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A Randomized Trial on Comparative Effect of *Shatpushpa Kalpa* and *Yogasanas* in *Pushpaghni Jataharini* (Polycystic Ovarian Syndrome)

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ABSTRACT

Background: PCOS is a common endocrinological disorder of females in today's era with increasing incidence and has several adverse reproductive and systemic effects. Changing lifestyle contributes in its development. In Ayurveda, it depicts similarity in features of *Pushpaghni Jataharini*.

Objectives: Effect of *Yogasanas* and an ayurvedic drug *Shatpushpa* on the disease was evaluated in the given research trial. Both the groups showed improvement on interval of menstruation and on pain during menstruation.

Material and methods:-A randomized parallel group comparative clinical trial was done on total 35 patients which were randomly divided into two groups. Individuals having symptoms of PCOS, according to Rotterdam's criteria, for six months or more were included for the study from the outpatient department of prasuti tantra & stree rog, Rishikul campus, Haridwar. Total 30 patients completed the trial- Group A=17 and Group B=13. One group was on *Shatpushpa kalpa* (*Anethum sowa* powder) and other was on *Yogasanas* for a period of 3 months.

Result:-Both the interventions were effective in improving the symptoms. Both the groups showed improvement on interval of menstruation (group A $p=0.002$; group B $p=0.005$) and on pain during menstruation (group A $p=0.029$; group B $p=0.039$). Group A was also effective on follicular study ($p=0.014$) and group B was effective on improving the BMI ($p=0.020$).

Conclusion: This clinical trial concludes that *Shatpushpa kalpa* and *Yogasanas* have effective results on PCOS and are also without any adverse effects.

Key Words *Pushpaghni Jataharini*, *Yogasanas*, *Shatpushpa Kalpa*, *Anethum sowa*, PCOS

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INTRODUCTION

Disturbances in endocrine system are becoming increasingly common due to lifestyle changes and other environmental factors such as excessive stress and sedentary habits. Polycystic ovarian syndrome (PCOS – ICD code E28.2¹) is a similar disorder primarily characterized by

signs and symptoms of androgen excess and ovulatory dysfunction. Its main cause is disruption in HPO axis function. Patients present with variety of symptoms including menstrual irregularities, increase in body weight, hyperandrogenism in form of hirsutism or acne and inability to conceive. Patients of PCOS may

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depict single symptom or more than one symptom. It is the most common endocrine abnormality among women of reproductive age and leading cause for infertility. Its incidence is 4-12%, may be as high as 15% depending on the criteria used for diagnosis².

PCOS has been attributed to several causes including change in lifestyle, diet and stress. Genetic and familial environment factors (autosomal dominant inherited factors) were later added with ovarian causes as aetiological factors in the development of PCOS.

Menstrual dysfunction typically occurs in PCOS, ranging from oligomenorrhoea to amenorrhoea. As a rule, patients with PCOS exhibit anovulation. Even in hyperandrogenic women with regular menstrual cycles, the rate of anovulation is about 20 per cent³. In contrast to amenorrhea, women with PCOS may have heavy and unpredictable bleeding. In these cases, progesterone is absent due to anovulation and chronic estrogen exposure results. This produces constant mitogenic stimulation of the endometrium. The instability of the thickened endometrium leads to unpredictable bleeding⁴.

Present treatment for PCOS includes use of oral contraceptives, ovulation induction drugs, antidiabetic drugs and surgical interventions.

Oral contraceptive pills prevent cysts formation and regulates menstrual cycle. However, these are to be taken for a limited duration and suppress the physiology of ovulation. Also, risk of venous thrombosis and decrease of bone density may occur due to these pills⁵.

Metformin, an insulin sensitizer, is prescribed in PCOS to lower the levels of insulin and androgens. Side effects of metformin include lactic acidosis, tiredness, dizziness, drowsiness, cold skin, muscle pain, stomach pain, nausea, vomiting and diarrhoea⁶. For ovulation induction, aromatase inhibitor like letrozole and anti estrogen medication clomiphene citrate is advised. Anti-androgens such as spironolactone, cyproterone acetate are also administered for hyperandrogenism⁷.

These all treatment are effective to limited extent. Also, one particular treatment covers only single aspect of the disease. Besides, these have several adverse effects as stated earlier.

Thus, it can be seen that PCOS emerges as an ovarian pathology but has widespread complications. It affects nearly all the systems leading to several complications. Women with PCOS may be at increased risk of developing non-insulin dependent diabetes mellitus (NIDDM), cardiovascular diseases due to the disturbance in insulin resistance and lipid profiles and risk of endometrial cancer due to exposure to unopposed estrogen⁸.

As seen that these methods of treatment have several limitations and also some major side effects, conventional methods such as ayurvedic medicines along with lifestyle changes can be opted for management.

