

Clinical Evaluation of Shatapushpa Shatavari Modak in Perimenopausal Syndrome: An Open-Label Single-Arm Study

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Abstract

Background: Perimenopause is a transitional phase preceding menopause and is associated with somatic, psychological, and urogenital complaints. Hormone replacement therapy is available in modern medicine; however, the source document notes several concerns related to long-term use and adverse effects. Ayurveda describes this stage in relation to Vata predominance and Dhatukshaya, where Rasayana and supportive formulations may be clinically useful. [1,4]

Objective: To evaluate the clinical effect of Shatapushpa Shatavari Modak in women with perimenopausal syndrome using the Menopausal Rating Scale (MRS).

Methods: This was an open-label, single-arm clinical study conducted in the OPD of Streeroga and Prasutitantra. Women aged 35-55 years with clinical features of perimenopausal syndrome were included. Fifty-five patients were enrolled after baseline screening; three were withdrawn due to loss to follow-up and 52 completed the study. Each patient received one Modak of approximately 35 g orally once daily at Rasayana Kala for 60 days. Follow-up assessments were performed on day 30, day 60, and day 90. Outcomes were assessed using MRS subscale and total scores. Wilcoxon signed-rank test was applied because observations were recorded on an ordinal scale.

Results: Significant improvement was observed in somatic, psychological, urogenital, and total MRS scores. Median somatic score reduced from 6 to 2.5 with 54.04% effect. Median psychological score reduced from 4 to 1 with 57.21% effect. Median urogenital score reduced from 5 to 3 with 37.31% effect. Total MRS median score reduced from 15.5 to 8 with 49.32% effect. Overall, 3.85% patients showed marked improvement, 40.38% showed moderate improvement, 53.85% showed mild improvement, and 1.92% showed no change.

Conclusion: Shatapushpa Shatavari Modak showed statistically significant clinical improvement in perimenopausal syndrome, especially in somatic and psychological complaints. Further controlled trials with larger samples are recommended.

Keywords: Shatapushpa, Shatavari, Modak, perimenopausal syndrome, Menopausal Rating Scale, Ayurveda, Rasayana

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1. Introduction

Menarche and menopause are two major biological milestones in a woman's life. Menarche marks the beginning of reproductive capacity, while menopause marks the end of the reproductive cycle. Menopause is defined as cessation of menses for more than one year. The perimenopausal phase refers to the few years before menopause, during which a woman's body gradually transitions into menopause and estrogen levels progressively decline. [1]

During this transition, women may experience vasomotor, psychological, urogenital, and musculoskeletal symptoms. These changes are gradual and variable, but in some women they become clinically troublesome and are recognized as perimenopausal syndrome. The source document reports that menopausal health is particularly important in India, where the number of women above 45 years is increasing and the average age of menopause is around 48 years, although it may occur earlier in some women. [1]

Modern management commonly includes hormone replacement therapy and symptomatic treatment.

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However, the source document notes that hormone replacement therapy may be associated with complications such as vaginal bleeding, breast and endometrial cancer risk, and gallbladder disease. Long-term use of sedatives, hypnotics, and anxiolytics for psychological symptoms may also lead to adverse effects such as drowsiness, impaired motor function, memory loss, allergic reactions, dependence, and social or behavioral concerns.

In Ayurveda, menopause is understood in relation to Jarapakva Avastha, Vata predominance, and Dhatukshaya. Rasayana therapy, Panchakarma, meditation, yoga, and herbal preparations are considered supportive without the adverse-effect concerns noted for long-term hormonal or sedative therapy. Herbs such as Shatapushpa, Shatavari, and Guduchi are traditionally described as useful in women's health and are considered sources of phytoestrogenic and rejuvenating support. [4]

Acharya Kashyapa described Shatapushpa and Shatavari as beneficial for women suffering from conditions such as amenorrhoea, infertility, oligomenorrhoea, menometrorrhagia, delayed menarche, and menopause-related complaints. Therefore, Shatapushpa Shatavari Modak was selected in the present study to assess its effect in perimenopausal syndrome. [4]

2. Aim and Objective

The aim of the study was to evaluate the clinical efficacy of Shatapushpa Shatavari Modak in the management of perimenopausal syndrome. The main objective was to assess improvement in signs and symptoms using the Menopausal Rating Scale before and after treatment.

