

CLINICAL STUDY TO EVALUATE THE EFFICACY OF CERTAIN INDIGENOUS DRUGS IN PERIMENOPAUSE

Megha Udai¹, Ramadevi G², Vidya.K³

¹Final year PG Scholar, ²Professor, ³Associate Professor

Dept. of Prasooti Tantra and Stree Roga, Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi, Karnataka, India

Email: dr.meghaudai.ayu@gmail.com

ABSTRACT

Woman goes through variable stages during her reproductive life, where, Menarche and Menopause are the landmarks of it. Perimenopause or climacteric is the time period in late reproductive years, which characteristically begins with menstrual irregularities and ends 1 year after permanent cessation of menses, more aptly called as menopausal transition, which encompasses the time, between onset of climacteric and the year after the last menses. It is a phase of adjustment between active and inactive ovarian function, where they may have many symptoms, which are physiological, but may need medical intervention, once they start interfering with the quality of daily life. Ayurveda, even if have seldom told about the treatment aspect of the perimenopausal symptoms, encompasses various methods to tackle the condition from the perspective of *paripakwatha* (highly or over matured dhatus) of dhatus at that stage.

Objective: To evaluate the effect of *Jatamansyadi churna* on perimenopausal symptoms. **Methods:** An open labelled clinical study with pre-test and post-test design. Patients were assigned in single group of 20 patients. *Ksheerapaka* prepared as told in *Sarangadhara samhita* with *Jatamansyadi choorna* made from *Jatamansi*, *Ashwagandha*, *Satavari*, *Amalaki*, *Gokshura* and *Guduchi* 12.5g of *Jatamansyadi churna* added to 8 parts of *ksheera*, i.e. 100 ml, and 32 parts of *jala* i.e. 400ml and was boiled & reduced to 100ml, i.e. *ksheeravashesha*. The patients were advised to prepare the *ksheerapaka* similarly and were taken 100 ml twice daily, i.e. morning and evening 1 hour before food for 2 months. **Results:** The study revealed substantial efficacy of *Jatamansyadi churna* in perimenopausal symptoms with respect to subjective parameters. *Jatamansyadi churna* produced apparent decrease in the intensity of symptoms like vaginal dryness and hot flashes, and was not significant statistically in the beginning, but was found statistically significant in the follow ups. However, statistically significant improvement was observed in reducing memory loss, insomnia, irritability, anxiety, and night sweat. **Conclusion:** *Jatamansyadi churna* worked as a whole to give combined effect to reduce the symptoms of perimenopause effec-

tively. The drug is proved to be safe, easily available and cost effective and no adverse effect has been seen.

Keywords: Perimenopause, Menopause, *Rajonivritti*, Hormonal Replacement therapy, *Rasayana*.

INTRODUCTION

Woman goes through variable stages in her reproductive life, where, Menarche and Menopause are landmarks of it. The midway between the challenges of adulthood and old age come the compulsory change, menopause in women. The lifestyles changes have made occurrence of menarche at an earlier age and thus that more women reach menopausal age earlier due to used up ovarian reserve and suffer from climacteric symptoms and as the lifespan of women is increasing, approximately one third of her life has to be spent in post-menopausal years.

Menopause marks the beginning of a new stage of women's life, with new opportunities. Gynaecologists have a privileged position and great responsibility, to know about menopause and care for who approaches them for treatment, with latest development in scientific understanding of the subject. The sequel of Menopause and its related psycho-somatic problems are turning into an important and major health concern now-a-days. This is evident from the launch and works of UK based organisation 'The International Menopause Society' (IMS) in 1978, which mainly aims at promoting knowledge, study and research on all aspects of aging in men and women, especially menopause and climacteric. Targeted efforts, such as conferences and initiatives and enhanced research funding by National institutes of Health Departments and other organisations have helped stimulate new scientific exploration of the menopause and its sequel. It is not only quantity of life but quality of life of menopausal women

which is important and hence should go for preventive aspects and life style managements which should be started early in life, that is just beyond thirty-five years itself.^[1]

