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A Randomized Control Open Label Clinical Trial on the Efficacy of Shatapushpa Churna and Madhutailika Basti in Nashtartava w. s. r. to Polycystic Ovarian Syndrome

Dr. Shalvi Sharma¹, Dr. Bhagya Ranjan Dash²

¹Ayurvedic Medical Officer, GAHC Kharsi, Distt. Mandi, H.P. (Previous M.S. Scholar,
Prasuti Tantra evam Stree Roga, NIA, Jaipur.)

²Assistant Professor, PG Dept. of Roganidan, Govt. Ayurvedic College & Hospital, Tulasinagar, Balangir,
Odisha.

Corresponding author: Dr. Bhagya Ranjan Dash

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Abstract

Introduction (Background) - The health of society depends largely on the health of women. A woman should have normal regular menstrual cycle in order to maintain normal reproductive health. Now a day, Polycystic Ovarian Syndrome is becoming a major health problem worldwide. It is a major non-communicable health problem affecting the women of different age groups.

Methods - 33 clinically diagnosed patients of *Nashtartava* were selected from OPD and IPD of *Prasuti Tantra* and *Stri Roga* department of NIA, Jaipur as per criteria of inclusion. These patients were randomly divided into two groups and the study was completed on 30 patients; 15 patients in each group.

Result - It was found on comparing both the groups on the basis of symptomatic improvement, that, average percentage of relief was higher in 'Group A' i.e., 67.41%, while that in case of 'Group B' was found 55.92%. Thus, the effect of therapy was found more in 'Group A' in comparison to 'Group B'.

Conclusion - *Shatapushpa Churna* was found more effective than *Madhutailika Basti* in improving the symptoms of *Nashtartava* (w. s. r. to PCOS).

Keywords : *Madhutailika Basti*, *Nashtartava*, *Oligomenorrhoea*, *PCOS*, *Shatapushpa Churna*.

Introduction :

PCOS is becoming a burning health issue as it may lead to several serious complications like diabetes mellitus, cardiovascular diseases, hypertension, endometrial carcinoma, breast cancer etc. in later life. Due to adoption of western culture by most of the women and increased stress and strain in day-to-day life, the incidence of Polycystic Ovarian Syndrome is increasing alarmingly in adolescent and women of reproductive age group along with other life style related disorders. In India, out of every 5 women [1] is affected with PCOS, having prevalence in 20 - 30 years age group. It is diagnosed on the basis of presence of any two out of the following three criteria, viz., Oligo and or anovulation, Hyperandrogenism (Clinical and /or biochemical), polycystic ovaries [ASRM/ESHRE, 2003]. Women who are having irregular menstrual periods have very high chances of having PCOS (91%) and the women who are suffering from PCOS are 15 times more likely to suffer from infertility.[2]

As per Ayurveda, any change in the equilibrium of Doshas, Dhatus and Malas, leads to Samprapti of the diseases. As PCOS is a syndromic condition, so it cannot be correlated with a single disease condition, but given under the headings Yonivyapad (genital disorders) and Artava Dushti (menstrual disorders) as per Ayurvedic literature is concerned. After describing eight disorders of Artava, Nashtartava has been described by Acharya Sushruta and Vagbhata respectively^[3,4]. , Nashtartava is a symptom as well as a disease caused due to vitiation of Vata and Kapha Doshas as they cause Margavarodha of Artava Vaha Srotas leading to absence of menses or abnormal flow of Artava. Acharya Vagbhata mentioned that, due to

Vata and Pitta, the Raja is decreased leading to Lohitakshaya.^[5] Decreased menstrual flow is the main feature of Vataja Yonivyapad, Rajodhatu Kshaya, Vataja Artava Dushti, Kshina Artava Dushti etc. Acharya Kashyapa described Pushpaghni Jataharini which is having features like Vrutha Pushpa (futile ovulation) and Sthula Lomasha Ganda (hairy cheek).^[6] The features of PCOS may also be correlated with these. Acharya Bhavamishra also mentioned about Nashtartava in Yoniroga Chikitsa Prakarana.^[7] Initially, in early stage, PCOS could be considered as a Vata-Kapha predominant disease and later on in chronic condition, it becomes a Tridoshaja Vyadhi due to involvement of all three Doshas. Here, mainly Rasa Dhatudushti is involved, due to which improper Artava Upadhatu formation occurs.

