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Research Article

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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PATHADI KWATH AND KANCHANARA GUGGULU ON PCOS

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ABSTRACT

Polycystic Ovarian Syndrome (PCOS) is one of the most common problems affecting approximately 5% of all women. PCOS can affect menstrual cycle, fertility, and hormone level as well as appearance including acne, facial hair growth and balding, overweight. Some women may suffer from depression. It is also a metabolic problem that affects several body systems. The condition gets its name because there are often an increased number of small painless cysts in the ovaries (polycystic ovaries). It is very difficult to cure in contemporary system and treatment is also very costly. Therefore the present study was carried out for the clinical evaluation of the efficacy of *Ayurveda* treatment regimen on PCOS. Total 60 patients were selected by using purposive sampling method. The treatment was conducted for the duration of 60 days. The response to the treatment was recorded and therapeutic effects were evaluated by symptomatic relief and through

Trans Vaginal Scan and LH, FSH hormone levels. The results revealed that, menstrual irregularities due to PCOS can be cured successfully by using this *Ayurveda* treatment regimen.

KEYWORDS: PCOD, PCOS, Ayurveda, Artava Dusti, menstrual i rregularities.

INTRODUCTION

"Stree" being the root cause of progeny, utmost care should be given to protect her from any ailments that affect her motherhood. PCOD is one of the conditions affecting this unique capacity of woman. [1] The disorder is probably the most common hormonal abnormality in women of reproductive age and certainly a leading cause of infertility. [2] PCOD is not a complete curable disease. The treatment in modern medicine is mainly symptomatic. Moreover it may fail in preventing the long term consequences of PCOD. Our system of medicine Ayurveda- the science of life, makes use of the advanced modern techniques in the diagnosis and symptom analysis through the Nidana Panchakas helps in assessing the nature, course and chronicity of any disease. Going through our classical text books in detail, no direct reference involving the clinical spectrum of PCOD was found; instead the symptoms were explained as a part of various diseased conditions. Therefore, it is necessary to postulate an ayurvedic view for PCOD which is multifectorial, heterogeneous disease. Numerous causes and treatment of menstrual irregularities and anovulation has been given in ayurvedic text. Even many research works have been carried out on the symptoms of PCOD separately but, not a single concrete research has been carried out so far on this topic- PCOD till date as per records available. As this disease is manifested due to mixed aetiological factors and presents with complex symptopathology, the treatment should also be broad spectrum. This prompt us to think that the drug which is useful for vata and kapha dosha shamana and the drug which increases the agneya guna vriddhi of pitta may also be useful for PCOD. Keeping this hypothesis in mind and the scattered references in samhitas, we planned to carry out some research. In modern science, PCOD is treated by hormonal therapy along with symptomatic treatment and the last option is surgery (Partial oopherectomy or Drilling of the ovaries) and long term use of these drugs produces many side effects. [3] So, it is very essential to find out some effective ayurvedic medicines for this condition. We hope this preliminary study may prove to be an accepted concept in coming years.

AIM AND OBJECTIVES

- To find out the etiopathogenesis of PCOS (Poly Cystic Ovarian Syndrome) in *Ayurveda* parlances.
- To evaluate the efficacy of both the selected drugs (Pathadi Kwath & Kanchanara Guggulu) on menstrual irregularities & anovulation caused by PCOS.

GROUP AND POSOLOGY

The study was planned in three groups. Such as

- Group A [Treated with Pathadi Kwath]
- Group B [treated with Kanchanara Guggulu]
- Group C [treated with both Kanchanara Guggulu and Pathadi Kwath]

Trial drugs

• **Reference:** Pathadi Kwath (*Su. Sha 2/14*), Kanchanara guggulu (*Bh.R. 44/64 - 69*).

Group	Drug	Method	Dose	Duration
Group - A	Pathadi Kwath	Decoction,Oral Route		Twice daily in empty stomach with water for 60 days.
Group - B	Kanchanara guggulu	Vati, Oral route	Dauma	2 Tabs twice daily with lukewarm water for 60 days.
Group - C	Kanchanara guggulu & Pathadi Kwath	Oral route	⊥ /III mI	2 Tabs twice daily with 40 ml decoction for 60 days.

Duration of clinical trial and follow up study

All the patients will be treated with the respective drugs for 60 days. Follow up of each patient will be done once in a month for another 60 days to find the improvement and complications if any.