Major action of some herbal medicines has been found on symptoms of PCOS. Some of these includes *Glycyrrhiza glabra*, *Aloe vera*, *Cinnamomum verum*, *Curcuma longa*, *Actaea*

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racemose, *Gymnema sylvestre*, *Sesamum indicum*, etc. These medicines have been found to decrease androgen level, reduce insulin resistance and promote ovulation⁹.

In a clinical trial on 40 patients, ayurvedic treatment was given for 6 months. It included *Triphala Kwath*, *Chandraprabha Vati*, *Manibhadra Choorna*, *Shatavari*, *Shatpushpa*, *Guduchi*, *Krishna Jeeraka*, *Atibala* and *Uttar basti* of *Shatpushpa* oil. The polycystic appearance of ovaries was reduced and LH:FSH ratio normalized. 75% of the patients got conceived¹⁰.

Lifestyle modification is considered as first line therapy in the treatment of PCOS. It includes specific diet habits and increase in physical activities so that progression of the disease can be controlled. One such method of incorporation of lifestyle modification is through *yogasanas*. *yogasana* is a holistic approach of treatment both for the body and mind. Apart from physical benefits, it emphasizes on breath regulation, awareness during practice, maintenance of posture and calming down mind. *Bhagwada Gita* describes yoga as *yogah karmasu kaushalam*, meaning efficiency or expertise in actions is *yoga*¹¹. Patanjali explains *asanas* as steady and comfortable position- *sthirsukhamasanam*¹².

In present time, *yogasana* is considered for therapeutic benefits rather than spiritual benefits. Generally, it is practiced for maintenance of health or to counteract any disease. It is considered as one of the promising alternative therapy due to its efficacy and cost effectiveness.

Non communicable or lifestyle disorders are on rise. Stress is the major shareholder in this. *yogasana* can be the best approach for this occurrence. It has multiple benefits including physical and mental and has both preventive and curative effects.

When we go through Ayurvedic literature, pathological conditions of female reproductive system have been thoroughly covered. One such concept is of *jataharini* which has mythological origin and aetiologies include faulty eating habits, negative emotional state and other lifestyle factors. Description of *jataharini* has been given as- it destroys *pushpa* (menstruation/ovum), *garbha* (foetus), getting born or to be born foetus of especially those who avoid religious practices. It afflicts woman during three stages- *rajaswala* (menstrual), *garbhini* (pregnant) and *prasuta* (puerperal) and also during three stages of life- childhood, middle age and old age. One of the *jataharini* is *Pushpaghni jataharini* which bears resemblance to the condition of hyperandrogenism and anovulation which is a key feature of polycystic ovarian syndrome. Its features have been given as *vritha pushpam* (anovulation) and *sthoola lomash ganda* (fatty and hairy cheeks)¹³.

Also, *artavakshaya*¹⁴, *nashtartava*¹⁵ and *granthibhoot artava dushti*¹⁶ mentioned in *Ayurveda* bear resemblance to symptoms of PCOS.

Although exact nomenclature of the disease is not possible from Ayurveda perspective, its management can be possibly planned considering

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the literature. One such drug is *Shatpushpa kalpa* mentioned in *Kashyapa Samhita*. It has been taken as intervention in one group of the trial. Other group was advised a series of four *yogasanas*- *Nadi Shodhana Pranayama*, *Surya Namaskara*, *Savasana* and *Vajrasana*.

A single line of treatment of PCOS cannot be established as it is a multifactorial disease having various systemic complications. Current established treatment has certain limitations. Therefore, ayurvedic management can prove beneficial in this disease alongwith certain *yogasanas*. Present clinical trial was done to study the benefits of these forms separately.

Specific objectives

The presented clinical trial was done to study the effect of a single ayurvedic drug *Shatpushpa* in *kalpa* form and lifestyle modifications through *yogasanas* on features of PCOS relating with *Pushpaghni jataharini*.

Acharya Kashyapa has narrated *Shatpushpa* as a single drug in multiple female reproductive disorders ranging from *anagat-artava* (delayed menarche), *anartava* (amenorrhoea), *viphala artava* (anovulation), *alpa-artava* (scanty menstruation) to *ati krantam artava* (peri menopausal) stages. Also, he has indicated it for women who are *avisransi* (having complete loss of strength) and *prachurmurtya* (multiple systemic disorders). The drug was given in *kalpa* form as described in *Kashyapa samhita*¹⁷.

