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A Single-Arm Clinical Study Of *Shatavari Churna* in *Pitta Avritta Vyana Vayu* W.S.R. To Premenstrual Syndrome

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Abstract

Introduction: Premenstrual Syndrome is one of the major but underrated diseases of female physiology. Ignorance and ill-treatment may complicate it to a more severe form, premenstrual dysphoric disorder. *Shatavari Churna* is an *ayurvedic* herbal drug that has the potential to impact largely the female reproductive system. Here is an attempt to study the role of *Shatavari Churna*, especially in Premenstrual Syndrome.

Methods: The present study implemented an open-label, single-arm before and after a study conducted at Yashwant Charitable Hospital, by Yashwant *Ayurved* College Kodoli, Kolhapur with 100 individuals (who fulfilled the inclusion and diagnostic criteria). A random sampling technique was adopted for the study. The trial drug was given at the dose of 3 grams twice daily after food with water for 3 menstrual cycles. A predefined symptom scale was used to measure the efficacy before and after the treatment. Statistical analysis of subjective parameters was assessed using the Wilcoxon Signed rank test and McNemar test. In subjective parameters, statistical significance was obtained in *Sarvanga Daha*, *Klama*, *Santapa* & *Vedana* ($P < 0.05$).

Conclusion: The *Shatavari Churna* (3 grams twice daily after food with water for 3 menstrual cycles) is effective in the management of *Pitta Avritta Vyana Vayu* (Premenstrual syndrome) and requires further study like an animal study by using a more vigorous method.

Keywords : *Shatavari*, Pre Menstrual Syndrome, *Pitta Avritta Vyana Vayu*

Introduction

Premenstrual syndrome is a psycho neuroendocrine disorder of unknown *etiology* often seen in the luteal phase of menstruation

i.e. just 7-10 days before menstruation which resolves after menstruation. It is characterized by dramatic physical, mental, psychological, social & behavioural changes which are alternatively reflected in her day-to-day activities. A lot of women of reproductive age suffer from this syndrome. In the modern world, women work throughout the month with upbringing lot of physical & mental stress & such multitasking women have learned to ignore the natural rhythm of the reproductive cycle which ultimately results in hormonal imbalance. In females, the reproductive cycle is largely dependent on their psychological health. Thus prevalence of psychiatric disorders in females is three times more than that of males. In the Indian population, about 20% of women suffer from premenstrual syndrome out of them 8% undergo a severe form of PMS i.e. Premenstrual Dysphoric Disorder (PMDD). Unfortunately, in modern medicine there is no specific medication available to treat PMS.

In *Ayurveda*, there is no absolute evidence of a disease premenstrual syndrome. *Ayurveda* permits the treatment of disease without nomenclature by judging the involvement of *Dosha Dushya*. So a learned physician should recognize the balanced or imbalanced state of *Doshas* in the body and then treatment should be initiated after deciding the nature of the disease. Taking all this into consideration, the *Ayurvedic* concept of PMS has been made. According to the classic text of *Ayurveda*, premenstrual syndrome can be correlated with *Pitta Avritta Vyana Vayu*. A single-arm clinical study was conducted to assess the role of *Shatavari Churna* in Premenstrual Syndrome w.s.r to *Pitta Avritta Vyana Vayu*.

Need of Study

In the modern era, premenstrual syndrome becoming a common disease with both its mild & severe forms. Undiagnosed & untreated patients may convert into premenstrual dysphoric syndrome. Despite having availability of various treatment regimens for Premenstrual syndrome. Despite having different variety of treatment patterns for premenstrual syndrome no single medication can manage the premenstrual syndrome without affecting the normal rhythm of the reproductive cycle. Also, the symptomatic management becomes temporary & after withdrawal of treatment disease worsens. So there is a need to find a solution to overcome this problem.

