

THE MANAGEMENT OF MENOPAUSAL SYNDROME WITH SHIRODHARA AND SHAMAN YOGA - A PILOT STUDY**Dr. Shrawan N. Kamble^{*1}, Dr. Vishwalata Dhole², Dr. Shilpa Donga³, Dr. Yogesh L. Manani⁴, Dr. Hemant Patel⁵**¹ Assistant Prof., Dept. of Streeroga & Prasootitantra, Ashvin Rular Ayurved College, Manchi hill, Sangamner, Maharashtra, India - 413714.² M.S. Shalakya, Nshik, Maharashtra.³ Associate Prof. Dept. of Streeroga & Prasootitantra, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India – 361008.⁴ Assistant Prof. Dept. of Streeroga & Prasootitantra, Noble Ayurved College and Research Institute, Junagadh, Gujarat, India – 362037.⁵ Assistant Prof. Dept. of Streeroga & Prasootitantra, RMD Ayurved College and Hospital, Vaghaldhara, Valsad, Gujarat, India – 396040.***Corresponding Author: Dr. Shrawan N. Kamble**

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ABSTRACT

The present clinical trial was conducted to evaluate the efficacy of Shirodhara and Shaman Yoga in the management of menopausal syndrome, along with the assessment of vatic and Paittik symptoms. . It was randomized open clinical trial. Total 10 patients were registered in the study and completed the course of therapy. Specialized rating scales like Menopause Rating Scale (MRS) and Menopause Specific Quality of Life (MENQOL) questionnaires were adopted for diagnostic as well as assessment criteria. The effects were examined based on MRS and MENQOL. Results were analyzed statistically using 't' test. The effects were examined on the chief complaints as well as the associated complaints. Patients undergoing therapy had better relief of the disturbances of Manasa Bhavas and psychic symptoms of menopause also showed encouraging results in management the associated somatic symptoms. Hence, we conclude that it can be used as an alternative therapy to HRT.

KEY WORDS: menopausal syndrome, Rajonivrutti, Shaman yoga, Shirodhara.**INTRODUCTION**

The propagation of the species is a basic aim of nature. In the multiplication of the human race 'woman has a pivotal role to play.' In the fashioning of a woman's bodily structure nature has proved its great capacity and efficiency in a very astonishing manner.

The phase of 'menarche' and 'menopause' have important influences on the physical, psychological, social, and emotional aspects of a woman. The menopause is a natural phenomenon and one of the life's important milestones. As both menarche and menopause are related to post-birth changes, both should be tackled with the same caution and care; however, sometimes increasing age and diminishing qualities from life make the menopausal condition more difficult to handle in the lack of proper understanding, sound medical advice, and good social support. Not every woman passes through a torrid time during this phase but every female surely knows about the negative changes associated with the onset of the menopause. This period is usually associated with unavoidable manifestation of aging process in women.^[1] Most women experience near complete loss

of production of estrogen by their mid-fifties.^[2] Hot flushes, sweating, changes in mood and libido are some of the important outcomes affecting the quality of life (QoL) during climacterium in women. QoL covers physical, functional, emotional, social, and cognitive variables up to 85% of menopausal women.^[3] The period of menopause is a time of tremendous changes in lifestyle. These changes may cause loss of equilibrium and discipline in her day-to-day life.

Though, Rajonivritti as a diseased condition is not described separately in the classical Ayurveda texts, Rajonivritti Kala is mentioned by almost all Acharyas without any controversy. According to Sushruta^[4] and various other references too^[5-7] 50 years is mentioned as the age of Rajonivritti, when the body is fully in grip of senility.^[8]

There has been extensive research on menopause in the West, but in India only a few research institutes have recognized the potential of research on this subject. Being a common and distressing problem, it needs

effective and safe treatment. In modern medicine, the management of menopausal syndrome is through hormone replacement therapy (HRT). Often there is spectacular relief from the symptoms of the disease but there is an associated risk of serious side effects such as increased probability of developing breast cancer, uterine cancer, venous thromboembolism, stroke, etc. HRT, however, is not very effective in managing the psychological symptoms associated with menopause. An effort to manage this with long-term use of sedatives, hypnotics, and anxiolytic drugs leads to side effects like drowsiness, impaired motor function, loss of memory, antisocial behavior, allergic reactions, etc. Thus modern science mainly concentrates on tackling the physical problems of menopause, but the psychological aspect is often neglected. Therefore, here we have made an attempt to focus on the other side of the coin, i.e., the psychological aspects of menopause. There is a great scope for research in Ayurveda to find a cure for the management of menopause.

Aims and Objectives

The present study was aimed to evaluate efficacy of Shirodhara and Shaman yoga on menopausal syndrome.

MATERIALS AND METHODS

Patients attending the Outdoor Patients Department of Streeroga & Prasootitantra, I.P.G.T. & R.A. Jamnagar, were randomly incorporated into the study irrespective of caste, religion etc. A suitable research proforma prepared for the assessment of therapy by adopting suitable grading pattern. A written and informed consent was taken from the patient before the commencement of treatment. Total 10 patients were registered and they completed the course of treatment.