Shatpushpa is a herbal drug having scientific name as *Anethum sowa*. (Apiaceae family, other names- *Satahva*, *Sowa*, etc). *Shatpushpa* has also

been mentioned in Ayurvedic Pharmacopoeia of India by its Hindi name *Satahva*¹⁸. Its description along with dose as mentioned in API is given below-

Satahva consists of the dried ripe fruits of *Anethum sowa Roxb.*, a tall, glabrous, aromatic herb found throughout tropical and sub tropical regions of the country and cultivated. Its properties and action are: *Rasa – Katu, Tikta; Guna- Snigdha; Virya- Ushna, Vipaka- Katu; Karma- Dipana, Kaphahara, Vatahara*.

DOSE - 3-6 g. of the drug in powder form.

Shatpushpa has been extensively studied for its effect on menstrual disturbances and infertility. It is given in *churna* form or *taila* form for *nasya* or *basti*.

One study shows significant reduction in menstrual interval and reduce ovarian volume by 6 gm *Shatpushpa churna* given for three months duration. Total 30 patients were selected of mean age 22.6 years and having oligomenorrhoea for more than three consecutive menstrual cycles and fulfilling Rotterdam criteria¹⁹. In another clinical trial, 30 patients of oligomenorrhoea aged between 15 and 35 years were given *Shatpushpa churna* 5 gm twice for three months. Significant results were obtained on interval of menstruation, duration of menstruation, amount of blood flow and pain during menstruation²⁰.

Research studies on *Shatpushpa* have demonstrated its several benefits on metabolism as well as on menstrual disorders and infertility.

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Kalpa method of treatment of *Shatpushpa* has not been studied previously. So this study was taken to evaluate its effectiveness in this form.

For the second group, life style modification through series of four *yogasanas*- *Surya Namaskara*, *Pranayama*, *Vajrasana* and *Savasana* were selected as method of intervention. *Yogasanas* are an effective form of physical exercises which can control body fat and thus balance the endocrine functions in PCOS.

Obesity is one of the major associated features as well as manifestation of PCOS. The adipose tissue (fat) is considered an endocrine and immunomodulatory organ; it secretes leptin, adiponectin and cytokines which interfere with insulin signalling pathways in the liver and muscle resulting in insulin resistance and hyperinsulinemia. Raised LH secretion by insulin can cause infertility or miscarriage through improper oocyte maturation²¹. Physical exercises in form of *yogasanas* can help in reduction of body fat and therefore, restoring endocrine balance. Previous researches have shown results of *yogasanas* on metabolism, menstrual disturbances, lipid profile and other factors.

Some trials on *yogasanas* have been quoted here: a series of *asanas* consisting of *Uttanapadasana*, *Pawanmuktasana*, *Naukasana*, *Bhujangasana*, *Dhanurasana*, *Vakrasana*, *Padhastanana*, *Nadishodhana Pranayama*, *Savasana*, etc - for 20 min for 6 days in 25 patients for 12 weeks was evaluated on PCOS patients between 18 and 35 years of age. The intervention group (n=25) underwent Y&N therapy for 12 weeks.

Significant improvement was observed in the ovarian morphology ($P<0.001$) and the anthropometric measurements ($P<0.001$) between the two groups²².

Thirty-one women with PCOS between the ages 23 and 42 years were recruited for a randomized controlled study arm consisting of a yoga intervention group and a control group. After 3-month intervention period, 13 in yoga group completed the treatment and had significantly lower free testosterone levels. Also, improvements were seen in anxiety and depression²³.

It can be seen from above results that *yogasanas* are beneficial to improve metabolism, reducing body weight and improving fertility and menstrual symptoms in females. Specific mechanism of action of these cannot be established. Some theories state that stretching and relaxing during certain postures such as *Paschimottasana*, *Bhujangasana* during *Suryanamaskara* activate sensory and motor cortex and activate other brain parts. This process also activates the sensory-motor cortex. At the same time body and breathing awareness activates many other regions of the brain and enables concentration. *Savasana* has been considered as 'Sense Reduction type' *asana*. Here, the sensory motor nerve activity is forcefully reduced. By detracting and diverting all the external and internal sensory motor organs' activity these types of *asanas* could produce relaxation feelings. During these *asanas* fullest

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contraction could be focused on the related muscles which activates the sensory-motor cortex²⁴.

MATERIALS AND METHODS

Trial Design

An open label randomised clinical trial consisting of two groups was conducted on female patients of reproductive age group (16 to 40 years) attending the out-patient department of the Rishikul Campus, Haridwar. Patients were randomized to both the intervention groups. Total 35 patients were registered which were diagnosed with symptoms of PCOS.

Screening

Patients presenting with symptoms of PCOS were examined thoroughly. Patients having symptoms of the disease for 6 months or more and not receiving any form of treatment were selected for the trial. Data was recorded systematically including height and weight. Besides, a research proforma was filled for every registered patient with informed consent and *prakriti* was also analysed. All the patients were subjected to investigations of CBC, LH and FSH ratio, prolactin, thyroid profile and ultrasound of lower abdomen.