Material & Methods

Literary review

In *Pitta Avritta Vyana Vayu*, the circulating *Vyana Vayu* gets occluded by dominant *pitta* resulting in *lakshanas* like *Sarvanga Daha* (Hot flushes), *Klama* (Exhaustion, tiredness without any work), *Gatra vikshepa*, *Sanga* (Luteal pattern of Catamenial epilepsy (seizure exacerbation that aligns with the luteal phase of the menstrual cycle)), *Santapa* of *Deha*, *Indriya*, *Manasa* (Raised temperature of body Mood and behavioural disorders irritability, anxiety, emotional up), *Vedana* (Cramps in the abdomen, Pain in breast, generalized aches). As Pre Menstrual Syndrome occurring in luteal phase i.e. *Rutavyateet kala* in *Ayurvedic* terminology which it *pitta* dominant phase. If *Vata* aggravating factors are to be consumed in the *pitta* dominant phase there is an uprise of *Avarana Samprapti* resulting into *Pitta Avritta Vayu*. Out of five types of *Vayus*, *Vyana Vayu* is responsible for *Gati*,

Prasarana, *Aakunchana*, *Utkshepa*, *Avakshepa*, and *Nimesh Unmesha Adi Kriya*. The *Avarana Samprapti* of *Pitta Avritta Vyana Vayu* results in manifestations like *Sarvanga Daha*, *Klama Gatra vikshepa*, *sanga*, *Santapa*, and *Vedana* resembling symptomatology of pre-menstrual syndrome.

Methodology

This study was a single-arm controlled clinical trial designed with 100 samples. The ethical clearance was obtained by the Institutional Ethics Committee (IEC No. YAC/PG/730/2021). The study was registered on 27 April 2022, under the clinical trial registry India (CTRI/2022/04/042193). The study individuals were recruited from the Outpatient Department of Yashwant *Ayurved* College, *kodoli*, based on diagnostic criteria such as clinical features of premenstrual syndrome.

Inclusion criteria

Consenting (in written form) individuals diagnosed with per criteria ICD 10 94.3 DSM 625.4 N (94.3), aged between 15 and 30 years, irrespective of marital status, education, obstetric status socioeconomic, religious background, and occupation were included.

Exclusion criteria

Women with a known history of mood disturbance because of any systemic disorder / any other psychiatric disorders or having severe systemic illnesses were not included in the study. Women who took oral contraceptives and hormone replacement therapy were also excluded from the study. Women with Premature ovarian failure or any other Major gynaecological disorders were also excluded from the study.

Withdrawal criteria

Individuals were allowed to withdraw from the trial in case of any adverse reaction from the trial drug, worsening of clinical condition, or patient wanted to quit the trial.

Intervention

Patients were treated with *Shatawari choorna* orally for 3 cycles of menses 3 grams Twice a day after meal. Follow-up of each patient has taken on 1st day of menses in every cycle During treatment. The drug was purchased from an authentic pharmacy.

Outcome measures

Subjective parameters such as *Sarvanga Daha* (Burning sensation), *Klama* (fatigue), *Gatra vikshepa Sanga*, *Santapa* (Irritability), Mood Swing, Anger, Depressed Mood, Lethargy, Sleep changes, Change in appetite, Breast Pain/Tenderness/Swelling and Sensation Of Bloating were ranked either present or absent and were assessed pre-and post-treatment. Also, Objective parameters such as *Vedana* (pain) were employed in the study by using the Visual Analogue Scale.

Overall assessment

The overall effect of the therapy was graded in terms of complete remission (75% or more relief in signs and symptoms), marked improvement (50% - <75% relief in signs and symptoms), moderate improvement (25% - <50% relief in signs and symptoms), and no improvement or unchanged (< 25% relief in signs and symptoms).

Statistical Analysis

SPSS (Statistical Package for the Social Sciences) Version 23 (IBM Corp., Armonk, N.Y., USA) tabulated and analyzed the collected data. Descriptive statistics were used to analyze demographic data and other

relevant information. Ordinal data were analyzed using nonparametric tests such as the Wilcoxon Signed rank test, and McNemar test. The changes with $P < 0.05$ were considered statistically significant.

Results

Study population

One hundred individuals diagnosed with *pitta avritta vyana vayu* and who fulfilled the eligibility criteria of premenstrual syndrome were enrolled in the study. All hundred women completed the trial. The incidences of age, religion, occupation, *Prakriti* diet, BMI, marital status, obstetric status, and economic Class noted in the patients were as follows.

