



Research Article

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CLINICAL EVALUATION OF THE EFFECT OF SHATAVARIYADI KSHEERAPAKA ON PERIMENOPAUSAL SYNDROME

Aswathi Sara Varghese ^{1*}, Sandhya K ²

¹ Assistant Professor, Department of Prasuti Tantra and Stree Roga, KMCT Ayurveda Medical College, Kozhikode, Kerala, India

² Professor, Department of Prasuti Tantra and Stree Roga, GAMC Bangalore, Karnataka, India

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*Corresponding author

E-mail: aswathisara88@gmail.com

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ABSTRACT

Menopause is an important phase in women's life. However, alteration in hormonal level leads to many undefined anatomical and physiological changes in women. As women spend near one third of their life span after menopause, the consequences of menopause are also experienced for a longer period of time. In Ayurveda classics, *Artava Nivritti* or menopause is considered as a normal physiology of *Jaravastha*, and hence, its effects on body are not explained directly. The treatments available for menopause in the modern medicine come with many known side effects. According to, the period of menopause belongs to *Parihanikala*, leading to *Vridhdhavastha*. Therefore, *Rasayana* can be considered as an effective treatment option. On this basis, a *Ksheerapaka* named as *Shatavariyadi Ksheerapaka* has been formulated. It comprises of a mixture of powders of *Ashwagandha*, *Shatavari*, *Guduchi* and *Yasthimadhu*. *Shatavariyadi Ksheerapaka* shows significant reduction in the symptoms of perimenopausal syndrome.

Keywords: *Artava Nivritti*, Perimenopausal syndrome, *Jaravastha*

INTRODUCTION

Menopause literally means the "end of monthly cycles" from the Greek word *pausis* (cessation) and the root *men-* (month). Menopause is an event that typically (but not always) occurs in women in midlife, during their late 40s or early 50s and it signals the end of the fertile phase of a woman's life. Perimenopause is a transition period around menopause in women (40 – 55 years)¹ accompanied with psychological and somatic symptoms. 80% of women suffer from psychological symptoms like mood disturbance, insomnia, cognitive difficulty, anxiety, depression, memory loss, irritability and somatic symptoms like hot flushes, sexual disturbance etc for 1/3rd part of their later life span. In Ayurveda menopause is described as *jarapakwavastha*^{2,3} of body. But further references regarding menopausal or postmenopausal period of woman's life are unavailable. *Jara* and *Rajonivritti* are manifested due to progressive alteration in the functional aspects of *Agni* at *jatharagni* and *dhatwagni*, which results in inadequate tissue nutrition. This nutritional imbalance triggers the irreversible degenerative changes in *Sapta Dhatus*. Though menopause is a natural event as a part of the normal process of aging in women, it is turning in to a major health problem in recent years in developed as well as developing countries like India.

MATERIALS AND METHODS

Research Design

This was open label, single arm clinical study on 30 out-patients basis conducted in *Ayurveda* hospital located in Hassan, Karnataka with pre and post-test design in female patients having perimenopausal symptoms. The study was carried out as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per Declaration of Helsinki guidelines.

Diagnostic Criteria

Diagnosis was made on the basis of the following symptoms of Perimenopause occurring in a woman with irregular menses just prior to menopause or one year after the menopause (40 years to 55 years)

Hot flushes, Night sweat, Sleep disturbance, Irritability, Depression, Decrease libido, vaginal dryness, Painful intercourse

Inclusion Criteria

- Age group of 40-55 years
- Vaginal dryness
- Hot flushes
- Night sweat
- Sleep disturbance
- Irritability
- Depression
- Decrease libido
- Painful intercourse

Exclusion criteria

- Any pre-existing psychological disorder
- Diabetes mellitus
- Age > 55 years.
- Post-menopausal women t flushes

General investigations

Hb%, TC, DC, ESR, RBS, Urine Routine was carried out in all the patients

Follow up study

The patients were asked to report for follow up once in every 15 days for 2 months during this period of study and 15 days after study period.

Assessment criteria

- The patient was assessed on the basis of improvement in the symptoms of perimenopause
- Greene Climacteric scale will be used to measure the difference before and after treatment
- Hot flushes
- Night sweat
- Sleep disturbance

- Irritability
- Decrease libido
- Vaginal dryness
- Painful intercourse

Assessment of clinical study was done based on subjective parameters. Selected symptoms for study were assessed on the basis of Greene Climacteric Scale.