Inclusion criteria

Females of age between 16 to 40 years were included fulfilling at least 2 of following 3 criteria (in accordance with Rotterdam revised criteria for PCOD, 2003)²⁵

1. Oligomenorrhoea and / or amenorrhoea

2. Hyperandrogenism (clinical and/or biochemical)

3. Polycystic ovaries- diagnosed by USG showing

Number: >12 follicular cysts.

Cyst size: 2-9 mm diameter

Ovarian volume: $\geq 10 \text{ cm}^3$.

Exclusion criteria

1) Patient suffering from acute and chronic medical and systemic diseases like hypertension, T.B. or heart disease.

2) Severe anaemia (Hb < 10 gm/dl) or bleeding disorders

3) CAH (Congenital Adrenal Hyperplasia)

4) Cushing's syndrome

5) Thyroid dysfunction

6) Severe hyperprolactinaemia

7) Abnormal (benign or malignant) growth of reproductive organs (fibroids or TO mass)

8) Females who have practiced any form of *yogasanas* previously.

9) Any organic lesions of reproductive tract- carcinoma or congenital deformities or any pelvic pathology.

10) Patients having contraindicated conditions for *yogasanas* (h/o surgery or any diseases of spine or joints or any other acute conditions).

Interventions

Number of patients assessed were 42 and 7 patients were excluded as they did not fulfil the inclusion criteria. Total 35 patients were included in the study and randomly distributed into two groups (Group A-21 patients and Group B -14 patients) by simple randomization method. More

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number of patients were assigned in group A to study the results of this unique method of treatment i.e. *kalpa chikitsa*.

One group was advised oral drug – *Shatpushpa kalpa* and another group was advised *yogasanas*. Duration of both the interventions was three months (90 days) followed by a follow up period of one month.

GROUP A

Identification of the drug

Seeds of the herb *Shatpushpa* were properly identified and verified from *Dravayaguna* department of the institute (letter no. D6-RC-UAU 38) and then made into powder in the local pharmacy. Packets containing 6gm each of *Shatpushpa* powder were made for distribution to patients. The powder was provided to patients and dose was advised in a specific manner with *gau ghrita* as *anupana*. [Table 1]. Patients were instructed to take light diet during the course of treatment. First dose was to be taken empty stomach in the morning and second dose after 12 hours with a gap of two hours after last meal.

Kalpa form of medicine

The reference of use of *Shatpushpa* in gynaecological disorders is given in *Kashyap Samhita*. The dose of 100 *pal* has been stated to provide maximum benefits in *kalpa* form. It is to be started from $\frac{1}{4}$ *pal* (12 gm), $\frac{1}{2}$ *pal* (24 gm) or 1 *pal* (48 gm)²⁶. *Kalpa* is a specific type of intervention given in ayurvedic classics in which the dose of a particular drug is gradually increased from minimum to maximum. Then the dose is gradually tapered again to reach the initial

dose. This method is applied to make the drug wholesome and provide the maximum benefits of the drugs. All the benefits of *Shatpushpa* as mentioned by *Acharya Kashyapa* can be achieved by using it in *kalpa* form. So, to study the efficiency of the drug, the *Kalpa* method was adopted.

The *kalpa* form of treatment has been mentioned in *Charak Samhita*²⁷ and *Sushruta Samhita*²⁸ and also by *Acharya Vagbhata*²⁹. *Chakarapani* has also mentioned *parpati kalpa* in *Grahani chikitsa*³⁰. The dose of *Shatpushpa kalpa* was decided in a specific order so that the maximum dose mentioned-100 *pal* (4800 gm) is consumed within the intervention time of the trial. Reference for the increasing and decreasing doses with duration was taken from the first chapter of *Chikitsasthana* of *Charak Samhita* where *kalpa* form of *Nagbala* is given for *rasayana* benefit³¹. The increasing and decreasing dose of *Shatpushpa* and duration is decided considering the above reference. *Acharya Kashyapa* has not mentioned any specific time duration for consuming 100 *pal* of *Shatpushpa*.

As this method was studied for first time, no reference for dose was available. Patients were able to consume maximum of 18 gm of *Shatpushpa*. Therefore, were kept at tolerable dose for three months period.

For further studies, dose can be adjusted to keep minimum.

