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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *PATOLADI KWATHA* ALONG WITH *NAVAKA GUGGULU* IN POLYCYSTIC OVARIAN SYNDROME WITH SPECIAL REFERENCE TO *ARTAVAKSHAYA*

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ABSTRACT

Polycystic ovarian syndrome is a systemic, endocrinal and also a metabolic disorder and it is the most common cause of hyperandrogenic chronic anovulation occurring in reproductive age group. Acharya Kashyapa mentioned about *Pushpagni jataharini*, it bears some resemblance with symptoms of PCOS. But most of the symptoms seen in this disease are related to the *Artavavaha srotas*. The factors which vitiate *Kapha*, *Vata*, and *Meda* have a considerable role in this disease. So here an attempt has been made to work on the efficacy of *Patoladi Kwatha* along with *Navaka Guggulu* in PCOS, as it is mentioned that *Patoladi Kwatha* is *Hitakara* for *Andadhara roga* in *Andadhaara roga chikitsa adhyaya* of *Bhaishajya Ratnavali.* **Methods:** Convenient sampling and interventional analytical experimental study were carried out for 30 patients fulfilling the diagnostic criteria for PCOS. Group A with *Patoladi kwatha* along with *Navaka guggulu* and Group B with *Varunadi kwatha* along with *Kanchanara guggulu* were given for 60 days and 30 days follow up also done by drug free period. **Results:** In group A, 60% had moderate improvement and 40% had marked improvement from PCOS. In group B, 46.66% had moderate improvement and 53.33% had minor improvement from PCOS. **Conclusion:** Polycystic Ovarian syndrome, the term itself indicates more than one symptom and hence possibility for multisystem involvement with ovarian dysfunction. The factors which vitiate *Kapha*, *Vata*, and *Meda* have a considerable role in this disease. So, to treat this, drugs should have the properties like *Ushna, Teekshna guna, Kapha vata hara* and *Medahara* or *Lekhaniya karma*. The *Patoladi kwatha* along with *Navaka guggulu* is having all these properties. Thus, *Patoladi kwatha* along with *Navaka guggulu* is superior to *Varunadi kwatha* along with *Kanchanara guggulu* for the treatment of PCOS w.s.r to *Artavakshaya*.

INTRODUCTION

Polycystic ovarian syndrome is a systemic, endocrinal and also a metabolic disorder and it is the most common cause of hyperandrogenic chronic anovulation occurring in reproductive age group. Stein and Leventhal initially described it in 1935[1]. The exact etiology of the PCOS remains unknown, but it is very common nowadays due to sedentary lifestyle and unhealthy eating habits.

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In Ayurvedic literature, no direct correlation of PCOS is available. As the name suggests it is group of many disorders hence a single *Yoni- vyapad* or any single disease cannot be corelated with this entity. Acharya Kashyapa mentioned about *Pushpagni jataharini*, it bears some resemblance with symptoms of PCOS. But most of the symptoms seen in this disease are related to the *Artavavaha srotas*. That is vitiated *Kapha dosha* blocks the physiological function of the *Apana vata*, leading *Anartava*. The factors which vitiate *Kapha*, *Vata*, and *Meda* have a considerable role in this disease.

One in every 10 women in India has PCOS. The incidence varies between 0.5-4 percent and it is prevalent in young reproductive age group (20-30%)[2]. The treatment given in modern system of

medicine is hormonal therapy and medications used in Diabetes like metformin etc. Prolonged use of these tablets causes adverse effect on body. So, to avoid these hazards, safe Ayurvedic non-hormonal therapy is required. In PCOS, considering the involvement of *Dosha* predominant, based on that the treatment should be planned and it should be aimed at pacifying the vitiated *Kapha*, making the *Vata anulomana* and increasing the *Agneya guna* of *Pitta*.

Acharya Govind das has mentioned about *Patoladi kwatha* in *Andadhara roga chikitsa adhyaya* in *Parishista prakarana* context of *Bhaishajya ratnavali*. He mentioned that *Patoladi kwatha* is *Hitakara* for *Andadhara roga.*

Acharya chakradutta in *Chikitsa samgraha* mentioned about *Navaka guggulu* in the context of *Sthoulya chikitsa*. It is used in all the diseases which is caused by *Medas, Kapha, Ama* and *Vata*.