Materials and Methods Patients:

33 clinically diagnosed patients of Nashtartava were selected from OPD and IPD of Prasuti Tantra and Stri Roga department of NIA Jaipur as per criteria of inclusion.

Inclusion criteria :

- Female patients of age group between 18 – 40 years (Both married and unmarried).
- ASRM/ESHRE (Rotterdam) Criteria, 2003- Affected individuals must have two out of three criteria :
 1. Oligo and /or anovulation
 2. Hyperandrogenism (clinical and /or biochemical).
 3. Polycystic ovaries (Confirmed on USG).

Exclusion criteria :

- Women of age <18years and >40years.
- Patients with chronic systemic illness (Congestive cardiac failure, Hypertension, cirrhosis of liver, chronic renal disease, diabetes mellitus, Tuberculosis etc.).
- Patients using oral contraceptive pills.
- Patients with any organic reproductive system abnormalities (Excluded clinically and radiologically), pelvic inflammatory disease, hydrosalpinx, endometriosis, adenomyosis, fibroid uterus, carcinoma of reproductive organ.
- Any type of malignancy.
- Patients with positive Sexually transmitted diseases (STDs), Human Immunodeficiency Virus HIV, Hepatitis B Surface Antigen (HbsAg).
- Patients suffering from adrenal hyperplasia, severe insulin resistance, androgen secreting neoplasm, thyroid abnormalities, Cushing's syndrome.

Drugs :

Drugs for both the groups were procured from the pharmacy of NIA Jaipur. *Shatapushpa Churna* in the form of coarse powder and *Basti* drugs were obtained separately in the form of raw drugs. Report of drug analysis was obtained from the Drug Testing Laboratory of NIA Jaipur.

Investigations :

Blood and serological tests - Complete Blood Count, Erythrocyte Sedimentation Rate, VDRL

(Venereal Disease Research Laboratory), HIV (Human Immunodeficiency Virus), HBs Ag (Hepatitis B Surface Antigen), Random Blood Sugar, RFT (Renal function test), LFT (Liver function test). Urine routine and microscopic investigations were done. Hormonal tests including FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), PRL (Prolactin), Thyroid function test (TFT). USG were done on 2nd or 3rd day of menses. Investigations like Hemoglobin, Total Leukocyte Count, Erythrocyte Sedimentation Rate, Random Blood Sugar, Liver Function Test, Renal Function Test, Thyroid Profile, Serum Luteinizing Hormone and Serum Follicular Stimulating Hormone.

Study Design: A randomized control open label clinical study was done. Before taking the patient in trial, informed consent was taken from every patient.

Management of patients :

Drug dosage, duration, and method of administration

Grouping :

From the selected patients, two groups were made by randomly dividing them.

Group A : *Shatapushpa Churna* was given orally to the patients before meals in a dose of 6gm, twice a day with *Goghrita* and warm water. Medicine was started from 1st day of menses and was continued for 3 consecutive cycles. Total 17 patients were clinically diagnosed and registered in Group A, out of which 15 continued the treatment and 2 patients discontinued.

Group B – *Madhutailika Basti* was given in a dose of 400ml through anal route empty stomach in morning. In case of irregular cycles, it was given for 7 days (after initial screening), then there is a waiting period of fifteen days, during which the patient may get her periods. The next seven days of medicine is started seven days prior to the expected date of next menstruation, in case she does not get her periods, medicine again started for seven days, after the waiting period, this follows for three cycles of medicine administration. While, in case of regular cycles, *Basti* was given seven days prior to the expected date of menstruation for three consecutive cycles. Total 16 patients were clinically diagnosed and registered in Group A, out of which 15 continued the treatment and 1 patient discontinued.

Duration – 90 Days / 3 Menstrual Cycles.