Rajonivritti (menopause) though a *Swabhavikaawastha* (natural phenomenon) in woman, when it causes discomfort by either interfering with normal functions of mind or body, it needs attention. According to Acharya Sushruta, this phenomenon has been mentioned as *Kshaya* (depletion) of the *dhatu* which occurs due to *jarapakwaavastha* (ageing of body tissues) of *sarira*. All Acharyas have mentioned *Kshaya* of artava as a normal physiology, occurring at age of 50 years, owing to *dhatukshaya* (depletion of body tissues) and *jaraavastha*, in the transitional kala from Pitta to *Vata* predominance. The commentator *Arunadatta* has considered this age as a probable one, which is also seen practically.^[2] According to Acharya Bhela, *Raja Srava* starts occurring, once *Dhatuparipurnata* (completion of body tissues) has been attained which explains the reason for absence of *rajah srava* in *tarunavayah* (young age).^[3] This also explains the importance of *dhatu* (body tissues), especially *Rasadhatu* (essence of digested food) in formation of *Rajah* and the role of *Rasayana* therapy in *Rajonivritti janya lakshanas*.

Due to the unacceptable risk of malignancy, mainly in uterus and breast, on using conventional hormonal treatment for long period has necessitated new modalities of management and here, Ayurveda can provide safe and effective

preventive measures to support the perimenopausal women from landing with complications in a long run with estrogen deprivation, like osteoporosis, heart diseases and psychological disorders like depression. Thus the present study was undertaken to make an effective drug combination, to prevent the progress of symptoms to worse. *Jatamansyadi Choorna* has *Rasayana*, *Vayasthapana* (longevity promoters), *Medhya*, *Vata-Pitta hara* properties, which is in the perimenopausal symptoms.

OBJECTIVE OF THE STUDY

- To study the concept of Rajonivritti
- To study the concept of Menopause
- To evaluate the effect of certain indigenous drugs on Perimenopausal symptoms

Materials and methods:

The study was initiated after obtaining the Institute's Human Ethic Committee Permission.

(Ref No: - SDMCAU/ACA - 49/EC46/14 -15)

- The patients were selected regardless of their Religion, Socio economic status etc. fully satisfying the clinical criteria for perimenopausal symptoms.
- 20 patients full filling the inclusion criteria and attending the OPD
& IPD of Prasoothi tantra and Stree roga Department, S.D.M.C.A hospital, Udupi were selected for the study.

Method of collection of data:

- Selected patients were assigned into a single group of 20 patients.
- A special Proforma was prepared with all the points of history taking, physical examinations, laboratory investigations, as mentioned in our classics and allied sciences and

the patients were analyzed and selected accordingly.

- Signs and symptoms were analyzed on the basis of standard method of statistical analysis.

Study design

- It is an open labelled clinical study with pre-test and post-test design.

Inclusion criteria

- Women with age group 40-55 years
- Up to one year after menopause.

Symptoms:

- Hot flushes
- Night sweat
- Memory loss
- Insomnia
- Irritability
- Vaginal dryness
- Anxiety

Patients presented with any 3 of the 7 clinical features were included in the study

Exclusion criteria

- Any pre-existing psychological disorder.
- Any systemic illness like diabetes mellitus, hypertension, asthma etc.
- Post-menopausal women.
- Patients diagnosed or suspected malignancy.
- Cardiac diseases

Follow up:

Patients were asked to have follow up every 15 days during the study period and after the study period once in 15 days for 1 month.

Method of preparation of drug:

Drug was prepared in Shri Dharmastala Manjunatheshwara Pharmacy. (Batch no- 160135, Manufacture date-25.02.2016)

- Ksheerapaka was prepared as told in *Saran-gadhara samhita*, with *Jatamansyadi choorna* made from *Jatamansi*, *Ashwagandha*, *Satavari*, *Amalaki*, *Gokshura* and *Guduchi*. 12.5gms of *Jatamansyadi churna* was added with 8 parts of *ksheera*, i.e. 100ml and 32 parts of *jala* i.e 400ml and then boiled & reduced to 100ml, i.e. *khseeravashsha*.^[4]
- The patients were advised to prepare the *ksheerapaka* similarly and were taken twice daily, i.e. morning and evening 1 hour before food.
- **Dosage:** 100 ml of *ksheerapaka* twice daily 1 hour before food.^[5]

Assessment criteria:

Assessment of clinical study was done by scoring method. Here the symptoms of Perimenopause were grouped and scored according to the scoring method and each criterion was considered, rated and the total score at the end was calculated to check the efficacy of the treatment protocol.