OBJECTIVES OF THE STUDY

- To evaluate the effect of *Patoladi Kwatha along* with *Navaka Guggulu* in the management of PCOS.
- To re-evaluate the effect of *Varunadi Kwatha* along with *Kanchanara Guggulu* in the management of PCOS.
- To compare the efficacy of *Patoladi Kwatha* along with *Navaka Guggulu* and *Varunadi Kwatha* along with *Kanchanara Guggulu* in the management of PCOS.

MATERIALS AND METHODS

Since the present study was a controlled clinical study two drugs i.e., trial drug and control drug were selected. They are

1. *Patoladi Kwatha* along with *Navaka Guggulu* orally.
2. *Varunadi Kwatha* along with *Kanchanara Guggulu* orally.

The raw drugs for *Patoladi Kwatha* was collected from authentic sources and was identified and approved by Department of *Dravya guna* and preparation of medicine were done in pharmacy of *Rasashastra* and *Bhaishajya Kalpana* of Sri Sri College of Ayurvedic Science and Research, Bengaluru. The *Navaka Guggulu* tablet, *Varunadi Kwatha* and *Kanchanara Guggulu* tablet were procured from GMP certified pharmacy.

Sampling Method and Research Design

Source of data- A 30 subjects fulfilling the diagnostic criteria of PCOS irrespective of their caste, religion, race, socioeconomic status was taken from OP and IP department of *Prasuti tantra* and *Streeroga* of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. The selected 30 patients were divided in to 2 equal groups of 15 patients and detailed proforma were prepared considering all points pertaining to the study subject.

Research Design

- A simple randomized open label controlled clinical study.
- Thirty subjects fulfilling the diagnostic criteria of PCOS symptoms were selected and randomly categorized to Group A and Group B by using lottery method.

Diagnostic Criteria

Diagnosis is based on presence of the following criteria:

- Subjects who meet Rotterdam criteria[3] (oligo/anovulation, polycystic ovaries, clinical presentation of hyperandrogenism).
- Pattern of uterine bleeding (i.e., amenorrhea or oligomenorrhea).
- Polycystic ovaries (diagnosed with USG).
- Clinical presentations like obesity, hirsutism, *Yoni vedana*.
- All the subjects conforming to the above said inclusion criteria were included in the study and subjected to thorough interrogation, physical and sonographic examinations.

Inclusion Criteria

- Subjects between the age group of 20 years to 45 years, irrespective of marital status.
- Subjects who meet Rotterdam criteria.
- Subjects presenting with the classical symptoms of *Artavakshaya*.
- Subjects presenting with the symptoms of oligomenorrhea, secondary amenorrhea or hypomenorrhea.
- Polycystic ovary (5 or more follicles in at least one ovary measuring 2-9mm[4]) confirmed with USG.

Exclusion Criteria

- Subjects with primary amenorrhea.
- Subjects using of oral contraceptives (current or within the last 3 months).
- Subjects with menorrhagia, metrorrhagia, menometrorrhagia were excluded.
- Subjects suffering from malignancies and chronic systemic diseases.

General Investigation

- Hb%
- RBS
- Hormonal assay (LH and FSH)
- USG

Intervention

	Group A	**Group B**
Medicines	*Patoladi Kwatha along* with *Navaka Guggulu*	*Varunadi Kwatha along* with *Kanchanara Guggulu*
Dose	*Kasaya*- 50ml BD, Tablet-2 BD	*Kasaya*-50 ml BD, Tablet-2 BD
Time of administration	Before food	Before food
Duration of study	90 days (Trial period-60 days, drug free period- 30 days)	90 days (Trial period-60 days, drug free period- 30 days)

Follow Up On 30th day, 60th day and 90th day

Assessment Criteria

In classics, *Artava kshaya lakshana* like *Akaala darshana*, *Alpa artava* and *Yonivedana* is mentioned. Based on these symptoms we can assess the subject who is having PCOS with *Artavakshaya*.