OBSERVATION AND RESULT

- ❖ In the present study total 65 patients were registered, among them 60 patients had completed the treatment and 5 patients left the treatment against medical advice.
- ❖ The information gathered on the basis of above observations was subjected to statistical analysis. Anova test was applied to analyze the effect of therapy by using Statistical software- Sigma stat 3.5. The results were interpreted at p <0.05, p<0.01 and p <0.001 significance levels.
- ❖ Level of Significance: p value of
- < 0.001 : Statistically Highly Significant (HS).
- < 0.05 & < 0.01: Statistically Significant (S).
- > 0.05 : Statistically Insignificant (IS).

OBSERVATIONS

Table No. 1: Distribution of 65 Patients of PCOS (Artava Dushti).

Sr. No.	Status	Group A	Group B	Group C	Total
1.	Registered	22	21	22	65
2.	Completed	20	21	19	60
3.	Discontinued	02	00	03	05

Total 65 patients were registered among which 22 patients were in Group A, 21 patients were in Group B and 22 patients were in Group C. Among them total 60 patients completed the course of treatment. From total of 65 patients 5 patients were dropped i.e. 02 patients from Group A and 03 patients from Group C were dropped out due to their personal cause.

Table No. 2: Comparison between Group A, Group B and Group C.

Variable	Group	N	Mean Rank	Sum of Rank	Kruskal Wallis Test	P- Value	Result
	Group A	20	27.18	543.50		0.02797	Sig
Hirsutism	Group B	21	31.45	629.00	2.548		
THI SUUSIII	Group C	19	32.88	657.50	2.340		
	Total	60					
	Group A	20	21.00	420.00			
A on o	Group B	21	35.00	700.00	16.409	0.00003	Sig
Acne	Group C	19	35.50	710.00	10.409		
	Total	60]		
Interval Between	Group A	20	22.05	441.00			
Two Menstrual	Group B	21	29.85	597.00]		
Cyala	Group C	19	39.60	792.00	13.080	0.00014	Sig
Cycle	Total	60			13.080		Sig
	Group A	20	26.83	536.50		0.02429	Sig
Duration Of	Group B	21	30.85	617.00	2.831		
Bleeding	Group C	19	33.83	676.50	2.831		
	Total	60]		
Dain A	Group A	20	25.68	513.50		0.01358	
Pain Associated With	Group B	21	30.43	608.50	2 004		Sig
with Menstruation	Group C	19	35.40	708.00	3.994		
ivienstruation	Total	60]		

Kruskal Wallis Test (Non-parametric ANOVA) is carried out for comparison among Group A, Group B and Group C. From above table, we can observe that, P-Value is less than 0.05. Hence, we can conclude that, there is significant difference observed among Group A, Group B and Group C.

Further, we can observe that, mean rank for Group C is greater than Group A and Group B. Hence, we can conclude that, effect observed in Group C is better than Group A and Group

В.

Table No. 3: Comparison on Statistical Analysis of before and after treatment between Group A, Group B And Group C on the Volume of Right Ovary.

Volume (Ri Ovary)	ght	Mean	N	SD	SE	t - Value	P - Value	% Change	Result
Crown A	BT	17.60	20	3.42	0.77	6.525	0.000	10.51	C:~
Group A	AT	15.75	20	3.13	0.70	0.323	0.000	10.51	Sig
Crown D	BT	17.60	20	3.42	0.77	5.723	0.000	15.63	C:~
Group B	AT	14.85	20	3.15	0.70				Sig
(_roun ()	BT	17.60	20	3.65	0.82	0 007	0.000	18.57	Cia
	AT	14.25	20	2.57	0.58	8.807	0.000	10.37	Sig

Since observations are quantitative, we have used paired t-test to test significance in Group A, Group B and Group C. From above table, we can observe that, P-Value for Group A, Group B and Group C is less than 0.05. Hence, we can conclude that, effect observed in Group A, Group B and Group C is significant.

Table No. 4: Comparison on Statistical Analysis of before and after treatment between Group A, Group B And Group C on the Volume of Left Ovary.

Volume (Left	t Ovary)	Mean	N	SD	SE	t - Value	P - Value	% Change	Result
Group A	BT	15.20	20	3.79	0.85	19.000	0.000	12.50	Sig
Group A	AT	13.30	20	3.73	0.83	19.000			
Group B	BT	15.20	21	3.79	0.85	11.804	0.000	14.47	Sig
	AT	13.00	21	3.46	0.77				
Croup C	BT	15.00	19	3.74	0.84	12.899	0.000	19.00	Cia
Group C	AT	12.15	19	3.07	0.69				Sig

Since observations are quantitative, we have used paired t-test to test significance in Group A, Group B and Group C. From above table, we can observe that, P-Value for Group A, Group B and Group C is less than 0.05. Hence, we can conclude that, effect observed in Group A, Group B and Group C is significant.