Objective Criteria:

Improvement in:

- General condition and all symptoms described in perimenopause
- Psychological symptoms.
- Results were obtained within the group and the data observed in BT (on 1ST day), AT (after 2 months), FU1 (after 15 days) FU2 (after 30 days) are compared by using paired

't' test and the effect of the treatment is analyzed with assessment parameters. Statistical analysis was done using the graph pad In Stat software.

Observations and Results:

- Table -1 shows the maximum distribution of parameters taken for the study.
- Incidence on Cardinal symptoms of perimenopause: Among selected samples, cardinal symptoms of Perimenopause like hot flushes were present in almost all the women, i.e., 100%, 95% women had night sweats, memory loss in 80%, insomnia in 90%, irritability in 95%, vaginal dryness in 75%, and anxiety in 70% of women.
- The study reveals that majority of the women were presented with maximum percentage of hot flushes, irritability, night sweats, insomnia followed by memory loss, vaginal dryness and anxiety symptoms of perimenopause, which may be owing to the impact of hormonal fluctuations and professional stress on them leading to maximum Psychological symptoms.
- Statistical analysis revealed hot flushes, vaginal dryness were not significantly affected by the treatment, but night sweats, memory loss, insomnia, irritability and anxiety gave extremely significant results. In **memory loss**, BT (1st day) & AT (on 60th day) showed a change from 2.85 to 2.60, and a reduction of 0.250(8.9%) which is statistically significant ($P < 0.05$), in **insomnia** BT (1st day) & AT (on 60th day) showed a change from 2.30 to 1.60, and a reduction of 0.70(30.43%) which was statistically significant ($P < 0.0001$), in **irritability**, BT (1st day) & AT (on 60th day) showed a change

from 2.20 to 1.55, with a reduction of 0.65(29.55%) which was statistically extremely significant ($P < 0.0001$) and in **anxiety**, BT & AT (on 60th day) showed a change from 2.30 to 1.55, with a reduction of 0.75 (32.61%) which was statistically highly significant ($P < 0.0001$) in **night sweat**, BT (1st day) & AT (on 60th day) showed change from 2.25 to 1.90, with a reduction of 0.35(15.5%) which was statistically significant ($P < 0.05$). This exemplifies the role of *Jatamansyadi churna* role in managing the perimenopausal symptoms which has shown successful result in symptomatic relief. Follow up showed extremely significant results in all the criteria.

- Table 2-8 shows the effect of treatment on hot flushes, night sweats, memory loss, insomnia, irritability, vaginal dryness and anxiety.
- Table 9 shows the effect of treatment on perimenopausal symptoms after study period.

DISCUSSION

Goksheera is the best natural *dhatuposhaka dravya* (enhancing body tissues), which has all other special qualities like *Jivaniya* (vitalizing), *Rasayana* (rejuvenating), *Medhya* (enhancing intellect), *Balya* (enhancing strength), *Sara*, *Stanyakara* (enhancing breast milk) and also *Vatapitta hara*.^[6] It is a good source of calcium supplementation, needed by the women in that particular age and also increases the intestinal absorption of Calcium by facilitating paracellular absorption. These qualities make it an excellent choice of natural remedy for perimenopausal symptoms, where there is *dhatu kshaya* (loss of tissues) and loss of *Snigdhatta* (unctuousness), of body. 87.5% of the patients