3. Materials and Methods

3.1 Study Design and Setting

The study was designed as an open-label, single-arm clinical study. It was conducted at the OPD of Streeroga and Prasutitantra. The clinical trial was reported as registered under the Clinical Trial Registry of India.

3.2 Study Population and Sampling

Patients attending the Streeroga Prasutitantra OPD with clinical features of perimenopausal syndrome were screened. Sequential sampling was used. The calculated sample size was 52, based on the formula $n = z^2 p(1-p)/d^2$, using $z = 1.96$, prevalence $p = 3.5\%$, and error $d = 0.05$. A total of 55 patients were enrolled after baseline screening; three patients did not attend follow-up and were withdrawn. The final analysis was performed on 52 completed cases. [2,3]

Table 1. Study design summary

Parameter	Details
Type of study	Open-label single-arm clinical

Parameter	Details
	study
Study setting	OPD of Streeroga and Prasutitantra
Study population	Women with clinical features of perimenopausal syndrome
Age group	35-55 years
Sampling method	Sequential sampling
Enrolled cases	55
Completed cases	52
Intervention duration	60 days
Follow-up schedule	Day 30, day 60, and day 90
Assessment tool	Menopausal Rating Scale
Statistical test	Wilcoxon signed-rank test

3.3 Eligibility Criteria

Inclusion criteria	Exclusion criteria
Women aged 35-55 years	Evidence of malignancy
Women having clinical features of perimenopausal syndrome	Surgical menopause
	Established mental illness
	Known case of diabetes mellitus
	Major systemic illness requiring long-term drug treatment such as rheumatoid arthritis or psycho-neuro-endocrinal disorders
	Clinical evidence of heart failure
	Prolonged medication with corticosteroids, antidepressants, hormone replacement therapy, or other drugs influencing outcome
	Concurrent serious hepatic disorder

Withdrawal criteria included unwillingness to continue the trial, development of allergic condition or adverse effects, and undesirable or unbearable aggravation of symptoms.

3.4 Trial Drug and Preparation

The drug selected for the study was Shatapushpa Shatavari Modak. Shatapushpa and Shatavari were purchased from an authentic source and authenticated. The materials were powdered using a disintegrator with mesh size 60. Each Modak was prepared using Shatapushpa Churna, Shatavari Churna, Sita/Khanda Sharkara, and Goghrita. Standardization of the Modak was reported in the source document. [4]

Ingredient	Quantity per Modak	Role as per source rationale	Remarks
Shatapushpa Churna	5 g	Vata-pacifying, Deepana-Pachana, Srotoshodhaka, Manasdosha	Authenticated raw material

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Ingredient	Quantity per Modak	Role as per source rationale	Remarks
Shatavari Churna	5 g	Rasayana, Balya, Vata-pittahara, Medhya, phytoestrogenic support	Authenticated raw material
Sita/Khand a Sharkara	20 g	Madhura rasa, Sheeta virya, Vata-Pittahara, Prinana	Double the amount of Churna
Goghrita	5 g	Yogavahi, Vata-Pitta shamaka, Medhya support	Used to formulate Modak
Total approximate weight	35 g	Single oral dosage form	One Modak per day