Subjective Parameters

- Duration of bleeding
- Interval between 2 menstrual cycles
- Amount of bleeding
- Pain during menstruation (*Yoni vedana*)

Objective Parameters

- No of follicular cysts
- LH: FSH Ratio
- Volume of the Ovary
- BMI
- Hirsutism (Ferriman - Gallway scale)
- Acne (Global acne grading system)

Assessment Schedule

In both the groups' assessment was done on:

- 0th day – before treatment
- 30th day- after 1st month of treatment
- 60th day- after 2nd month of treatment
- 90th day- follow up

Table 1: Showing Grading of subjective and objective criteria

Parameter	**Grading**	**Findings**
Duration of bleeding	0	6-7 days
	1	4-5 days
	2	3-4 days
	3	1-2 days
Interval between 2 menstrual cycles	0	25-34 days
	1	35-44 days
	2	45- 54 days
	3	>54 days
Amount of bleeding	0	4pads/day
	1	3 pads/day
	2	2 pads/day
	3	1 pad/day
Pain during menstruation	0	No pain
	1	Mild pain
	2	Moderate pain
	3	Severe pain

Number of follicular cysts	0	<5
	1	5-10
	2	11-15
	3	>15
LH: FSH Ratio	0	≤ 2:1
	1	3:1
	2	4:1
	3	>4:1
Volume of ovary	0	<10cc
	1	10-12cc
	2	13-15cc
	3	16-18cc
	4	>18cc
BMI	0	Lean (<18.5)
	1	Normal (18.5-24.9)
	2	Over weight (25-29.9)
	3	Obese (30-39.9)
	4	Morbid obesity (>40)
Hirsutism	1	<8-Normal
	2	8-15-Mild
	3	>15 Moderate/Severe
Acne	0	1-18 (Mild)
	1	19-30 (Moderate)
	2	31-38 (Severe)
	3	>38 (Very severe)

OBSERVATIONS

In the present study, 30 patients were diagnosed with PCOS were randomized in to 2 groups. The following observations were done during the study.

Age: Among the 30 cases registered for the study, 33.33% of cases were from the age group of 20-25 years; 36.66% from 26-30years, 26.66% from 31-35years, 3.33% from 36-40years and 0% from 41-45 years of age.

Marital Status: Among the 30 cases, 30% of subjects are unmarried and 70% of subjects are married.

Religion: Among the 30 subjects, all patients are in Hindu religion.

Domicile: In this study, 43.33% of people were live in rural area and 56.66% were live in urban area.

Education: Among the 30 cases, no illiterate persons were there (0%), 3.33% of subjects completed primary education, 33.33% completed secondary education, 63.33% of subjects studied in college.

Nature of Work: Among the 30 cases, 36.66% of subjects were following the sedentary lifestyle, 63.33% of subjects doing moderate work.

Exercise: In this study, 10% of subjects were doing physical exercises and 90% of subjects were not doing physical exercises.

Diet: In this study, 26.33% subjects were vegetarians and 73.33% subjects were in mixed diet.

Sleep: In this study, 30% of subjects had disturbed sleep, 70% of subjects had continuous sleep.

Bowel Habits: Among the 30 cases, 26.66% of subjects had constipation problem, 3.33% of subjects had loose motion and 70% of subjects had normal bowel habits.

Appetite: Among the 30 cases, 16.66% of subjects had poor appetite, 63.33% of subjects had moderate appetite, 13.33% of subjects had good appetite and 6.66% of subjects had excessive appetite.

Psychological Status: Among the 30 cases, 16.66% of subjects had experienced anxious, 10% of subjects had irritable mind and 73.33% of subjects had experienced stressed.

Prakriti: Among the 30 cases, 10% of subjects had *Vata-pitta prakriti*, 26.66% of subjects had *Vata-kapha prakriti*, 6.66% of subjects had *Pitta-vata prakriti*, 10% of subjects had *Pitta-kapha prakriti,* 20% of subjects had *Kapha-vata prakriti*, 26.66% of subjects had *Kapha-pitta prakriti.*

RESULT

In the present study, Mann Whitney rank sum test was carried out for comparison between the groups, Wilcoxon signed rank test and Friedman Repeated Measures Analysis of Variance on Ranks with in the group.