Age

Maximum patients were from the age group 20 to 25 years. Out of 100 patients, 13 patients belonged to the age group 15 to 20 years, 64 patients were from the age group 20 to 25, and 23 patients belonged to the age group 25 to 30 years.

Religion

Out of 100 patients, 95 patients were Hindu while only 05 patients belonged to the Muslim religion.

Occupation

out of 100 patients, 82 patients were students, 17 patients were housewives and only 01 patient was doing service.

Prakriti

Out of 100 patients, 22 patients had *Vatapradhan Pitta Prakriti*, 13 had *Vatapradhan Kapha prakriti*, 10 patients had *Pittapradhan Vata Prakriti*, 26 patients had *Pittapradhan Kapha Prakriti*, 03 patients had *Kaphapradhan Vata Prakriti* while remaining 26 belongs to *Kaphapradhan Pitta Prakriti*.

Dietary habits

Out of 100 patients, 02 were pure vegetarian while 98 patients belonged to the mixed diet category.

BMI

Out of 100 patients, 06 had BMI values between 15 to 20, 64 patients had a BMI between 20 to 25, 18 patients had have BMI between 25 to 30, and 12 patients had BMI values between 30 to 35.

Marital Status

In the present study out of 100 patients, 16 patients were Married while 84 patients belonged to the Unmarried category.

Obstetric Status

Out of 100 patients, 86 were *Nulligravida*, 05 patients had having obstetric history of P1L1, One patient had having status as P1L1A1, another 05 patients had having obstetric status as P2L2, One patient had having status as P2L2A1 while remaining 02 patients belongs to P3L3 category respectively.

Economical Class

Out of 100 patients, 96 patients were from the middle class, while 04 patients belonged to the higher class category.

Clinical scenario

The most prevalent symptoms amongst the trial sample were *Santapa* (79%) & *Klama* (77%). *Gatra Vikshepa Sanga* (Catamenial epilepsy - seizure exacerbation) which is one of the symptoms of *Pitta Avritta Vyana Vyana Vayu* didn't appear in any one of the patients of this clinical trial.

Effect of intervention: *Shatavari Churna* for 3 menstrual cycles has shown a 74.35%

improvement in *Sarvanga Daha*, and 77.92% in *klama* with statistically extremely significant. There was 67.08% and 93.46 relief in *Santapa* & *Vedana* parameters respectively. Subjective parameters according to criteria ICD 10 94.3 DSM 625.4 N (94.3) Shows 78.87%, 66.66%, 84.48%, 73.52%, 83.33%, 80.00%, 91.12% and 82.60% relief in Mood Swing, Anger, Depressed Mood, Lethargy, Sleep Changes, Change in Appetite, Breast Pain and Bloating Sensation respectively, with statistically extremely significant in all parameters. Overall *Shatavari Churna* has shown complete improvement in 69% & marked improvement in 23% of patients.

Parameter	BT	AT	Mean Difference	Relief	SD	SE	P	Remark
Sarvanga Daha	0.39	0.1	0.29	74.35 %	0.456	0.0456	<0.0001	S
Klama	0.77	0.17	0.6	77.92 %	0.4924	0.04924	<0.0001	S
Santapa	0.79	0.26	0.53	67.08 %	0.5016	0.05016	<0.0001	S
Vedana	1.53	0.1	1.43	93.46 %	1.265	0.1265	<0.0001	S
Mood Swing	0.71	0.15	0.56	78.87 %	0.4989	0.04989	<0.0001	S
Anger	0.69	0.23	0.46	66.66 %	0.5009	0.05009	<0.0001	S
Depressed Mood	0.58	0.09	0.49 %	84.48	0.5024	0.05024	<0.0001	S
Lethargy	0.68	0.18	0.5 %	73.52	0.5025	0.05025	<0.0001	S
Sleep Changes	0.3	0.05	0.25 %	83.33	0.4352	0.04352	<0.0001	S
Change in Apetite	0.25	0.05	0.2 %	80.00	0.4020	0.04020	<0.0001	S
Breast Pain	1.24	0.11	1.13 %	91.12	1.276	0.1276	<0.0001	S
Bloating Sensation	0.23	0.04	0.19 %	82.60	0.3943	0.03943	<0.0001	S

Note: BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, P: Probability value, S: Statistically significant.

