



TO EVALUATE THE EFFICACY OF SINGLE DRUG THERAPY OVER POLYCYSTIC OVARIAN SYNDROME.

Dr. Anu Koul^{1*}, Dr. Tanuja Manoj Nesari², Dr. Kiran Jadhav³

¹Technical Program officer, Department of Pharmacovigilance, AllA, Sarita Vihar, New Delhi-110076.

²Director & HOD, Department of Dravyaguna Vidyan, AllA, Sarita Vihar, New Delhi-110076.

³P.G. Scholar, Department of Dravyaguna Vidyan, AllA, Sarita Vihar, New Delhi-110076.

***Corresponding Author: Dr. Anu Koul**

Program officer, Department of Pharmacovigilance, All India Institute of Ayurveda, Sarita Vihar, New Delhi-110076.

Article Received on 14/11/2019

Article Revised on 04/12/2019

Article Accepted on 25/12/2019

ABSTRACT

Polycystic ovary syndrome (PCOS) affects 20-25% of women of reproductive age and up to 30% in some high-risk groups. PCOS leads to irregularity in the menstrual cycle and the appearance of superfluous male hormones (androgens/testosterones). Menstrual cycles might be regular prior but subsequently turn out irregular, or the incipience of menses may be delayed. Women may experience infertility by meagreness of ovulation in the menstruation cycle resulting out for difficulty in conceiving. *Ayurvedic* single drug therapy has been emerging in addition to established medical and surgical medication for PCOS. PCOS is a disorder involving *Pitta, Kapha, Medas, Ambhuvahasrotas & Artava Dhatu*. The causes of PCOS as per *Ayurveda* can be taken as eating excessive sweet and kaphagenic foods, *mandagni* because of this is *kapha* getting aggravated in PCOS, we find *kapha* disorder. In present case study, we have studied safety and effectiveness of exclusive single drug therapy with use of reserve wellness wrapping technique in PCOS patients. Study eventuate reveal that majority of hormonal level significantly changed post-medication compared to pre-medication. Study results shown that there was statistically significant improvement in Luteinizing Hormone (LH), Prolactin, AMH, Fasting Insulin, SGPT, post medication from the preoperative values ($P < 0.05$). LH/FSH Ratio at pre-medication was 2.82:1, which was reduced to 1.01:1 at post medication ($p < 0.001$). No adverse event was reported during conduct of present study.

KEYWORDS: Polycystic ovary syndrome, *Ayurveda*, *Artava Dhatu*, hormones.

INTRODUCTION

PCOS (Polycystic ovary syndrome) is coined since detection of enlarged ovaries carrying multiple small cysts. PCOS has also been referred to as Stein-Leventhal syndrome and polycystic ovarian disease (PCOD). Polycystic ovary syndrome (PCOS) affects 20-25% of women of reproductive age and up to 30% in some high-risk groups. PCOS leads to irregularity in the menstrual cycle and the appearance of superfluous male hormones (androgens/testosterones). Menstrual cycles might be regular prior but subsequently turn out irregular, or the onset of menses may be delayed. Women may experience infertility by meagreness of ovulation in the menstruation cycle resulting out for difficulty in conceiving. Hirsutism; excessive, abundant, pigmented hair growth occurs on the upper lip, chin, around the nipples, and on the lower abdomen, acne and baldness due to an increase in the production of androgens (male hormones) by the ovaries in PCOS. Women with PCOS have truncate levels of the hormone progesterone resulting in growth stimulation of the endometrium, leading to dysfunctional uterine bleeding and

breakthrough bleeding and consequently develop endometrial hyperplasia and uterine cancer. Insulin resistance, weight gain, and obesity are also common in PCOS. Observers have suggested that about one-half of women with PCOS are obese. Insulin resistance, accompanied by elevated blood levels of insulin, occurs in most women with PCOS, independent of the presence of obesity. Women with PCOS have also been reported to have an increased risk of developing type 2 diabetes, and many studies have shown abnormal blood lipid levels and elevated levels of C-reactive protein (CRP), a predictor of coronary artery disease. The combination of type 2 diabetes, elevated cholesterol and LDL levels, and elevated CRP levels suggest an increased risk of coronary heart disease on women with PCOS, although this risk has not yet been scientifically established.^[1] In *Ayurveda* majority of gynaecological disorders have been described under the heading of *Yonivyapada*, though some of the menstrual abnormalities like *Asrigdara*. For complete knowledge of menstrual disorders, the knowledge of *Yonivyapada & Aartvadashti* is essential. *Acharya Sushruta* described