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Table 1 Dose of *shatpushpa* according to *kalpa* method - Increasing method

Dose	Minimum dose	Days	Total dose
24 gm	12 gm BD	5 days	120 gm
24 gm	12 gm BD	6-11 days	144 gm
36 gm	18 gm BD	12-17 days	216 gm
48 gm	24 gm BD	18-23 days	288 gm
60 gm	30 gm BD	24-30 days	420 gm
72 gm	36 gm BD	31-37 days	504 gm
84 gm	42 gm BD	38-45 days	672 gm

Decreasing method

Dose	Minimum dose	Days	Total dose
84 gm	42 gm BD	46-53 days	672 gm
72 gm	36 gm BD	54-60 days	504 gm
60 gm	30 gm BD	61-67 days	420 gm
48 gm	24 gm BD	68-73 days	288 gm
36 gm	18 gm BD	74-79 days	216 gm
24 gm	12 gm BD	80-85 days	144 gm
24 gm	12 gm BD	86-90 days	120 gm

Total dose of 90 days 2400gm (app.) + 2400gm (app.) = 4800gm (app.) i.e. 100 *pal*

GROUP B

Four *Yogasanas*- *Nadi Shodhana Pranayama*, *Surya Namaskara*, *Savasana* and *Vajrasana* were selected for second group. *Pranayama* is a method of inhaling and exhaling which relaxes the mind. The blood receives a larger supply of oxygen in *Nadi Shodhana* as compared to normal breathing, so the nerves are calm and purified³². *Surya Namaskara*, consists of series of 12 different *asanas* in one cycle (*Pranamasana*, *Hastauttanasana*, *Hastapadasana*, *Ashwasanchalanasana*, *Dandasana*, *Ashtanga Namaskara*, *Bhujangasana*, *Adhomukha Svanasana*, *Ashwa Sanchalanasana*, *Hastapadasana*, *Hastauttanasana* and *Tadasana*). These *asanas* provide complete physical workout to the body³³. *Savasana* is a form of relaxing technique in which the person lies flat on the ground concentrating on the breathing. It is done to remove fatigue from other

asanas and for calmness of mind³⁴. *Vajrasana* is a sitting posture performed just after meals. It helps in improving digestion³⁵.

Only such females were selected who have not received any form of *yogasanas* previously.

Patients, after registration, were demonstrated these *asanas* under guidance of yoga expert of the institute. Patients attended morning yoga classes in the institute. They were advised to practice at home if they were not able to attend the classes. To start with, 8 to 10 rounds of *Nadi Shodhana Pranayama* were done. Then 4 rounds of *Surya Namaskara* were done and increased gradually upto maximum 12 rounds at one time. It was followed by 10 to 15 minutes of *Savasana* for relaxation. *Vajrasana* was advised to be done just after meals, two times, for duration of 3 to 5 minutes. Total duration of intervention was 3 months and to be avoided during menstruation.

Assessment and outcome

Subjective criteria (menstrual history table 2)

- Duration of menstruation
- Interval of menstruation
- Amount of bleeding
- Pain during menstruation

Objective criteria

- Obesity (on basis of BMI)
- Endometrial thickness (ultrasonography)
- Hirsute (Ferriman and Gallway scoring)³⁶
- Ovulation profile (ultrasonography)
- Number of follicles and ovarian volume (ultrasonography)

Data collection

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Table 2 Menstrual history wise distribution

MENSTRUAL SYMPTOM	GROUP A	GROUP B	TOTAL	PERCENTAGE
Menstrual bleeding				
Scanty (1-2 pads/day)	07	04	11	31.42%
Normal (3-4 pads /day)	11	09	20	57.14%
Excessive (7-10 pads/day)	03	01	04	11.42%
Menstrual Duration				
3-5 Days	17	11	28	80 %
1-2 days	1	2	03	8.57 %
1 day only	01	01	02	5.71%
Spotting only for 1 day	2	00	02	5.71%
Menstrual Interval	01	00	1	2.85%
21-35 days				
36 -50 days	0	03	03	8.57%
51-65 days	18	04	22	62.85%
66-80 days	0	0	0	0
>80 days interval	02	07	9	25.71 %
Menstrual Pain				
Mild	01	02	03	8.57%
Moderate	05	02	07	20%
Severe	04	03	07	20%
Without pain	11	07	18	51.42 %

Table 3 Sociodemographic details of patients

	GROUP A	GROUP B	TOTAL	PERCENTAGE
Age				
16-25 years	7	11	18	51.42%
26-35 years	14	3	17	48.57%
35-50 years	0	0	0	0
Marital status				
Married	10	1	11	31.42%
Unmarried	11	13	24	68.57%
BMI (Kg/m²)	12	7	19	54.28%
18.50-24.90				
25-29.99	9	5	14	40%
30-34.99	0	2	2	5.71%

Table 4 Chief complain wise distribution

	GROUP A	GROUP B	TOTAL	PERCENT
Infertility	9	0	9	25.71%
Delayed menses (>50 days interval)	12	12	24	68.57%
Hirsute	2	4	6	17.14%
Weight gain	3	5	8	22.85%
Unilateral PCO (USG)	1	0	1	2.85%
Bilateral PCO (USG)	19	12	31	88.57%
Normal finding (USG)	1	2	3	8.57%
LH; FSH <2	15	11	26	74.28%
LH; FSH >2	6	3	9	25.71%