Table 2: Duration of bleeding at different points of time

Duration of bleeding at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	2.000 (1.000-2.000)	1.000 (1.000-1.000) @ *
Group B	2.000 (2.000-3.000)	2.000 (2.000-2.000)

@- P< 0.05 in comparison to D0 values. Duration of bleeding increased after 2 months of treatment and 1 month follow up in group A (Wilcoxon signed rank test).

*- p= 0.001 In comparison to group B values. (Mann-Whitney Rank Sum Test)

- In Group A significant difference could be observed after 90 days of follow up in increase in duration of bleeding within the group. In group B no significant difference could be observed after 90 days of follow up in increase in duration of bleeding within the group. Comparison shows that the difference between the groups was highly significant after 90 days of follow up.
- r =0.51 in group A and r =0.29 in group B after 90 days of follow up.
- In Group A, effect size is found to be large after 90 days of treatment- indicative of more improvement in the clinical status in this parameter.

Table 3: Interval between 2 menstrual cycles at different points of time

Interval between 2 menstrual cycles at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	2.000 (1.000-3.000)	1.000 (0.000-1.000) @ *
Group B	2.000 (1.000-3.000)	2.000 (1.000-3.000)

@- P< 0.05 in comparison to D0 values. Interval between 2 menstrual cycles reduced after 2 months of treatment and 1 month follow up in group A (Wilcoxon signed rank test).

*- p= 0.001 In comparison to group B values (Mann-Whitney Rank Sum Test).

- In Group A significant difference could be observed after 90 days of follow up with decrease in interval between 2 menstrual cycles within the group. In group B no significant difference could be observed after 90 days of follow up in decrease in interval between 2 menstrual cycles within the group. Comparison shows that the difference between the groups was highly significant after 90 days of follow up.
- r =0.62 in group A and r =0.41 in group B after 90 days of follow up.
- In group A, effect size is found to be large after 90 days of treatment- indicative of more improvement in the clinical status in this parameter and in group B, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter.

Table 4: Amount of bleeding at different points of time

Amount of bleeding at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	2.000 (2.000-3.000)	2.000 (1.000-2.000) @ *
Group B	2.000 (2.000-3.000)	2.000 (2.000-2.000)

@- P< 0.05 in comparison to D0 values. Amount of bleeding increased after 2 months of treatment and 1 month follow up in group A. (Wilcoxon signed rank test)

*- p= 0.008 In comparison to group B values. (Mann-Whitney Rank Sum Test)

- In group A significant difference could be observed after 90 days of follow up in increase in amount of bleeding within the group. In group B no significant difference could be observed after 90 days of follow up in increase in amount of bleeding within the group. Comparison shows that the difference between the groups was highly significant after 90 days of follow up.
- r =0.48 in group A and r =0.41 in group B after 90 days of follow up.
- In group A, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter and in group B, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter.

Table 5: Pain during menstruation at different points of time

Pain during menstruation at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	2.000 (1.000-3.000)	0.000 (0.000-0.000) @ *
Group B	1.000 (0.000-3.000)	1.000 (0.000-2.000)

@- P< 0.05 in comparison to D0 values. Pain during menstruation reduced after 2 months of treatment and 1 month follow up in group A. (Wilcoxon signed rank test)

*- p= 0.001 In comparison to group B values. (Mann-Whitney Rank Sum Test)

- In group A significant difference could be observed after 90 days of follow up in reducing the pain during menstruation within the group. In group B no significant difference could be observed after 90 days of follow up in reducing the pain during menstruation within the group. Comparison shows that the difference between the groups was highly significant after 90 days of follow up.
- r =0.57 in group A after 90 days and r =0.26 in group B after 90 days of follow up.
- In group A, effect size is found to be large after 90 days of treatment- indicative of more improvement in the clinical status in this parameter and in group B, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter.