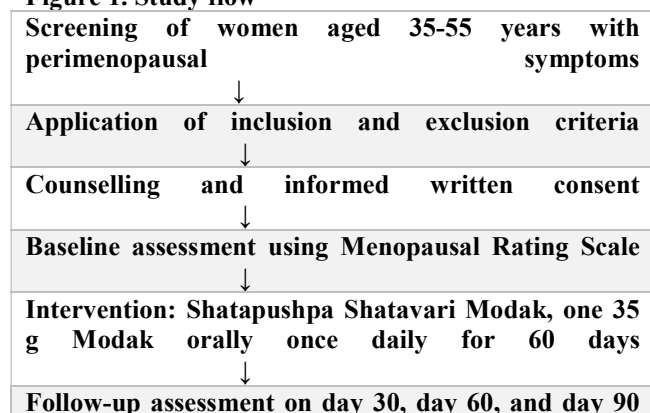
3.5 Intervention and Posology

Parameter	Details
Drug	Shatapushpa Shatavari Modak
Dose	One Modak once daily
Dose form	Modak
Approximate weight	35 g
Route of administration	Oral
Time of administration	Rasayana Kala, early morning
Duration of therapy	2 months / 60 days

3.6 Study Procedure

Detailed study of disease and drug was conducted from Ayurvedic and modern texts, research papers, journals, and other sources for the conceptual component. For the clinical component, eligible patients were counselled, screened, and enrolled after obtaining informed written consent. Cases were recorded in specially prepared case record forms. Observations were recorded at every follow-up, and data collected at the end of the study were subjected to statistical analysis. [4]

Figure 1. Study flow



↓
Compilation of data and Wilcoxon signed-rank analysis

3.7 Assessment Criteria

The Menopausal Rating Scale (MRS) was used to assess treatment outcome. Symptoms were scored according to severity as none = 0, mild = 1, moderate = 2, severe = 3, and very severe = 4. Subscale scores were calculated as follows: somatic subscale included hot flushes/sweating, heart discomfort, sleep problems, and joint/muscular discomfort; psychological subscale included depressive mood, irritability, anxiety, and physical and mental exhaustion; urogenital subscale included sexual problems, bladder problems, and vaginal dryness.

Subscale	MRS items included	Before treatment score	After treatment score
Somatic	Q1, Q2, Q3, Q11	Sum of item scores	Sum of item scores
Psychological	Q4, Q5, Q6, Q7	Sum of item scores	Sum of item scores
Urogenital	Q8, Q9, Q10	Sum of item scores	Sum of item scores
Total MRS score	All 11 items	Sum of all subscales	Sum of all subscales

3.8 Statistical Analysis

The observations were on an ordinal scale; therefore, the Wilcoxon signed-rank test was applied to evaluate the difference between before-treatment and after-treatment scores. Results were interpreted as significant when the reported P value was less than 0.05.

4. Results

4.1 Baseline and Demographic Observations

The study observations reported several demographic and clinical patterns among the analysed participants. Maximum patients belonged to the 40-45 year age group, and half of the participants were working women. The majority belonged to Hindu community, had non-vegetarian diet, and were of Vata-Pitta Prakriti. The following table summarizes the main observations available in the source document.

Observation	Finding	Interpretation as noted in source
Age group	40.38% patients belonged to 40-45 years	Hormonal imbalance in this age group may require medical help
Occupation	50% were working women	Stressful conditions may lead to seeking medical help
Education	32.69% were graduates	Troublesome symptoms prompted

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Observation	Finding	Interpretation as noted in source
		medical help
Religion	96.15% were Hindu	Attributed to local population characteristics
BMI	46.15% normal BMI; 30.77% overweight	Higher body fat may be associated with symptoms
Age at menarche	32.69% had menarche at age 14	No clear relation with menopause was concluded
Family history	15% had history of premature menopause in first-degree relative	May indicate risk of earlier menopause
Contraception	53.84% permanent; 46.16% temporary methods	Reported as background observation
Diet	73.08% had non-vegetarian diet	Role requires further study
Habit	50% had tea habit; 3.85% had tobacco/coffee habit	No clear correlation concluded
Prakriti	55.77% Vata-Pitta; 32.69% Vata-Kapha	Vata-Pitta may be more prone to perimenopausal symptoms
Sara	30.77% Asthisara; 26.92% Medasara	No specific significance concluded
Haemoglobin	38.46% had Hb between 10.1 and 12 g%	No specific significance concluded