got relief from hot flushes and 66.66% patients from night sweats. This action might probably due to the *Vata-Pitta hara*, *Vayahsthapana* (longevity promoters) and *Rasayana* (rejuvenating) property of the *Jatamansyadi churna*. The presence of phyto-estrogens in *Satavari* (*Asparagus racemosus*), and effect of *Ashwagandha* (*Withania somnifera*) would help in thermoregulation to reduce hot flushes. As the incidence of hot flushes decreases, night sweats also declines gradually. Due to the *Medhya* and *Rasayana* effect of *Guduchi* (*Tinospora cordifolia*) and *Medhya* property of *Jatamansi* (*Nardostachys jatamansi*), helps in improving *Dhi* (acquisition and learning), *Dhriti* (retention of information), *Smruti* (long term memory) and reducing the intensity of memory loss. *Jatamansi*, *Satavari* and *Ashwagandha* have been proved for their *nidrajanana* (sleep inducing) property. Due to the presence of alcohol, alkaloids & glycosides, anti-stress property of *Ashwagandha* and also glycoside *Shatavarin I* & alkaloid *Asparagamine* in *Shatavari* helps in reducing stress and sleeplessness. *Jatamansi* a *Manaprasadana dravya* (pleasing mind) also acts as *Nidrajanana* (sleep inducing).

There was very slight changes in vaginal dryness, which may be due to the perceiving nature of women, but these changes are owing to the presence of *Rasayana dravyas* in the combination and also especially due to the presence of phytoestrogens in *Satavari*. *Shatavari* & *Ashwagandha* have *Vatahara*, *Rasayana* (rejuvenation), *Hrdya* (pleasing heart), *ManahPrasadkara* (pleasing mind), *NidraJanaka* (sleep inducing), *Medhya* properties helping in reducing mental & nervous exhaustion & thus alleviate the symptoms. Withanolide free aqueous fraction isolated from the roots of *Withania somnifera* exhibited anti-stress activity helps in calming down the

nerves. As nocturnal sleep was induced, it also reduced the rate of depression, anxiety & irritability. *Gokshura* with its *mutrala* (diuretic), *dahahara* (reducing burning sensation) property reduces the possibility of urinary symptoms which are common during this stage and the Harmine content of *Tribulus* acts as Monoamine Oxidase (MAO) inhibitor, leading to higher levels of dopamine in the brain enhancing concentration and improves mood by reducing anxiety and stress and increases sexual performance of women. *Jatamansi* has been proved for its properties of anti-stress, anti-depressant, and anxiolytic. *Jatamansi* acts as nervine tonic and reduces mental exhaustion. According to Ayurveda, it stimulates the healthy nervous functions and provides nourishment to the brain and improves cognitive performance, also significantly reduce stress and provide feeling of well-being. So as a whole the combination of drugs in *Jatamansyadi choorna* has mainly *Vata-pitta hara*, *Rasayana* (rejuvenation), *Medhya* (intellect), *dhatuposhaka* (enhancing tissues) property which brings the desired effect due to synergistic action by working as a whole.

CONCLUSION

Menstrual syndrome is very exasperating when it includes Vasomotor, Genitourinary, Psychological and general manifestation of natural ageing process. *Jara* (ageing) is a natural process which influences the body, causing fluctuations in physiological functions. Single drugs and compound formulations which can be made useful for the symptoms of perimenopause opens new avenues in managing menopausal syndrome. The probable mode of action of *Jatamansyadi choorna* on perimenopausal symptoms may be due to *Prabhava* (specific action) of drugs which are a combination of *Rasayana* (re-

juvenating), *Balya* (strengthening), *Dhatuposhana* (enhancing body issues), *Vrushya* (aphrodisiac), *Vayasthapana* (longevity promoters) and *Vata-Pitta hara* properties. *Ksheera* (milk), a complete food, being *Rasayana*^[7] and rich source of calcium too, when added to *oushadha*, will amplify the effect of medicines in the form of *Ksheerapaka* and acts as a *Poshakadravya* (enhancing body tissues). The drug was well accepted by women, and no side effects were reported and were easily administrable and safe, so can be concluded that *Jatamansyadi choorna* can be used in perimenopausal symptoms for managing and preventing it from further complications.

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Table 1: Showing the maximum distribution of parameters taken for the study.

Parameter	Maximum	%
Age	48-51yrs	35%
Religion	Hindu	60%
Education	High school	45%
Occupation	House wife	25%
Socio-economic status	Lower middle class	50%
Nature of sleep	Disturbed	45%
Diet	Mixed	55%
Cycle	Irregular	75%
Menstrual cycle	Menopause	20%
Nature of flow	Normal	55%
Mala pravritti	Regular	70%
Mutrpravritti	Normal	70%
Prakruti	Vata-pittaja	55%
Saara	Madhyama	65%
Samhanana	Madhyama	65%
Satva	Madhyama	90%
Pramana	Madhyama	85%
Manasikaprakruti	Rajasika	65%
Vyayama sakthi	Madhyama	75%
Ahaarashkati	Madhyama	62%
Agnibala	Samaagni	85%

Table 2: Showing effect of treatment on Hot flushes.