Table 6: LH: FSH Ratio at different points of time

LH: FSH Ratio at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	1.000 (0.000-2.000)	0.000 (0.000-1.000) @ *
Group B	1.000 (1.000-2.000)	1.000 (1.000-2.000)

@- P< 0.05 in comparison to D0 values. LH: FSH ratio reduced after 2 months of treatment and 1 month follow up in group A. (Wilcoxon signed rank test)

*- p = 0.001 In comparison to group B values. (Mann-Whitney Rank Sum Test)

- In group A significant difference could be observed after 90 days of follow up in normalizing the LH: FSH ratio within the group. In group B no significant difference could be observed after 90 days of follow up in normalizing the LH: FSH ratio within the group. Comparison shows that the difference between the groups was highly significant after 90 days of follow up.
- r =0.55 in group A after 90 days of follow up.
- In group A, effect size is found to be large after 90 days of treatment- indicative of more improvement in the clinical status in this parameter.

Table 7: Number of follicular cysts in right ovary at different points of time

Number of follicular cysts in right ovary at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	1.000 (1.000-2.000)	1.000 (1.000-2.000)
Group B	1.000 (1.000-2.000)	1.000 (1.000-2.000)

- In group A, no significant difference could be observed after 90 days of follow up in reducing the number of follicular cysts in right ovary within the group. In group B no significant difference could be observed after 90 days of follow up in reducing the number of follicular cysts in right ovary within the group. Comparison also shows no significant difference between the groups after 90 days of follow up.
- r =0.18 in group B after 90 days of follow up.
- In group B, effect size is found to be small after 90 days of treatment- indicative of mild improvement in the clinical status in this parameter.

Table 8: Number of follicular cysts in left ovary at different points of time

Number of follicular cysts in left ovary at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	1.000 (1.000-1.000)	1.000 (1.000-2.000)
Group B	1.000 (1.000-2.000)	1.000 (1.000-2.000)

- In group A, no significant difference could be observed after 90 days of follow up in reducing the number of follicular cysts in left ovary within the group. In group B, no significant difference could be observed after 90 days of follow up in reducing the number of follicular cysts in left ovary within the group. Comparison also shows no significant difference between the groups after 90 days of follow up.
- r =0.18 in group A and r =0.18 in group B after 90 days of follow up.
- In group A, effect size is found to be small after 90 days of treatment- indicative of mild improvement in the clinical status in this parameter and in group B, effect size is found to be small after 90 days of treatment- indicative of mild improvement in the clinical status in this parameter.

Table 9: Right ovarian volume at different points of time

Right ovarian volume at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	1.000 (0.000-2.000)	2.000 (0.000-2.000)
Group B	1.000 (1.000-2.000)	1.000 (0.000-2.000)

- In group A, no significant difference could be observed after 90 days of follow up in reducing the right ovarian volume within the group. In group B no significant difference could be observed after 90 days of follow up in reducing the right ovarian volume within the group. Comparison also shows no significant difference between the groups after 90 days of follow up.
- r =0.27 in group A and r =0.24 in group B after 90 days of follow up.
- In group A, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter and in group B, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter.

Table 10: Left ovarian volume at different points of time

Left ovarian volume at different points of time (Data: Median, 25th & 75th percentile)		
Group	Day 0	After 3 months
Group A	0.000 (0.000-1.000)	0.000 (0.000-1.000)
Group B	1.000 (1.000-2.000)	1.000 (0.000-2.000)

- In group A, no significant difference could be observed after 90 days of follow up in reducing the left ovarian volume within the group. In group B no significant difference could be observed after 90 days of follow up in reducing the left ovarian volume within the group. Comparison also shows no significant difference between the groups after 90 days of follow up.
- r =0.1 in group A and r =0.32 in group B after 90 days of follow up.
- In group A, effect size is found to be small after 90 days of treatment- indicative of mild improvement in the clinical status in this parameter and in group B, effect size is found to be medium after 90 days of treatment- indicative of moderate improvement in the clinical status in this parameter.

Table 11: BMI at different points of time

BMI at different points of time (Data: Median, 25th & 75th percentile)				
Group	Day 0	Day 30	Day 60	Day 90
Group A	2.000 (1.000-3.000)	2.000 (1.000-3.000)	2.000 (1.000-3.000)	2.000 (1.000-3.000)
Group B	2.000 (2.000-3.000)	2.000 (2.000-3.000)	2.000 (2.000-2.000)	2.000 (2.000-2.000)@

@-p value < 0.05 in comparison to D0 values within the group in group B. (Friedman Repeated Measures Analysis of Variance on Ranks).