4.2 MRS Subscale and Total Score Outcomes

Outcome	Median BT	Median AT	Wilcoxon W	P value	Effect / Result
Somatic subscale	6	2.5	-6.182	<0.05	54.04%; Significant
Psychological subscale	4	1	Not specified in source table	<0.05	57.21%; Significant

Outcome	Median BT	Median AT	Wilcoxon W	P value	Effect / Result
Urogenital subscale	5	3	-5.931	<0.05	37.31%; Significant
Total MRS score	15.5	8	-6.100	<0.05	49.32%; Significant

BT = before treatment; AT = after treatment. The source document reports statistically significant improvement in all subscales and total MRS score.

4.3 Symptom-wise Clinical Effect

Subscale	Symptom	No. of patients affected	Median BT	Median AT	Effect observed
Somatic	Hot flushes / sweating	48	2	1	58.62 %
Somatic	Heart discomfort	44	2	1	50.00 %
Somatic	Sleep problems	34	1	0	68.33 %
Somatic	Joint and muscular discomfort	51	2	1	44.66 %
Psychological	Depressive mood	51	1	0	71.00 %
Psychological	Irritability	52	1	1	52.54 %
Psychological	Anxiety	47	1	0	79.24 %
Psychological	Physical and mental exhaustion	46	1	0	52.94 %
Urogenital	Sexual problems	49	3	3	13.48 %
Urogenital	Bladder problems	44	2	0.5	65.00 %
Urogenital	Vaginal dryness	34	1	0	67.57 %

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4.4 Overall Effect of Therapy

Overall effect category	Frequency	Percentage
Marked improvement	2	3.85%
Moderate improvement	21	40.38%
Mild improvement	28	53.85%
No change	1	1.92%
Total	52	100.00%

4.5 Safety Observation

The source document reports that one patient experienced increased psychological symptoms and suicidal tendency after two months of treatment and was advised to seek psychiatric opinion. No additional adverse-event details were provided in the supplied file.

5. Discussion

The findings indicate that Shatapushpa Shatavari Modak produced significant improvement in perimenopausal syndrome as assessed by MRS. The total median MRS score decreased from 15.5 before treatment to 8 after treatment, showing a 49.32% effect. The improvement was most prominent in the psychological subscale followed by the somatic subscale, whereas urogenital improvement was comparatively lower.

Among somatic symptoms, sleep problems showed 68.33% relief, followed by hot flushes with 58.62% relief, heart discomfort with 50% relief, and joint and muscular discomfort with 44.66% relief. Relief in hot flushes may be attributed to the Pittahara property of Shatapushpa, Shatavari, and Sharkara. Improvement in joint and muscular discomfort may be related to Vatashamana property of Shatapushpa, Shatavari, Sharkara, and Ghrita. Improvement in disturbed sleep may be related to Vata-Pitta-Rakta Shamaka, Manas Tarpaka, Indriya Tarpaka, Rasayana, Medhya, and Balya properties described for Shatavari and Ghrita. Relief in heart discomfort may be associated with the Hrudya property of Shatavari, Sharkara, and Ghrita.

Psychological symptoms showed considerable relief. Depressive mood improved by 71%, anxiety by 79.24%, physical and mental exhaustion by 52.94%, and irritability by 52.54%. These effects may be due to the Medhya, Madhura, Snigdha, Sheeta, Balya, and Rasayana properties of Shatavari, Sharkara, and Ghrita. The source document also notes that patients felt more enthusiastic, energetic, and fresh after treatment.

In the urogenital subscale, bladder problems improved by 65% and vaginal dryness by 67.57%, while sexual problems showed only 13.48% improvement. This suggests that the formulation may be more useful in bladder and vaginal dryness complaints than in libido-

related symptoms. The overall urogenital subscale median changed from 5 to 3 with 37.31% effect.