Bandhya Yonivyapada whose main feature is Nashtartava.^[2] Ayurveda suggests that this is vata type disorder (Apan vayu) though the involvement of other dosha can be there but in some measure because the gynaecological disorder are mainly supposed to be due to vitiation of vata. PCOS is a disorder involving Pitta, Kapha, Medas, Ambhuvahasrotas & Artava Dhatu. The causes of PCOS as per Ayurveda can be taken as eating excessive sweet and kaphagenic foods, mandagni because of this is kapha getting aggravated in PCOS, we find kapha disorder. As well as pitta and vata dosha disorder. Because of all three doshas play important & distinctive role in the production, development, maturation & release of ovum & therefore the ovarian cycle & menstrual cycle is under control of three doshas. In *Ayurveda*, Several drugs and formulae are available in Ayurveda classics for the remedy of *PCOS/PCOD*, among them *Shatapushpa (Anethumsowa Kurz.) Churna (powder)* mentioned by Kashyapa Samhita is selected for clinical study.^[3]

MATERIALS AND METHODS

Null Hypothesis -H₀= *Shatapusha churna* orally oral has no effect over the PCOS.

Research Hypothesis -H_R= *Shatapusha churna* orally has effect over the PCOS.

Research Question: Whether *Shatapusha churna* orally has role of over the PCOS.

Source and method of collection of the data

Data of 10 PCOS diagnosed patients were taken for the study, from the OPD & IPD of All India Institute of Ayurveda, Sarita Vihar, and New Delhi. A special proforma including consent form was made incorporating all points of history taking, physical signs and symptoms of PCOS and lab investigations. Accordingly, the patients were selected and were subjected to a detailed clinical history and complete examination.

Inclusion criteria

Female aged 15-35yrs.

Diagnosed Cases of PCOS

Exclusion criteria

Oligomenorrhoea

An ovulation

Amenorrhoea,

Minimum–maximum of age (in years), height (in cm), weight (in kg) and BMI at baseline is presented in Table Below:-

Parameters	Age (In Years)	Height (In cm)	Weight (In Kg)	BMI
Mean	25.65	152	65.44	28.3
SD	4.75	3.55	4.19	-
Min	19	150	64.5	-
Max	35	163	79.2	-

Study results revealed that majority of hormonal level significantly changed post medication compared to pre-

Dysmenorrhoea,
Metrorrhagia
Metrorrhagia
Uterine fibroids
Hirsutism
Obesity not due to PCOS.
Pregnant females
Systemic illness.

Assessment Criteria^[4]

Subjective criteria

Menstrual cycle Interval between two cycles

Duration of bleeding

Quantity of bleeding

Acne

Hirsutism

BMI

Objective Criteria

Ovulation

Intervention

A total of 10 females who fulfilled predefined inclusion/exclusion criteria were enrolled in present study. Baseline demography of Patient age, height and weight was recorded for individual patients. Individual patient was given prescheduled appointment and asked to visit clinic for study procedure which was done for approximately 1 hour and repeated every 4th day for 1 complete menstrual cycle. Medication was recommended to be taken after meal. 5 ml blood was collected on 3rd day of menstrual cycle to investigate hormonal level in individual patient at baseline before medication and post medication (3rd day of next menstrual cycle). Laboratory investigation for hormones AMH, FSH, Prolactin, LH, TSH, Insulin resistance was performed for efficacy evaluation. Efficacy was evaluated by Improvement in hormone balance (AMH, LH, FSH, LH/FSH ratio, Prolactin, TSH and Insulin resistance). Safety was evaluated throughout study procedure as well as at end of study. Safety was evaluated by analyzing number of adverse events and patients with adverse events

RESULTS

All enrolled (10) patients had completed the study and were included for safety and efficacy analysis. Mean age of patients enrolled in present study was 25.65 ± 4.52 years.

medication. in Luteinizing Hormone (LH), Prolactin, Anti-Mullerian Hormone (AMH), Fasting Insulin, and

SGPT and LH/FSH ratio there was statistically significant improvement, post-medication from the preoperative values ($P < 0.05$).