- In group A, no significant difference could be observed after 30th day, 60th day, and 90th day of follow up in reducing the BMI within the group when compared to the D0 values. In group B, there is significance difference could be observed after 30th day, 60th day and 90th day of follow up in reducing the BMI within the group in comparison to D0 values. Comparison also shows no significant difference between the groups after 1month, 2month, and 3rd month of follow up.
- W= 0.02 in group B after 1 month, W= 0.06 after 60 days, W= 0.05 after 90 days of follow up r =0.05 in group B after 90 days of follow up.
- The effect size is found to be marginal after 30, 60, 90 days of follow up which is clinically significant within the group in favor of group B.

Table 12: Hirsutism at different points of time

Hirsutism at different points of time (Data: Median, 25th & 75th percentile)				
Group	Day 0	Day 30	Day 60	Day 90
Group A	2.000 (2.000-2.000)	2.000 (2.000-2.000)	2.000 (2.000-2.000)	2.000 (2.000-2.000)
Group B	2.000 (2.000-2.000)	2.000 (2.000-2.000)	2.000 (2.000-2.000)	2.000 (2.000-2.000)

In group A and group B, no significance difference could be observed after 30th day, 60th day and 90th day of follow up in reducing the hirsutism within the group in comparison to the initial values. Comparison also shows no significant difference between the groups after 1 month, 2 months, and 3rd month of follow up.

Table 13: Acne at different points of time

Acne at different points of time (Data: Median, 25th & 75th percentile)				
Group	Day 0	Day 30	Day 60	Day 90
Group A	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000 (0.000-0.000)
Group B	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000 (0.000-0.000)	0.000 (0.000-0.000)

In group A and group B, no significant difference could be observed after 30th day, 60th day, 90th day of follow up in reducing the acne within the group in comparison to the initial values. Comparison also shows no significant difference between the groups after 1month, 2month, and 3rd month of follow up.

OVERALL RESULTS

Table 14: Showing the overall results

Results	Group A	%	Group B	%
Minor Improvement (Grade 1)	0	0	8	53.33
Moderate Improvement (Grade 2)	9	60	7	46.66
Marked Improvement (Grade 3)	6	40	0	0
Complete Improvement (Grade 4)	0	0	0	0

Effect size calculation for the above (Chi square-based test)- by calculating Cramers's is 0.223. The effect size falls under the medium effect size band indicating that there is moderate improvement in the overall effect.

DISCUSSION

The disorder which hampers the general health as well as the reproductive health of women should be considered with special care. Now a days, there is increase in the prevalence and incidence of the reproductive disorders have seen probably due to various factors such as newer gene mutation, migration, increase in population, radiation, life style changes etc. *Ayurveda* is the science of life which helps us diagnosing the diseases and symptom analysis through the *Nidana panchaka*, which helps us assessing the nature and chronicity of all diseases.

Discussion on Disease Review

PCOS is a condition in which the ovaries produce an abnormal amount of androgens, male sex hormones that are usually present in women in small amounts. The name polycystic ovary syndrome describes the numerous small cysts (fluid filled sacs) that form in the ovaries.

Approximately 6-10% of women within their reproductive age group suffering with PCOS and this percentage is slowly increasing due to the sedentary lifestyle. Polycystic ovarian syndrome can be considered as one of the leading causes for female infertility and one of the leading reproductive endocrine disorders in the world. It is the syndrome of hyperandrogenism, chronic anovulation and polycystic ovaries as per Rotterdam criteria. Similarly, there can be associated symptoms like menstrual irregularities (amenorrhea, oligomenorrhoea, hypomenorrhea or metrorrhagia), obesity, acne, increased hair growth etc. Also, there can be elevated serum testosterone level, LH level, increased insulin resistance and reduced serum SHBG level[5].

Pushpagni jathaharini[6]

The term *Pushpagni jathaharini* consists of two words *Pushpagni* and *Jathaharini*, where *Pushpa* can be considered as *Artava* and *Ghni* can be understood as destruction. The term itself conveys the destruction of *Artava,* which is mentioned in *Kashyapa Samhitha* as the cardinal symptom of this syndrome.