Discussion

The study showed higher incidences at a young age. This reason may be because young age is mainly a *Pitta* dominant age. *Pitta*, *artava*, and *rajas* are invariably related. Participated students had higher expectations during studies, and various stressors during studies may contribute to this. This shows stress-generating factors leading to *manas* involvement in *pitta avritta vyana vayu*. *Vata* & *Pitta* Dominance *prakruti* are more prone to PMS, because of mental disturbance & *Vedana* having *vata* predominance. *Shatawari* has a *sheeta veerya*, so it reduces the *daha*, which may be due to *ojokshaya*. It supports to increase in the amount of *oja*. *Shatawari's* action towards the *dhatu samyata*, reduces the *klama*. Due to *Madhura rasa*, *Madhura Vipaka*, and *Sheeta Veerya*, it also reduces the *Santapa*.

Probable Mode of Action of *Shatavari*

The probable mode of action of *Shatavari* on PMS can be explained based on its *Rasa Panchaka*.

Rasa: *Tikta*: *Tikta rasa* by its *Khara* and *Soshana* properties, which is similar to *asthi dhatu* when used with *kshira* is *asthi vriddhikara*. *Madhura*: *Madhura rasa* is *vata shamaka* and *Prithvi mahabhuta* dominant. This helps in minimizing *asthi kshaya*.

Guna: *Guru*: *Guru guna* is again *Prithvi mahabhoota* dominant and hence can be thought to be acting at the level of all *dhatu poshana*. *Snigdha*: *Tikta rasa* along with *Snigdha guna* is again *asthi vriddhi kara*. Both these properties are *vata shamaka*.

Vipaka: *Madhura Vipaka* acts by the *Prithvi* dominant *Mahabhoutik* constitution.

Prabhava: *Shatavari* Possesses *Rasayana Prabhava*. *Rasayana* promotes qualities of all *dhatu*. This is achieved by improving digestion and metabolism, leading to enriched nutritional status at the level of *dhatus*. *Rasayana* increases the endurance and sustaining capacity of individuals by promoting *deha bala*. These all properties of *Rasayana* herbs delay ageing phenomena. The antioxidant, immune-modulating, and adaptogenic effects of *Shatavari* are well known. The main mechanism of action of *Shatavari* as *Rasayana* is at the level of nutrition of *Ahara rasa*; promoting nutrition of all *dhatus*.

Hence, *Shatavari* promotes *Asthi Poshana* and prevents *asthi kshaya* in age by counteracting the vitiation of *vata*. Inhibiting tissue depletion (*dhatukshaya*), maintaining the qualities of tissues (*Prashastha dhatus*), enhancing strength (*bala*), and promoting digestion and metabolism (*Jathargni* and *dhatvagni*). *Shatavari* possesses Antisecretory, antiulcer, Antitussive, Adaptogenic, Antibacterial, Antiprotozoal, *Molluscicidal*, Antihepatotoxic, Antineoplastic and Immunomodulatory activity. It also has Immunoadjuvant potential activity, Antioxidant, Antidepressant, Anti-stress, and Anti-inflammatory properties. It enhances memory and protects against amnesia. Its diuretic activity helps to relieve the bloating sensation. It has unique Aphrodisiac activity, especially towards females, so it works as A versatile female tonic. In *Ayurveda*, it is considered a female

tonic. Despite being a rejuvenating herb it is beneficial in female infertility, as it increases libido, cures inflammation of sexual organs and even moistens dry tissues of the sexual organs, enhances *folliculogenesis* and ovulation, prepares the womb for conception, prevents miscarriages, acts as Post Partum tonic by increasing lactation, normalizing uterus. In this way, *Shatavari Churna* proves its role in the management of premenstrual syndrome with special reference to *Pitta Avritta Vyana Vayu*.

Conclusion

The *Shatavari Churna* (3 grams twice daily after food with water for 3 menstrual cycles) is effective in the management of *Pitta Avritta Vyana Vayu* (Premenstrual syndrome) and requires further study like an animal study by using a more vigorous method.

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