Table 5 Result of interventions

Group A n=17

Group B n=13

PARAMETER	INTERVENTION PERIOD	GROUP A SD	p	GROUP B SD	p
Interval of menses	0 days	1.27	.002	0.76	.005

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	90 days	1.00		0.82	
Duration of menses	0 days	0.83	0.257	0.44	1
	90 days	0.71		0.44	
Amount of bleeding	0 days	0.72	0.039	0.44	1
	90 days	0.39		0.44	
Pain during menstruation	0 days	1	0.029	0.52	0.039
	90 days	0.39		0.48	
Endometrial thickness	0 days	0.61	0.317	0.44	1
	90 days	0.51		0.44	
BMI	0 days	0.72	0.317	0.69	0.020
	90 days	0.62		0.48	
Hirsute	0 days	0.39	1	0.66	1
	90 days	0.39		0.66	
Follicular study	0 days	0.00	0.014	-	-
	90 days	0.93			
Ovarian volume	0 days	0.82	0.102	1.19	1
	90 days	1.14		1.19	

The patients were advised to report every month to assess changes in the menstrual interval, duration, amount of bleeding, etc. During each visit, the required medicine was given. The study drug was administered for three months continuously. For the *yoga* group, patients attended the morning *yoga* classes in the institute and examined monthly. Following this, the next one month was considered as a follow-up period in which the clinical changes in the patients were assessed.

Sample size

The study was a randomized parallel group comparative design clinical trial. Assuming 95% confidence interval and 80% power, the calculated sample size was 30 with 10% margin of error (30 patients in each group- total 60 patients). However, the study was conducted during the covid epidemic and had to be completed within specified time for fulfilment of thesis work, resulting in lesser number of patients assessed.

Randomization

Eligible and willing patients were enrolled from the out patient department of prasuti tantra & stree rog, Rishikul campus. Patients were randomized to both the intervention groups. The randomization, enrolment and allotment to groups was done by independent professionals not involved with the trial. Total 42 patients were assessed and 7 patients were excluded as they did not fulfil the eligibility criteria. Simple randomization method was used and patients were randomized to both groups- 21 in group A and 14 in group B.

Statistical methods

The results were analysed by Mann Whitney and Wilcoxon sign rank sum test using IBM SPSS statistics subscription. The confidence interval was considered at 95%. $p < 0.05$ is considered as significant and $p < 0.01$ was considered highly significant.

Intra group test: Observation of subjective and objective parameters was analysed by Wilcoxon Signed Rank Test. Inter-group comparison test: Observation of subjective and objective

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parameters was analysed by Mann Whitney U test.

RESULTS

Participant flow

Total 42 patients were assessed for the trial, out of which 7 patients did not meet the inclusion criteria. Remaining 35 patients were randomly distributed in two groups. 21 patients were allotted in group A (*Shatpushpa Kalpa*) and 14 patients were allotted for group B (*Yogasanas*).

Out of these, 4 patients from group A does not wish to continue treatment and 1 from group B left the treatment due to change of workplace. So, total 17 patients in group A and 13 in group B were finally analysed for the results.

Baseline data

Table 3 and table 4 shows baseline demographic and clinical characteristic of the patients in both the groups.

Outcomes

Out of 35 registered patients, 5 patients dropped out of the study. Total 30 patients completed the trial- 17 in group A and 13 in group B.

Feature of delayed menses (*yathochit kala adrashanam*) is a frequent complain of patients presenting with PCOS. Total 26 patients had above complain. *Shatpushpa kalpa* and *Yogasanas* both have shown significant improvement in this symptom. Pain during menses (*kashtartava*) has also shown improvement in both the groups. Although

anovulatory cycles are generally painless, mild to moderate variety of pain during menses was the complain of some of the patients (n=17). *Shatpushpa kalpa* was also effective on amount of menstrual bleeding and follicular study. Patients of PCOD/PCOS can present with symptom of both hypomenorrhoea or menorrhagia. In present study, majority patients were of hypomenorrhoea (*alpata*) in which *Shatpushpa* showed improvement by increasing the amount of menstrual blood loss (n=8). Follicular study was advised in patients complaining of infertility (n=9). *Shatpushpa kalpa* showed improvement in follicular study by evidence of follicular rupture.

Besides, second intervention group *yogasanas* also showed results on BMI (n=9).

Other symptoms such as hirsutism, endometrial thickness and ovarian volume showed no changes in the trial. The results of the trial with standard deviation and their significance level are shown in table 5.

Registration

The study was approved by institutional ethical committee, letter number- UAU/RC/IEC/2019/04-02/42 dated 28 Feb 2020 and registered under CTRI - **CTRI/2020/03/024114**. Duration of study was from April 2020 to April 2021.