Pathya – Apathya :

Pathya Ahara – Patients were advised to take *Yava, Shali Rice, Tila, Tila Taila, Matsya, Kulattha, Amla Dravyas, Masha, Dadhiⁱ, Puranaghrita, Purana Raktashali, Mudga, Patola, Raktashigru, Ruksha, Katu, Deepana Dravyas, Guggulu, Shilajatu.*^[9]

Pathya Vihara – Patients were advised to develop the habit of reading good books, doing regular *Yoga and Pranayama (Kapalabhati, Anulom a–Viloma, Bhramari, Suryanamaskara, Paschimottana Asana, Halasana, Sarvangasana, Shalabhasana, Makarasana etc.)*, brisk walking, *Bramha-Muhurta Jagarana*, taking dinner before sunset, *Chankramana*, early sleeping habits, meditation, *Sharirika* and *Manasika*

Bramhacharya, Kala Maithuna, Achara Rasayana.

Apathya Ahara – Patients were asked to avoid *Kaphakara, Vatadushtikara, Medovriddhikara Ahara; Atyashana, Adhyashana, Vishamashana, Paryushita Ahara, Atisheeta Udaka Evam Ahara, Ruksha Ahara* e.g., Besana etc, *Vatala Ahara* e.g., Potato, Chickpea, ladies' finger etc., *Navanna, Kodrava, Nishpava, Kalaya, Gramya Mamsa, Anupa Mamsa, Varaha Mamsa, Gomamsa, Shushka Shakha, Sheetala Jala, Mahisha Khseera, Phanita*, artificial sweeteners, *Ruksha, Guru Anna, Abhishyandi Dravya*, Fast food, spicy foods, *Panipuri*, burger, pizza, chocolates, cold drinks, fermented foods, oily and fried food.

Apathya Vihara – Patient was asked to avoid *Divaswapna, Ratrijagarana, Avyayama, Vegadharana, Ativyavaya, Atichinta, Atibhaya, Atikrodha, Atishoka.*

Follow up :

1. During trial – After completion of every menstrual cycle.
2. After completion of the trial, the cases were followed up to one consecutive menstrual cycle.

Assessment Criteria :

Before and after the treatment, clinical features were observed and assessed and at the end, total effect of therapy was evaluated in every patient. To assess the clinical improvement, a specific scoring pattern was framed.

Assessment of overall response :

Effects	Percentage of Relief
Good	>75-100 %
Fair	>50-75 %
Poor	>25-50 %
No response	≤25%

Statistical analysis :

The data was subjected to statistical analysis after obtaining observations. $P < 0.05$ was considered as statistically significant. $P < 0.01$ or $P < 0.001$ was considered as statistically highly significant. $P > 0.05$ was considered as statistically non-significant.

Observation and Result :

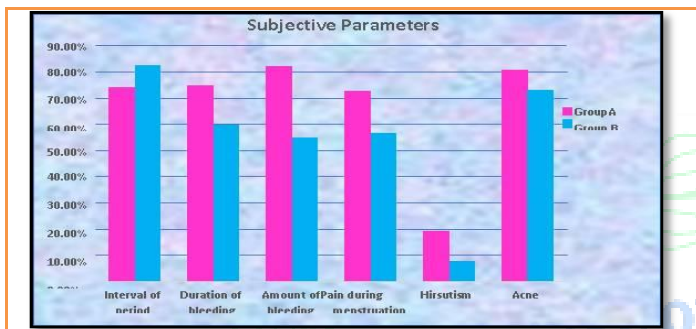
In the present study out of total 30 patients, majority i.e. 22 (73.33%) were from 18 – 25 years age group, 23 (76.67%) patients were Hindus, 25 (83.33%) were unmarried, 26 (86.67%) patients were from urban habitation, 03 (10%) patients took allopathic medicine for the same problem previously, 20 (66.67%) revealed a positive family history, oligomenorrhoea was present as a chief complaint in maximum 26 (86.67%) patients, reduced quantity of flow was present in 18 (60%) patients, hirsutism was present in 19 (63.33%) patients, mid-body obesity was present in 17 (56.67%) patients, acne was present in 17 (56.67%) patients, acanthosis nigricans was present in 04 (13.33%) patients, alopecia was present in 15 (50%) patients, infertility was present in 04 (80%) married patients, menstruation was irregular in 19 (63.33%) patients, 11 (36.67%) patients were having chronicity more than 3 years, interval of bleeding was found > 45 days in 50% patients,