Table No. 5: Overall Effect Between The Group A, Group B And Group C.

Overall Effect		Group A		Group B	Group C		
		%	N	%	N	%	
Marked Improvement	1	5.00%	4	20.00%	12	60.00%	
Moderate Improvement	7	35.00%	14	65.00%	7	40.00%	
Mild Improvement	11	55.00%	3	15.00%	0	0.00%	
No Change	1	5.00%	0	0.00%	0	0.00%	
Total	20	100.00%	21	100.00%	19	100.00%	

From the above observation, the categorization of overall effect in various groups are follows

Group A

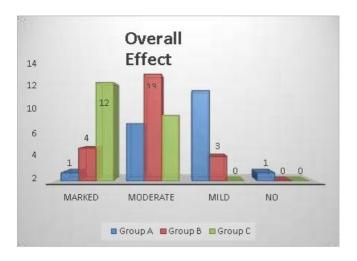
- The Marked Improvement was observed in 1 patient with an effect of 5.00%
- The Moderate Improvement was observed in 7 patient with an effect of 35.00%
- The Mild Improvement was observed in 11 patient with an effect of 55.00%
- The No Change was observed in 1 patient with an effect of 5.00%.

Group B

- The Marked Improvement was observed in 4 patient with an effect of 20.00%
- The Moderate Improvement was observed in 14 patient with an effect of 65.00%
- The Mild Improvement was observed in 3 patient with an effect of 15.00%
- The No Change was observed in none of the patients.

Group C

- The Marked Improvement was observed in 12 patient with an effect of 60.00%
- The Moderate Improvement was observed in 7 patient with an effect of 40.00%
- The Mild Improvement was observed in in none of the patients.
- The No Change was observed in in none of the patients.



Graph No. 1: Overall Effect Of Various Subjective Parameters.

It was observed that out of 60 patients; moderate improvement was found in 11.76% of patients, mild improvement in 64.7% while 23.52% remained unchanged in Group A. The same was 10% & 5%, 50% & 45%, 40% & 50% in Group B and Group C respectively. In

total 52.63% patients had mild improvement i.e.25-50%; 8.77% patients had moderate improvement i.e. 51-75%; 38.6 % patients remained unchanged with < 25% results. No patient was completely cured. Even though a total of 06 patients conceived, they were not considered as completely cured because of *Vyadhiswabhava* (nature of disease). This syndrome cannot be easily treated due to its relation to the deeper *Dhatus*.

DISCUSSION

The purpose of the discussion is to construe and describe the significance of the results in light of what was already known about the research problem being studied and to explain any new understanding or visions that developed as an outcome of your study of the problem. Health researches support the health systems by unearthing and expansion of new therapies, and providing information about the effectiveness and antagonistic effects of medical interventions.

Among 65 patients registered in trial, 60 completed the trial while 05 patients discontinued; due to their personal problems. The data generated is for 65 patients for demographic data and for 60 patients for effect of therapy.

CLINICAL FEATURES

- Chief complaints: A total incidence of *Anartava* (00%), *Aniyamita Artava* (88.33%), *Aatyartava* (6.66%), *Alpartava* (75.03%) were observed in the patients. The sample population had shown the above symptoms as one of these can be the leading complaint in PCOS. Primary Infertility (52%) and Secondary Infertility (28%) was observed as chief complaints. Primary & sec. infertility is indicator of PCOS related anovulation.
- Associated complaints: *Sthaulya* in 78.33% patients, pointing towards faulty & sedentary life style and Acanthosis nigricans (70%) shows insulin resistance in PCOS patients. Leading dermatological features of PCOS i.e. Hirsutism (75%) & Acne (61.66%), gives a clue of possible Hyperandrogenism in these patients. No significant observations were found on features of Virilism except for Hirsutism. Gynaecological examinations (P/v & P/s) were insignificant in women with PCOS.
- Menstrual history: Irregularity was elicited in 88.3% of patients, scanty bleeding in 66.67%, maximum patients(55%) had duration of 3-4 days, interval of 35 to 45 days (35%) as these are the main features of PCOS. Clotted appearance of bleeding (26.66%), blackish red

(38.33%) and delayed menarche(15-20yrs) in 20% patients points towards the clinical diagnostic parameters of menstrual complaints in patients of PCOS (Artava Dushti). Painless menses in 63.33% patients. It revels the anovulatory cycles which is one of the diagnostic criteria of PCOS.