If we considered the *Nidana* mentioned for *Jathaharini*, all were in the form of *Manasika* and *Aharaja nidanas*. Even though a clear cut *Samprapti* has not been explained for *Jathaharini* affliction, its *Lakshanas* are described which include - *Vruta pushpa* can be refers to the anovulatory cycles, *Lomashaganda* refers to hirsutism and *Sthoola* refers to obesity. Hence, we can

clarify that both hormonal and metabolic disturbance will be there in *Pushpaghni jathahaarini*.

Granthi[7]

Granti can be considered as round swelling or enlargement occurs in any part of the body. We can correlate the PCOS with *Granthi* because of the appearance of the cysts in the ovaries, which increase the volume of the ovary and gives it a swollen appearance. If we consider the *Nidana* mentioned for *Granthi* all *Nidanas* will vitiates the *Tridoshas* which in turn vitiates the *Mamsa, Asruk* and the *Medodhatu*. Due to the the predominance of the *Kaphadosha* causing *Khavaigunya* at any particular part leads to the formation of *Vrutta, Unnatashopha* called as *Granthi.*

Among all the types of *Granthi*, *Medhoja granthi* finds more close proximity with that of the cystic appearances in the ovary. That is due to the *Swanidanas* and with the predominance of *Kapha dosha* which causes *Khavaigunya* at the level of the *Garbashaya* leads to the formation of the *Medogranthi* in the ovaries.

Artava kshaya

It is the condition where in the menstruation does not appear in proper time period or is delayed or intermenstrual period will be prolonged and the quantity of menstrual flow is reduced or scanty along with association of pain. In PCOS, one of the symptoms are anovulation or oligomenorrhea. So, there will be decrease in amount and volume of the menstrual blood than the normal. Hence, the *Artava kshaya* can be considered as one of the symptoms in PCOS.

Proposed *Chikitsa Siddhanta* for PCOS:

Vatadosha is the main causative factor in the manifestation of all types of *Yonivyapad*. So, we should treat vitiated *Vatadosha* first. *Vatadosha* is considered as the *Pravartaka* of the other two *Doshas*. So, if we maintain the *Vata dosha* first, it may have some indirect effect on regulating the other two *Dosha*s.

PCOS is a *Apana vata vikruthijanya vyadhi*. As a treatment for this the drugs should possess *Agnideepaka, Anulomaka*, and *Pakvashayashuddhikara* properties. With *Deepana pachana* actions of the drugs it will regulate the normal function of *Agni* and with *Anulomana* action the *Kupitha dosha*s obstructed in the *Pakvashaya* will be expelled out. Thus, with this *Pakvashayashuddi* the *Avarana* in the *Artavavaha srotas* gets relieved and it will help to decrease the overall symptoms of PCOS.

Discussion on Drug Review

Probable Mode of Action of *Patoladi kwatha*

Almost all ingredients in *Patoladi Kwatha* are having *Katu, Tikta*, *Kasaya rasa, Ushna veerya, Rooksha, Teekshna, Sookshma guna, Katu* vipaka and *Kapha-vatahara* properties*. Katu rasa* has *Sneha-kleda-medo shoshana*, *Deepana - Pachana, Srotoshodhana* and *Kaphahara* properties. Due to *Ushna veerya*, it is *Aashupachana, Soshana*, and *Kapha-vatahara* properties.

Due to indulging in *Nidana sevana*, the *Manasika hetu* like stress, *Shoka* etc will cause *Tridosha prakopa* and *Santarpana hetu* like eating junk foods, following sedentary life style etc will cause *Kapha prakopa*. These *Tridosha prakopa* or *Kapha prakopa* will be leading to *Jataragni mandhyata*. So, the *Ushna Teekshna guna, Kapha vata hara*, and *Deepana-pachana* property of *Patoladi kwatha* will help to correct the *Jataragnimandhyata* and further *Dhatuvagni mandhyata* also get corrected. As we know if *Medodhatvagni mandhya* occur *Medo dushti* will happen and symptoms like *Sthoulya* or *Prameha poorvaroopa* also occur. Similarly, if *Shukra dhatvagnimandhya* occur *Shukradushti* will happen and symptoms like hirsutism, infertility etc can be seen. So, by correcting all these *Dhatvagnimandhyata* by *Patoladi kwatha* it will reduce all these symptoms in PCOS patients