DISCUSSION

Discussion on observations

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As seen in demographic data [table 3] maximum patients (n=18) were from the age group of 16-25 years followed by (n=17) age group of 26-35 years, which showed the increasing incidence of symptoms in younger age group just succeeding the teenage. Symptoms manifest as absent or delayed menses along with increase in weight and hirsutism; which made them concerned for treatment. It may be due to their sedentary life style, stress full conditions and unhealthy eating habits etc.

Patients of the age between 26 to 35 years are more conscious for the complaint of infertility. Their causes can be attributed to above factors along with late marriages in today's time.

Seeing marital status [table 3] maximum patients were unmarried (n=24) and remaining were married (n=11)

Majority of unmarried patients indicates that incidence of PCOS is increasing at a fast pace and affecting females from early age.

Considering the menstrual symptoms, it was observed that majority of patients had irregular cycles. Maximum patients (n=22) had menstruation at 51-65 days, (n=9) had >80 days and (n=3) had 36-50 days interval.

Duration of menstruation was normal (3-5 days) in majority of patients.

Considering chief complains, [table 4] Out of total registered 35 patients, maximum patients (n=24) had complain of delayed menstruation (50-65 days interval) followed by infertility (n=9). Weight gain and hirsutism were also

present as associated complains in (n=8) and (n=6) patients respectively.

Observing the USG finding [table 4], maximum patients were having bilateral PCO (n=31).

Presence of polycystic ovaries has also been included in the diagnostic criteria. It is due to arrest of follicles at primary stage of development.

Follicular study was carried out only in women with complaint of infertility (n=9) showing the follicular size <10 mm or between 10 to 12 mm which is considered as very small because for normal ovulation the size of the follicle should be between 18 to 20 mm³⁷.

Serum LH and FSH ratio [table 4]-In PCOS, gonadotropin-releasing hormone (GnRH) pulsatility leads to preferential production of luteinizing hormone (LH) compared with follicle-stimulating hormone (FSH). LH and FSH ratios are elevated and rise above 2:1 in approximately 60 percent of patients³⁸.

In the present study the LH and FSH ratio was <2 in maximum patients (n=26) while in rest of the patients, it was >2 (n=9). It may because it is raised in late manifestation or may show the severity of disease.

Discussion on results

Seventeen patients in group A and 13 in group B were analysed for results at the end of the trial after 90 days.

The research trial on PCOS shows results in improving the symptoms. Group A, *Shatpushpa kalpa*, showed its effect on oligomenorrhoea,

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improves hypomenorrhea, decreases dysmenorrhoea and promotes ovulation.

Group B, *yogasanas*, also showed its effect on oligomenorrhoea and reducing dysmenorrhoea. In addition, it also shows improvement in obese patients by reducing BMI. Other symptoms such as LH:FSH ratio, hirsutism, endometrial thickness and ovarian volume shows no changes in the trial.

The results of the trial after 90 days with standard deviation and their significance level is shown in table 5. Observations of subjective and objective parameters within the group were analysed by Wilcoxon Signed Rank Test using IBM SPSS statistics subscription. The confidence interval was considered at 95%. $p < 0.05$ is considered as significant and $p < 0.01$ was considered highly significant.

Inter group comparison result was non-significant.

For oligomenorrhoea (menses at interval > 50 days), after treatment of 3 months with *Shatpushpa kalpa*, maximum patients showed improvement (interval < 35 days). The result was statistically significant ($p = 0.002$). *Yogasana* group also shows significant ($p = 0.005$) result on oligomenorrhoea.

Amount of blood loss during menses was assessed according to menstrual pictogram³⁹.

Group A shows significant results ($p = 0.039$) on amount of menstrual blood loss. Group B shows no result on this parameter. Group A shows statistically very significant ($p = 0.029$) result on

dysmenorrhoea. Group B also shows significant ($p = 0.039$) result.

On BMI, statistically analysing the results, it is significant in group B ($p = .020$) and non-significant in group A. ($p = .317$)

Follicular study was advised in group A only as group B does not have any infertility related patients. Before treatment 8 patients were in grade 2 and after treatment 6 patients were in grade 0. It shows statistically significant result. ($p = .014$)

Probable action of *Shatpushpa Kalpa* and *Yogasanas*

In the features of *Pushpaghni jataharini*, *vritha pushpam* can be related to the condition of infertility and *sthoola lomash ganda* denotes physical conditions of fatty and hairy cheeks. In ayurveda, considering the role of *tridosha* in *rituchakra*, the condition of *vritha pushpam* results from aggravated *kapha dosha*, *apana vayu dushti* and *pitta dosha karma avrodha*. This *dosha* vitiation results from *jatharagni daurbalya* as *ahara rasa* is the foremost entity for *pushpa* formation and also responsible for the condition of *sthoolta*⁴⁰.