maximum 16 (53.33%) patients were having scanty menstruation, mild pain during menses in 15 (50%) patients, 18 (60%) were vegetarian, 13 (43.33%) patients were doing *Vishamashana*, maximum 21 (70%) patients were having addiction of tea, 08 (26.67%) patients were having waist-hip ratio > 0.86, 12 (60%) patients were having Ferriman and Gallwey score ≥ 8 , maximum patients showed predominance of *Pitta Kaphaja Prakriti* (40%), maximum 40% patients showed predominance of *Satva Tama Dosh*, 40% patients were having 12 follicles in right ovary and 30% patients were having 12 follicles in left ovary, 53.33% patients were having right ovarian volume 10cc and 56.67% patients were having left ovarian volume 10cc, in 76.67% patients endometrial thickness was between 5 – 12mm, in 10% patients LH level was >15mIU/ml, in 23.33% patients, FSH level was >10mIU/ml, in 10% patients, PRL level was >25 ng/ml.

In group A, statistically significant results were found in Amount of bleeding, Duration of bleeding, Hirsutism and Waist-Hip Ratio. Statistically Highly significant results were found in Interval of period, Pain during menses, Acne, Reduction in weight and BMI.

In group B, statistically significant results were found in Duration of bleeding, Amount of bleeding and Waist-Hip Ratio. Statistically Extremely significant result was found in Interval of period, Pain during menses and Acne. On comparing both the groups, statistically significant result was found in Amount of bleeding and Pain during menstruation

[Graph no.-1.]. Changes in hematological parameters were within normal limits.



Graph no. - 1 : Showing Percentage relief in subjective parameters in both groups

Average Percentage of relief

After comparison of both the groups, on the basis of symptomatic improvement, it was found that average percentage of relief was higher in ‘Group A’ i.e., 67.41%, while that in case of ‘Group B’ was found 55.92%. Thus, the effect of therapy was more in ‘Group A’ in comparison to ‘Group B’ [Table no. -1.].

So, based on above results null hypothesis is rejected and alternate hypothesis is accepted that *Shatapushpa Churna* is more effective than *Madhutailika Basti* in treating *Nashtartava* (w. s. r. to PCOS).

Subjective Parameters		
Symptom	Result in Percentage	
	Group A (in %)	Group B (in %)
Interval of period	74.28	82.77
Duration of bleeding	75.00	60.01
Amount of bleeding	82.37	55.01
Pain during menstruation	72.73	56.65
Hirsutism	19.35	7.99
Acne	80.78	73.11
Average % of Relief	67.41	55.92

Table no. 1: Showing Percentage Improvement of Subjective and Objective Parameters in Both Groups (Group A, n=15 and Group B, n=15)

Overall Effect of Therapy :

On comparison of symptomatic improvements, it was found that overall relief was higher in Group A, where 6.67% (01) patients showed good response, 60% (09) patients showed Fair response, 26.67% (04) patients showed Poor response while 6.67% (01) patients showed no response to the therapy. In group B, none (0%) of the patients showed good response, 46.67% (07) patients showed Fair response, 46.67% (07) patients showed Poor response while 6.67% (01) patients showed no response to the therapy [Table no. – 2].

S. No.	Effect of Therapy	Percentage % of Relief	Group A		Group B	
			No.	%	No.	%
1.	Good	>75-100 %	01	6.67	00	00
2.	Fair	>50-75 %	09	60	07	46.67
3.	Poor	>25-50 %	04	26.67	07	46.67
4.	No response	25%	01	6.67	01	6.67

Table no. 2. : Showing Overall effect of therapy in both groups

Adverse Drug Reactions :

No any complications were found during treatment and follow up in patients of both the groups (Group A – *Shatapushpa Churna*, Group B – *Madhutailika Basti*).

Discussion :

Effect on Interval of menstruation: Statistically extremely significant result was found in both the groups but comparatively group B shown better result this was due to *Shodhana* property of *Madhutailika Basti*, which works on *Margavaroga*

and causes the *Vatanulomana*, Thus, normalizing the interval of menstrual cycle.