Hot Flashes	N	BT Mean					Diff D	%	Paired t test				significant
			AT	2.2500	0.150	6.25			SD	SEM	t	p	
	20	2.4	AT	2.2500	0.150	6.25	0.5501	0.123	1.143	P=0.2674	NS		
			FU 1	1.6500	0.750	68.5	0.6708	0.150	4.265	P=0.0004 <0.001	ES		
			FU 2	0.30	2.10	87.5	0.47	0.10	13.07	<0.0001	ES		

Table 3: Showing effect of treatment on Night sweats.

Night Sweats	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	t	P	
20	2.25		AT	1.9000	0.3500	15.5	0.6407	0.1433	2.666	0.0153	S
			FU 1	1.9000	0.3500	15.5	0.5525	0.1235	0.5525	0.0153	S
			FU 2	0.75	1.50	66.66	0.63	0.14	8.816	<0.0001	ES

Table 4: Showing effect of treatment on Memory loss.

Memory loss	N	BT Mean			Diff d	%	Paired t test				Significant
							SD	SEM	t	p	
20	2.8500		AT	2.6000	0.2500	8.9	0.5982	0.13	2.517	0.0210	S
			FU 1	2.4000	0.450	16.07	0.7539	0.1686	3.327	0.0035	VS
			FU 2	1.5800	0.6000	21.42	0.6387	0.1428	5.339	P<0.0001	ES

Table 5: Showing effect of treatment on Insomnia.

insomnia	N	BT Mean			Diff d	%	Paired t test				Significant
							SD	SEM	t	p	
20	2.30		AT	1.60	0.70	30.43	0.59	0.13	6.658	<0.0001	ES
			FU 1	0.95	1.35	58.69	0.39	0.08	9.00	<0.0001	ES
			FU 2	0.30	2.00	86.96	0.47	0.10	10.42	<0.0001	ES

Table 6: Showing effect of treatment on Irritability.

Irritability	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	t	p	
20	2.2		AT	1.55	0.65	29.55	0.60	0.13	4.951	<0.0001	ES
			FU 1	0.70	1.50	68.18	0.73	0.16	8.816	<0.0001	ES
			FU 2	0.25	1.95	88.64	0.44	0.09	12.70	<0.0001	ES

Table 7: Showing effect of treatment on Vaginal dryness.

Vaginal dryness	N	BT Mean			Diff d	%	Paired t test				Significant
							SD	SEM	t	p	
20	2.8		AT	2.7500	0.1000	3.5	0.4443	0.09934	1.000	0.3299	NS
			FU 1	2.5000	0.3500	12.5	0.5130	0.1147	2.666	P= 0.0153	S
			FU 2	2.4500	0.3000	10.71	0.5104	0.1141	2.349	P= 0.0298	S

Table 8: Showing effect of treatment on effect on Anxiety.

Anxiety	N	BT Mean			Diff d	%	Paired t test				significant
							SD	SEM	t	P	
20	2.30		AT	1.55	0.75	32.61	0.51	0.11	7.550	<0.0001	ES
			FU 1	0.80	1.50	65.22	0.52	0.11	9.747	<0.0001	ES
			FU 2	0.25	2.05	89.13	0.44	0.09	13.35	<0.0001	ES

Table 9: Showing the effect of treatment on perimenopausal symptoms after study period.

Symptoms	% of improvement in Assessment criteria on 60 th day	% of improvement in Assessment criteria on 75 th day	% of improvement in Assessment criteria on 90 th day
Hot flushes	6.25	68.5	87.5
Night Sweat	15.5	15.5	66.66
Memory Loss	8.9	16.07	21.42
Insomnia	30.43	58.69	86.96
Irritability	29.55	68.18	88.64
Vaginal Dryness	3.5	12.5	10.71
Anxiety	32.61	65.22	89.13

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