Study results had shown that there is significant difference between pre and post medication at all hormonal levels given in the table below:

S. NO.	HARMONES	Pre Treatment		Post Treatment		P Value
		Mean	SD	Mean	SD	
1	FSH	10.84	1.25	6.79	0.18	<0.001
2	LH	11.52	2.16	5.2	0.94	<0.001
3	Prolactin	36.36	1.94	29.35	1.32	<0.001
4	TSH	3.63	0.65	3.62	0.64	0.207
5	AMH	10.84	1.25	6.79	0.18	<0.001
6	Fasting Insulin	15.77	1.94	15.32	1.53	0.018
7	SGPT	35.83	1.94	29.4	1.68	<0.001
8	LH/FSH Ratio	2.76	0.18	1.21	0.09	<0.001

The present study was performed to evaluate safety and efficacy of *Shatapushpa Churnain* patients of PCOS. Hormones play vital role in female reproduction system. improvement in hormonal balance may be beneficial in many gynaecological diseases including polycystic ovary syndrome (PCOS). There was statistically significant improvement in Follicular stimulating hormone (FSH), luteinizing hormone (LH), Prolactin, AMH, fasting insulin, SGPT and LH/FSH ratio, post-medication from the preoperative values ($p < 0.05$).

DISCUSSION AND CONCLUSION

In Ayurveda majority of gynaecological disorders have been described under the heading of *Yonivyapada*, though some of the menstrual abnormalities like *Asrigdara*. For complete knowledge of menstrual disorders, the knowledge of *Yonivyapada & Aartvadushti* is essential. Acharya Sushruta described *Bandhya Yonivyapada* whose main feature is *Nashtartava*. Detailed analysis of PCOS showed dominance of *kapha and Vata*. Through understanding the lakshanas, doshic involvement and samprapti, an effective treatment can be planned which helps in pacification of dosha, and samprapti vighatana, which in turn controls the disease effectively. *Shatapushpa* possess *madhura, kasaya, snigdha, rushya and bruhmana* property resulting in *yonishodhana, pathya, artava janaka*, and increases *bala* of the patient. *Shatapushpa* is a phytoestrogen; it exerts both estrogenic and anti-estrogenic activity depending on condition. It acts in both high oestrogenic and low oestrogenic condition^[5] *Shatapushpa Churna* helps in regulate & normalises the menstrual cycle, regulates ovulation, and helps in weight loss. A longer observation period may be taken as there will be scope to analyse the effect comprehensively.

REFERENCES

1. https://www.emedicinehealth.com/polycystic_ovarian_syndrome_pcos/article_em.htm#what_are_the_symptoms_of_pcos.

2. Sushruta Samhita of Mahrshi Sushruta edited with Ayurveda-Tattva-Sandipika Hindi Commentary by KavirajaAmbikaduttaShastri, Reprint edition, Vol.II publisher: Chaukhamba Bharti Academy, Varanasi, 2014; 202.
3. Kashyapa Samhita. 7th ed. Varanasi: Chowkhamba Sanskrit Pratisthana Vidyotini Hindi Commentary, 1994; 184.
4. BarabaraL. Hoffman, JohnO. Sehorge, Joseph I Schaffer, Lisa M Halvorron, Karen D Bradshaw, F Gary Cunnungham, William gynecology, McGraw Hill Dallas, second edition, 1401: 460-469.
5. Santhosha, D, Ramesh, A, Prasad, M.S, & Dhanalaxami, C.H Research Journal of Pharamaceutical, Biological and Chemical Sciences, 2011; 2(4): 427.