (iv) *Vatakapha Samana* , *Anulomana*, *Raktha Sodhana*, properties of the drugs may contribute to reduce pelvic congestion thereby reducing intensity of pain.

### **Effect on BMI, Hirsutism And Follicular Size**

#### **P value of all criteria of Group A and Group B**

Signs and symptoms	Mean difference and P value		Percentage of relief		t value (with 38df)	P value	Significance
	Group A	Group B	Group A	Group B			
Interval between the cycles	0.800 P < 0.001	0.150 P < 0.001	57.14%	10.34%	5.284	P <0.001	Equally effective (statistically highly significant)
Duration of bleeding	0.800 P <0.001	0.600 P < 0.001	41.02%	22.64%	1.378	P = 0.176	Equally effective (statistically insignificant)
Amount of bleed-	1.700	1.000	79.06%	47.61%	3.390	P = 0.002	Equally effective

(i)The result on this criterion on BMI, Hirsutism and Follicular size of both groups showed statistically insignificant result individually, which indicates both groups are ineffective. The comparative study proved to be statistically insignificant too.

### **Effect on Acne**

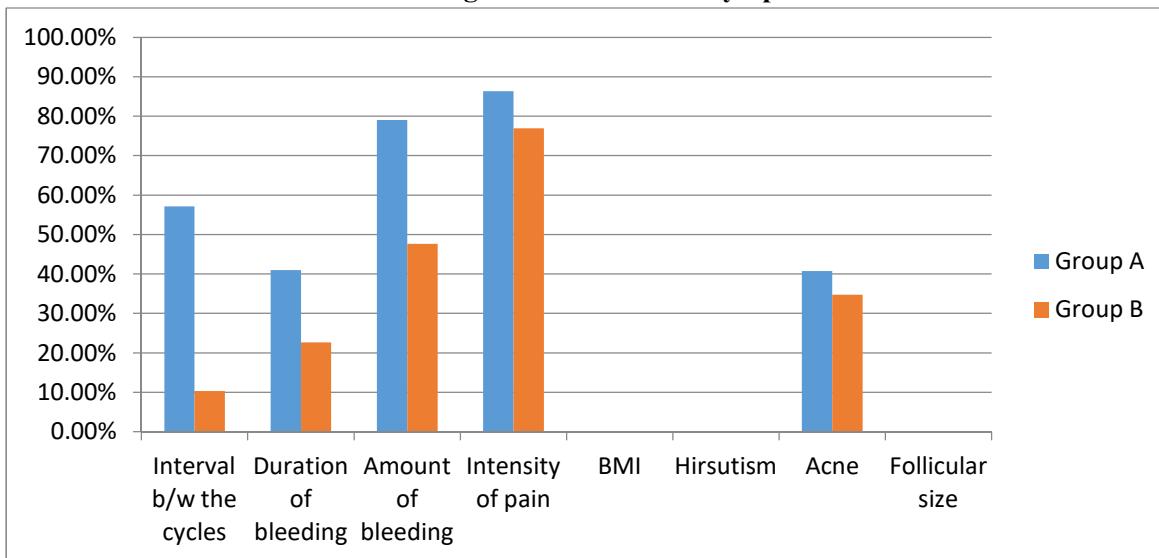
1. The result on criteria of acne in both groups showing statistically highly significant result individually, which indicates both the Group A and Group B are effective
2. The comparative study proved to be no significant difference in acne in the effect of treatment in both the groups
3. If we see the % of relief, it is evident that in Group A(40.74%), the percentage of relief on amount is highly compared to Group B (34.78%)
4. The drugs which are used in *Kanasatahwati* and *Shadushna Kwatha*, both are having the properties of *Deepana Pachana* and drugs like *Tila* is having *Varnya* properties and thus helps in the formation of *Dhatus* (*Poshana* of *Raktha Dhathu*) which aids in the reduction of *Mughadushika* and also acting on the pathophysiological aspect bringing about ovulation and thereby correcting the hormonal imbalance.

### **Overall assessment**

There was mild improvement in 90% of cases in group A and 35% of cases in group B; moderate improvement in 10% of cases in group A and 65% of minimal improvement is seen in Group B.

	P < 0.001	P < 0.001					(statistically significant)
Intensity of pain	0.950 P< 0.001	1.000 P<0.001	86.36%	76.92%	0.297	P= 0.768	Equally effective (statistically insignificant)
BMI	1.250 P = 1.000	1.150 P = 1.000	0%	0%	1.000	P= 0.324	Insignificant
Hirsutism	0.450 P = 1.000	0.700 P = 1.000	0%	0%	0.00	P= 1.000	Insignificant
Acne	0.800 P < 0.001	0.750 P = 0.008	40.74%	34.78%	0.853	P= 0.399	Equally effective (statistically insignificant)
Size of cysts	1.350 P = 1.000	1.000 P= 1.000	0%	0%	0.00	P = 1.000	Insignificant

Percentage of Relief in each Symptom



## CONCLUSION

- A sedentary and stress dominated lifestyle of the young woman today has led to the increased incidence of PCOS.
- Kapha-Vata avarana* to the *arthava vaha srothas* can cause *nashtartha* or *aartavakshaya* which is high up in PCOS.
- Agneya* quality of *Pitta* is reduced in PCOS which is essential for normal *arthava pravrithi*.
- The line of treatment should be of *kapha vata hara* and *pitta vardhana*.
- The study has shown *Kanasatahwati kwatha* is more effective than *Shadushna kwatha* in

oligo/hypomenorrhoea, acne and also helps in restoring the normal menstrual cycle. So the null hypothesis is rejected. Alternate hypothesis is accepted (H3) i.e. *Kanasathwadi kwatha* is more effective than *Shadushna kwatha* in the treatment of PCOS.

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