BMI: Maximum patients i.e. 43.33% had BMI 25-29.9 and 35% were having BMI above 30. It shows that obese patients are more prone to PCOS. Another potential explanation for the influence of BMI is that the anovulatory cycles is associated with increasing body weight. This mechanism would increase cumulative oestrogen exposure over time and simultaneously decreasing exposure to progesterone because of an absence of the luteal phase.

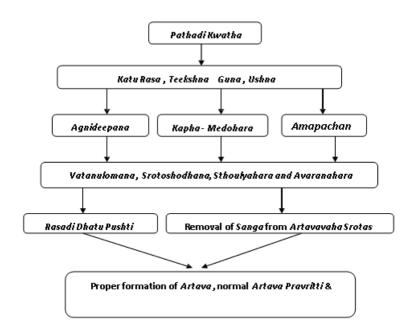
OBSERVATION ON SAMPRAPTI GHATAKA

- Dosha Vata and Kapha Dushti was observed in 100% of patients. As PCOS is a Vata Kaphaja Vyadhi & it is more prevalent in Vata Kaphaja Prakriti women.
- Dushya Rasa, Rakta, Mamsa, Meda, Asthi Dhatu Dushti was observed in 100%,100%, 100%, 100%, 75% patients respectively. As in PCO there is small cysts formation (Granthis) in the ovaries. The above said Dushyas except Asthi is involved in the formation of Granthi. As Artava is a synonym of Shonita i.e. Rakta and Acharya Kashyapa had mentioned "Artavam Shonitum" so due to vitiation of Rakta; Artava also get effected. Hirsutism is a feature of PCOS. Acc. to Acharya Susruta and Vagbhata the Mala of Asthi Dhatu is Nakha and Roma. So due to Dushti of Asthi Dhatu there is excessive hair growth.
- Upadhatu & Mala Dushti- 100% had Artava Dushti, 88.33% had Twak Dushti, Sweda Dushti 45%. This data shows the obvious linkage of Artava with Rasa as it is the Updhatu of Rasa Dhatu. When going through the symptoms of Rasavaha Srotodushti it seems to be mainly due to *Mandagni* which found in maximum patients.
- Srotodushti- Artavavaha (100%), Rasavaha (100%), Raktavaha (100%), Mamsavaha (100%) and *Medovaha* (100%), *Asthivaha* (75%), *Annavaha* (66.33%).

MODE OF ACTION OF PATHADI KWATHA

PCOS patients are coming with mixed symptomatology (Vyadhi Sankara). In the present study the emphasis has given to see the effect of the drug mainly on menstrual irregularities, follicular growth, ovulation, reduction in ovarian volume, weight loss and conception.

Simultaneously, the effect of therapy was also observed on associated findings like Acanthosis nigricans, Hirsutism, Acne and biochemical parameters In the present study, hypothesis behind the PCOS is mainly Kapha and Vata Dushti. So Pathadi Kwatha specified in Vatakaphaja Artava Dushti (Granthibhuta Artava Dushti) was selected. Contents of Pathadi Kwatha are mainly having Kapha-Vata Shamaka properties like Katu- Tikta Rasa, Ushna Virya and Katu Vipaka. Various Gunas and chemical constitutes of those are already given in drug review. With these properties, *Pathadi Kwatha* exerts effects like *Deepana*, Ama Pachana, Lekhana, Medovilayana and Srotoshodhana etc. Due to these actions, Sanga in Artavavaha Srotas has been removed and at the same time correction of Agni Dushti take place. As Artavavaha Srotas become free from Avarodha or Avarana, the vitiated Kapha and Vata comes to normal state. Thus normalizes functions of Apana Vata and causes regular Artava Pravritti (menstruation) andnormal Beeja Nirmana (ovulation). With the correction of Jatharagni, the Dhatwagnis also become normal. So there is good production of Artava as an Upadhatu from the Rasa Dhatu.



CONCLUSION

Polycystic Ovarian Syndrome is diverse multisystem endocrinopathy in woman of reproductive age with ovarian expression of various metabolic disturbances and a wide variety of clinical features such as menstrual abnormalities, obesity and hyperandrogenism. The successful treatment in PCOS alleviates infertility by using natural, non-invasive and

non-chemical remedies. 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 *ama*and thus hormonal imbalance that causes hyperinsulinemia to 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, Pathadi kwath with Kanchnaar guggulu showing better results in restoring normal menstrual cycle, BMI, Acne and in reducing the volume of right and left ovaries; while kanchnaar guggulu showing better results in amount and intensity of bleeding and duration 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, both the drugs are effective in PCOS.

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