Acharya Kashyapa has not explained *samprapti* of *Pushpaghni jataharini* or involvement of *doshas*, but, on the other hand, he has emphasised the multifaceted therapeutic effect of drug *Shatpushpa* in

Shatpushpashatavarikalpaadhyaya. *Shatapushpa* is having some unique combination of its *rasa panchaka* and their *prabhava* i.e., *katu-tikta rasa*, *tikshna-laghu guna*, *katu vipaka* and *ushna virya*.

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Even though it's not having *madhura rasa* or *vipaka* but *acharya Charaka* has included it in *madhura skandha*⁴¹ and *acharya Kashyapa* has also explained it as “*madhura brinhanai balya pushti vardhini*”⁴².

It can be assumed that the specific *dosha karma* of *rasa pakchaka* of *Shatapushpa-Kaphashamaka*, *amapachaka*, and *vatanulomaka*, lead to normal *rajah Utpatti* (menstruation) and *beeja nirmana* (ovulation) after removal of *avarana* of vitiated *kapha* & *ama* in *artavavaha srotas* and also normalises the *apana vata* functions. Its *madhura prabhava* strengthens the *srotas* (channels in the body) by its *balya* (nutritive) and *pushtivardhaka* (needful changes) effects for the functions of *artava*.

Phytochemical analysis of *Shatapushpa* revealed the presence of alkaloids, carbohydrates, tannins, triterpenoids, flavonoids and proteins in methanol extract⁴³. *Shatapushpa* significantly showed the presence of flavonoids which are protective in action. These are considered as naturally dietary biologic response modifiers, disease preventing and health promoting; therefore, may be effective in the management of infertility and pregnancy. Its steroidal presence indicates that this drug may have influence on the endocrine system as these are precursors for synthesizing sex hormones, especially progesterone and oestrogen, which are basic factors for maintaining reproductive and endocrine functions.

Yogasanas have been selected as second method of intervention. Four *yogasanas* (*Nadi Shodhana*, *Pranayama*, *Surya Namaskara*, *Vajrasana* and

Savasana) have been selected for the study keeping in mind their effect on physical as well as mental state. An exact mechanism for the benefits of these *asanas* cannot be established. Some theories and hypothesis for explaining mechanism of *yoga* has been discussed previously. Some more previous research studies have been narrated further.

In one study, 101 participants, (males and females) suffering from type 2 diabetes, age group 35 to 70 years, were involved comprising *yoga* interventions (*Pranayama*, meditation, *Paschimottanasana*, *Trikona asana*, etc.) Study showed significant improvements in insulin resistance, HbA1c and LDL⁴⁴. In another trial, 90 adolescent girls (15-18 years) according to Rotterdam criteria were randomized into two groups. The *yoga* group practiced *Surya Namaskara*, *Trikonasana*, *Sarvangasana*, *Halasana*, *Savasana*, *Pranayama*, etc. while control group practiced a matching set of physical exercise for 12 weeks. Reduced level of AMH, LH and testosterone, hirsutism score and improved menstrual frequency were found in *yoga* group⁴⁵.

Yogasanas have been found to be more beneficial than physical exercises in improving intelligence and reducing anxiety⁴⁶. A meta-analysis of randomized controlled trials states that it is an effective intervention for alleviating menstrual pain in women with primary dysmenorrhea⁴⁷. Lifestyle intervention improves body composition, hyperandrogenism (high male hormones and clinical effects) and insulin

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resistance in women with PCOS⁴⁸. The postulated mechanism of action of *yoga* is through parasympathetic activation and the associated anti-stress mechanism. It reduces perceived stress and HPA axis activation thereby improving overall metabolic and psychological profiles, increasing insulin sensitivity and improving glucose tolerance and lipid metabolism⁴⁹. *Surya Namaskara* benefits in improving the metabolic functioning of the body and regulates the secretion of the glands. It plays an important role in balancing the functioning of endocrine glands. This property helps to regulate the transition period between childhood and adolescence in growing children, especially females⁵⁰.

By above findings, it can be assumed that *yogasanas* have a holistic approach of treatment. As PCOS results due to disruption of metabolic and endocrine functions of the body, these *asanas* can restore the balance by their action at every physiologic level.

CONCLUSION

Shatpushpa kalpa showed improvement in oligomenorrhoea, hypomenorrhea and infertility in PCOS. It was found to be safe, well tolerated to the patients and without any adverse effects. Lifestyle intervention in form of *yogasanas* were also found to be beneficial in improving BMI and oligomenorrhea. These findings suggest that regular practice of *yoga* can be a useful

complementary therapeutic option for better health in women with PCOS.

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