Table 1: Assessment Scale

Parameters	Not at all Grade 0	A little Grade 1	Quite a bit Grade 2	Extremely Grade3
Hot flushes	Not at all	A little	Quite a bit	Extremely
Night sweat	Not at all	A little	Quite a bit	Extremely
Sleep disturbance	Not at all	A little	Quite a bit	Extremely
Irritability	Not at all	A little	Quite a bit	Extremely
Decrease libido	Not at all	A little	Quite a bit	Extremely
Vaginal dryness	Not at all	A little	Quite a bit	Extremely
Painful intercourse	Not at all	A little	Quite a bit	Extremely
Depression	Not at all	Occasional depression	Quite a bit	Extremely

Table 2: Friedmans Test

Parameter	Z value	N	p value	Interpretation
Hot flushes	102.757	30	0.001	HS
Sleep disturbances	99.967	30	0.001	HS
Depression	58.797	30	0.001	HS
Irritability	91.376	30	0.001	HS
Decrease libido	15.178	30	0.001	HS
Vaginal dryness	24.567	30	0.001	HS
Painful intercourse	14.571	30	0.001	HS
Night sweats	99.702	30	0.001	HS

Table 3: Wilcoxon Signed Rank Test

Parameter	Negative Ranks			Positive Ranks			Ties	Total	Z value	P value	Remarks
	N	Mr	Sr	N	Mr	Sr					
Hot flushes	28	14.5	406.0	0	.00	.00	2	30	-4.777	.001	Hs
Sleep disturbances	27	14	378.0	0	.00	.00	3	30	-4.674	.001	Hs
Depression	16	8.50	136.0	0	.00	.00	14	30	-3.611	.001	Hs
Irritability	25	13.0	325.0	0	.00	.00	5	30	-4.667	.001	Hs
Decrease libido	4	2.50	10.00	0	.00	.00	5	30	-1.890	.059	Ns
Vaginal dryness	7	13.0	325.0	0	.00	.00	23	30	-2.456	0.14	S
Painful intercourse	4	2.50	10.00	0	.00	.00	26	30	-1.841	0.066	Ns
Night sweats	27	14.0	378.0	0	.00	.00	3	30	-4.651	.001	Hs

Statistical analysis

Statistical analysis was done using SPSS VER.20 Friedman’s test was applied to analyse the significance of the change in subjective parameters. Wilcoxon’s signed rank test was applied for post hoc which showed significance in Friedman’s test to interpret the time of significant change.

RESULTS

In the present clinical study, 30 patients of perimenopausal symptoms were treated with *Shatavaryadi Ksheerapaka* for 2 months and followed up for 15 days.

Demographic Profile

All patients (100%) were in the age group of 40 to 50 years, with occupation as house wives (74%) with education up to primary standard (97%). 80% of the patients were having mixed diet and 83% had *vata prakriti*. 23% patients were practising yoga/medication regularly while 97% patients reported sleep disturbance.

Effect on therapy

In the 30 patients who were given *Shatavaryadi Ksheerapaka*, reduction in symptoms was observed after 2 months of treatment. There was an improvement of 72.3% in case of hot flushes, 47.3% in case of depression, 71.7% in case of sleep disturbance, 17.9% in case of decreased libido, 67.1% in case of irritability, 70.8% in case of night sweating, 22.4% in case of vaginal dryness with p value < .001. However, it was observed that painful intercourse does not show any improvement.

DISCUSSION

Shatavaryadi Ksheerapaka is one of the *anubhoota yoga*. Different references are available in Ayurveda classics regarding the individual components. *Shatavaryadi Ksheerapaka* consists of *Shatavari*, *Ashwagandha*, *Guduchi* and *Yashtimadhu*, which are known for having *Snigdha gunas*, *Madhura rasa* and *Madhura vipaka*⁴⁻⁷ and *sheeta ushna veerya*. It also poses properties of *Rasayana*, *Medhya*, *Vyasthapana*, *Balya* and *Tridosha shamaka*. The combination of all these drugs results in enhancement of *Rasa Nirmana* and thus helps in delaying the *Rajonivritti* and *lakshanopashma* of *Rajonivritti*.

CONCLUSION

Rajonivritti as a diseased condition is not described in the Ayurveda classics at all. It is a physiological state in the life of women. All the acharyas have mentioned 50 years as the age of *Rajonivritti*. The logic behind the age of *Rajodarshana* and *Rajonivritti* is that the raja is by product of rasa dhatu, which functions better in *tarunavastha* than the *praudhavastha*, at which pitta is dominated *dosha* and *vata* is dominating form. Proper diet, drug, and conduct are the only ways to effectively manage and overcome these changes, to maintain the quality of life in menopausal phase. *Rasayana* therapy is the preferred choice of treatment for ageing and *Rajonivrtijanya lakshanas* to prevent the long-term effects of decrement of dhatus. So *Shatavariyadi Ksheerapaka* is found to be effective in the management of Perimenopausal symptoms.

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