Probable mode of action of Tab. *Navaka guggulu*

Most of the ingredients of *Navaka Guggulu* have *Katu rasa, Ruksha, Teekshna* and *Sookshma guna, Katu vipaka* and *Kapha-vata hara karma*. *Triphala* is *Kaphameda hara* and used in *Meha. Trikatu* is *Stoulyahara* and *Agnimandyahara*. *Trimada* is *Deepana, Pachana* and having *Lekhana karma. Guggulu* has *Medohara, Lekhana, Vrishya,* and *Rasayana* properties.

Action of tab *Navaka guggulu* in *Sthoulya* and *Prameha*

Navaka guggulu helps to balance *Tridosha*. The *Kashaya rasa, Laghu, Ruksha guna* of *Triphala* causes *Vatanulomana. Katu, Tikta rasa, Laghu, Ruksha guna, Ushna virya* helps in clearing the obstruction from *Srotas* by removing *Kapha, Meda. Lekhana* and *Kaphameda hara* properties causes reduction in excessive *Kapha* and *Meda* thus helps in breaking *Samprapti* of *Sthoulya*. Tannins, gallic acid, chebulinic acid, ellagic acid and other bioactive substances such as flavonoids, saponins, anthraquinones, amino acids, fatty acids and different carbohydrates are found in *Triphala.* Due to which it has anti-obesity, hypolipidemic, hypocholesterolemia, hypoglycemic, insulin releasing, anti-stress, anti-oxidant and immunomodulatory activities. Cholesterol biosynthesis in the body is mainly maintained in the liver by the enzyme HMG-Co A and HMGR. HMG-Co A reductase is inhibited by *Triphala. Triphala* is high in fibres, which aid with digestion and bowel control. A reduction in cholesterol absorption may have resulted in considerable reductions in total cholesterol.

CONCLUSION

- The present study was done to evaluate the efficacy of *Patoladi kwatha* along with *Navaka guggulu* (trial group) in group A and *Varunadi*

kwatha along with *Kanchanara guggulu* (control group) in group B in the management of PCOS w.s.r. to *Artavakshaya.*

- Duration of bleeding and amount of bleeding improved in group A and having significant effect and clinical improvement when compare to group B.
- Group A is having significant effect in reducing the interval between 2 menstrual cycles. 60% and 40% of clinically improvement could be observed in group A and group B respectively.
- Group A is having significant effect in reducing the pain during menstruation between the groups. 50% and 20% of clinically improvement could be observed in group A and group B respectively.
- Group A is having significant effect in LH:FSH ratio between the groups. 55% of clinically improvement could be observed in group A.
- No significant effect is observed in ovarian volume, number of follicular cysts, hirsutism and acne. Clinically 20% of improvement could be observed in right ovarian volume in both the groups.
- Clinically 10% and 30% of improvement could be observed in left ovarian volume in group A and group B respectively.
- Clinically 10% of improvement could be observed in number of follicular cysts in right ovary in group B. Clinically 10% of improvement could be in number of follicular cysts in left ovary in both the groups.
- Reduction in BMI was significant within the group B in comparison to D0 value.
- The clinical effect size difference is not remarkable. However, when within the group difference was analyzed in different time period. It was observed that statistically significant improvement was observed in group A for 5 parameters out of 10, whereas in group B only 1 parameter is having statistically significant improvement out of 10.
- The effect size falls under the medium effect size band indicating that there is moderate improvement in the overall effect.
- So, *Patoladi kwatha* along with *Navaka guggulu* is superior to *Varunadi kwatha* along with *Kanchanara guggulu* for the treatment of PCOS w.s.r to *Artavakshaya*.
- Hence null hypothesis (H0) is rejected and alternative hypothesis (H1) is accepted.

Scope for Future Studies

- Further studies can be carried out on larger sample size for detailed analysis.
- Longer duration of treatment period can be considered for better results.
- The efficacy of *Patoladi kwatha* along with *navaka guggulu* over estrogen, serum testosterone and androgen levels can be assessed for future studies.

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