Effect on Duration of bleeding :

Statistically significant result was found in both the groups. This could be due to the *Ushna, Tikshna, Srotoshodhaka* properties of *Shatapushpa Churna*, which results in *Pitta-Vardhana* and *Srotoshodhana*.

Effect on Amount of bleeding :

Both the groups showed significant results on normalizing the scanty menstrual flow. But comparatively group A shown better result, this was due to the above-mentioned properties of *Shatapushpa Churna*, which was found better than *Madhutailika Basti*.

Effect on Pain during menstruation :

Statistically extremely significant results were found in both the groups. Maximum relief was seen in Group A. This may be due to the *Vata Shamaka* property of *Shatapushpa Churna*.

Effect on Hirsutism :

Statistically significant results were found in group A and statistically non-significant results were found in group B. This shows that better effect was found in group A, where an effective control was found on further hair growth. The probable reason for this could be that *Shatapushpa Churna* doing the *Vata-Shamana*, thus causing a decrease in *Malaroopa* of *Asthi Dhatu*.

Effect on Mid-body Obesity (in terms of Waist-hip Ratio) :

Statistically significant result was found in both the groups. Reduction of weight was found maximum in group A, this may be due to the *Agni- Vardhaka* property of *Shatapushpa Churna*, which increases the *Upachaya* of *Meda* and *Mamsa Dhatu*.

Effect on Hormonal analysis :

Both the groups showed statistically non-significant results on reduction of serum LH level, Reduction of Serum FSH level and Serum prolactin level. This was may be due to short duration of therapy due to which, no any significant result was found on hormonal analysis.

Probable Mode of Action of Drugs :

As *Guda* have *Siras* and *Dhamanis* it is considered as *Shareera Moola*. These *Shiras* and *Dhamanis*, spread all over body^[10]. Due to this reason, after entering into *Pakvashaya, Basti* works on entire body. It works by both, local as well as systemic mode of action. *Basti* helps in pacifying the vitiated *Apana Vata* resulting in proper *Vata Anulomana*. This result in enhancement of Purisha function i.e. '*Anila – Anala Dharana*'^[11]. In this way, it corrects *Agni Dushti*, resulting in proper *Rasa Dhatu Nirmana* and *Artava* formation, which leads to proper *Beeja Nirmana* and normal *Rajah Pravartana*. *Shatapushpa* is *Balya, Deepana, Pachana, Yonivishodhana, Artavajanana* and *Beejotsarga*. *Shatapushpa* is mentioned as *Vataprashamani* in *Sathapushpa- Shatavari Kalpadhyaya* of *Kashyapa Samhita*^[12]. It helps in alleviating *Vata*, which is the major factor in development of all *Yoni Rogas*. *Agneyatva* of *Shatapushpa* helps in *Artavajana* and acts as *Ritupravartini* (initiates menstruation or ovulation) and *Yoni-Shukra Visodhini*. According to the modern science, absorption of drug occurs through the mucosal layer when given through the rectal route. After entering into the gastro-intestinal tract, Enteric Nervous System (ENS) is stimulated by *Basti* and stimulatory signals are generated for

Central Nervous System (CNS) [13]. Endogenous opioids (mainly β -endorphin), which are present in GIT, are stimulated by these signals resulting in inhibition of GnRH release [14]. Thus regulating the H-P-O axis. This results in the normalization of ovarian and menstrual cycle.

Conclusion :

On comparison of both the groups, on the basis of symptomatic improvement, it was found that overall percentage of relief was higher in 'Group A' i.e., 67.41%, while that in case of 'Group B' was found 55.92%. This shows that effect of therapy was a higher in Group A in comparison to group B, which suggests that probably oral administration of *Shatapushpa Churna* increases the Artava quantity due to its Pitta-Vardhaka Property along with the removal of *Avarana* from *Artavavaha Srotas*. Also, the method of drug administration, which includes the *Goghrita* along with *Shatapushpa Churna*, having *Yogavahi* property, could be responsible for better results. No any complications were found during treatment and follow up in patients of both the groups (Group A – *Shatapushpa Churna*, Group B – *Madhutailika Basti*). Thus, these treatment options are safe, comparatively economic, non-surgical and effective. So, these can be used for the treatment of *Nashtartava* and PCOS.

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