The source rationale explains perimenopausal complaints as manifestations of Vata Vriddhi, Kapha Kshaya, Ashayapakarsha of Pitta by aggravated Vata, Manovaha Srotas vitiation, and Dhatukshaya associated with aging. From this perspective, Rasayana therapy is considered suitable because it may nourish Dhatus and reduce the severity of symptoms during the perimenopausal phase. [4]

6. Probable Mode of Action

6.1 Shatapushpa

Shatapushpa is described as Katu Rasatmak, Ushna Viryatmak, Katu Vipaka, Ruksha-Tikshna Guna, Srotovishodhaka, and Manasdosahara. Through Katu Rasa and Katu Vipaka, it supports Deepana, Pachana, Amapachana, and balance of Agni. Through Ushna Virya, it supports Anulomana of vitiated Doshas. Through Ruksha-Tikshna Guna, it acts as Strotoshodhaka and helps expel morbid Doshas. The source document describes it as anabolic, strength-promoting, nutrition-promoting, digestive and metabolic supportive, anti-inflammatory, antibacterial, antifungal, antioxidant, and anti-geriatric. By pacifying Vata and improving Agni, it may help relieve perimenopausal symptoms. [4]

6.2 Shatavari

Shatavari is described as Madhura-Tikta Rasatmak, Madhura Vipaka, Sheeta Virya, Guru-Snigdha Guna, Vatapittahara, Rasayana, Balya, Agnipushtikara, Vrushya, Kshayapaha, and Medhya. Its Madhura, Tikta, Sheeta, Guru, and Snigdha properties may pacify Vata and Pitta, nourish Dhatu and Upadhatu, and help relieve Margavarodha. The source document also highlights the phytoestrogenic and hormone-modulating potential of Asparagus racemosus, supporting its use in menopausal females. [4]

6.3 Goghrita

Goghrita is described as the best among Sneha Dravyas due to Yogavahi property, allowing it to assimilate with ingredients while preserving its own properties. It is Madhura in Rasa and Vipaka, Sheeta in Virya, and Snigdha in nature. It is considered supportive for Agni, memory, intelligence, strength, skin, immunity, lifespan, and eye strength. Due to Sheeta Virya and Snigdha, it may mitigate Pitta and Vata. The source document also notes that fat-soluble substances can act as carriers for drugs affecting the nervous system. [4]

6.4 Khanda Sharkara

Khanda Sharkara is described as Madhura Rasa, Madhura Vipaka, Sheeta Virya, and Snigdha Guna, with Vata-Pitta Hara, Saraka, Balya, Prinana, and Dhatu

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Prasadana effects. It may support nourishment and palatability of the Modak formulation. [4]

7. Conclusion

The clinical study showed that Shatapushpa Shatavari Modak produced statistically significant improvement in perimenopausal syndrome. The total MRS median score reduced from 15.5 to 8 after treatment, with 49.32% effect. The formulation showed better results in somatic complaints and psychological disturbances, while urogenital symptoms showed moderate improvement. In the final assessment, 53.85% patients showed mild improvement, 40.38% showed moderate improvement, 3.85% showed marked improvement, and 1.92% showed no change. Therefore, Shatapushpa Shatavari Modak may be considered a useful Rasayana-based formulation for mild to moderate perimenopausal syndrome, subject to confirmation in larger controlled studies.

8. Limitations and Future Scope

- The study was open-label and single-arm; therefore, placebo effect and natural symptom variation cannot be excluded.
- The sample size was limited to 52 completed cases.
- Long-term safety, recurrence of symptoms, and comparative efficacy against standard care require further study.
- Future randomized controlled trials with larger sample size, validated quality-of-life measures, and biochemical/hormonal assessment are recommended.

9. Declarations

Ethics and consent: Informed written consent was obtained from each patient before commencement of the clinical trial. The supplied source document mentions CTRI registration a registration number or ethics committee CTRI/2019/03/018063 [Registered on: 13/03/2019 approval details.

Funding: The study was self funded

Conflict of interest: Not specified in the supplied source document.

Data availability: All results presented in this There was no conflict of interest manuscript were derived from the supplied study document.

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