Inclusion criteria

1. Females of age between 40 and 55 years
2. Amenorrhea for ≥ 12 months
3. Follicle Stimulating Hormone (FSH) ≥ 20 IU/L
4. Thickness of endometrium ≤ 5 mm
5. Willing and able to participate for 16 weeks.
6. On the basis of Menopausal rating scale (MRS) were screened

Exclusion criteria

1. Women with uncontrolled medical conditions e.g. Hypertension, Heart disease, Diabetes mellitus.
2. Women who were undergoing treatment for cancer or were in remission, who had the H/O Hormone replacement therapy (HRT).
3. Women having H/O excessive and/or irregular bleeding per vagina.

Drugs

Drugs used in Shaman yoga i.e. Powder of Shatavari, Amalaki, Yashtimadhu (each 1 part) and Mukta Shukti Bhasma (1/2 part) were prepared in the Pharmacy of GAU, Jamnagar.

Investigations

All selected patients were subjected to routine investigations, which included the following:

- Blood: Hemoglobin (Hb), Total Count (TC), Differentiate Count (DC), Erythrocyte Sedimentation Rate (ESR), Packed Cell Volume (PCV), etc.
- Biochemical examination: Fasting blood glucose, lipid profile, liver function tests, renal function tests, Serum calcium, HbA1C, etc.
- Urine – Routine and microscopic examination
- Hormonal assessment: FSH, LH (Luteinizing Hormone)
- Ultra Sonography - TVS/TAS (Trans Vaginal Sonography/Abdomen.)

Study design

- Study type: - Intervention
- Purpose: - Treatment
- Masking: - Randomized open labelled clinical trial
- Timing: - Prospective
- End point: - Efficacy and safety

Ethical Clearance

Study was started after obtaining Ethical clearance from the Institutional Ethics Committee, IPGT&RA, Jamnagar Ref.PGT/7-A/2012-2013/1964 (Dated 21/09/2012).

COURSE OF TREATMENT

In the present pilot study, all the selected patients were administered Shirodhara up to 20 min. with half liter milk and half liter water for 7 days and given orally Shaman Yoga 3.5 gm. twice daily with Honey and Ghrita, after food, for 1 months.

Follow-up study: All patients were followed up for 8 weeks.

Criteria for assessment

Detailed history was taken thorough various physical examinations with the data being recorded in a special proforma that was specifically designed.

The result was assessed on the basis of Pittaja predominant symptoms i.e. subjective criteria's, menopause rating scale (MRS)^[9] and menopause specific quality of life (MENQOL)^[10] were given scoring depending upon their severity.

The obtained results were measured according to the grades given below:

1. No change or Less than 25% changes in the signs and symptoms.
2. Mild improvement: 26-50% relief in the signs and symptoms.
3. Moderate improvement: 51-75% relief in the signs and symptoms.
4. Marked improvement: 76-99% relief in the signs and symptoms.

5. Complete remission: 100% relief in the signs and symptoms.

Statistical analysis

The information collected on the basis of observation, were subjected to statistical analysis in terms of percentage of relief, Mean, Standard Deviation (SD) and standard Error (SE) and by the use of student paired 't' test, evaluate the significances at different levels i.e. at 0.05, 0.01 and 0.001 levels.

OBSERVATIONS AND RESULTS

In the present study, maximum 40% of patients were from the age group of 46-50 year and 51-55 years respectively; 100% were married; 70% of patients were housewives; 70% of patients had disturbed sleep; 80% of patients had regular bowel habit followed by 100% had constipation; 70% of the patients had menopause for 1-5 years; 70% of patients were having addiction of tea where as 30% having coffee; 70 % of patients were using condom as contraceptive; 90% patients were vegetarian; 30% of patients had Vatapitta and Vatakaph Prakriti respectively; Looking to the sign and symptoms, maximum, i.e. 100% patients were having Artavavaha and 94.28% having Swedavaha Srotodushti; In MRS, 100% of patients were having Hot flushes, Heart Discomfort, Sleep Problems, Depressive mood, Irritability, Anxiety, Physical & Mental Exhaustion, Sexual problems, Dryness of Vagina and joint and muscular discomfort while Bladder Problems was found in 90% of patients.

Rajonivritti is a representative syndrome of Praudhavastha, which lies in a Sandhikala (a mid-period between Yuvavastha and Vriddhavastha). During this period there is a peak level of Pitta, during Jarakala, Vata remains in aggravated condition along with vitiated Pitta creates hot flushes, excessive sweating, sleep disturbance, irritability, dryness of the vagina, etc., which are similar to Vataja-Pittaja symptoms. This is nothing but a Rajonivritti Avastha Janya Lakshana or menopausal syndrome.

Effect of Therapy

Effect of therapy on Menopausal Rating Scale has shown highly significant result i.e. $P < 0.001$ in Sexual subscale

score, Psychological subscale score, Urogenital subscale score. [Table 1]. The effect of therapy on MENQOL has shown that statistically highly significant result i.e. $P < 0.001$ in Night Sweats, Sweating, Feeling anxious or nervous and Vaginal dryness during intercourse. Where as insignificant results i.e. $P > 0.05$ in, Hot flushes, Being dissatisfied with personal life, Feelings of wanting to be alone, Change in sexual desire and Avoiding intimacy. [Table 2].

Therapy has shown Highly significant result i.e. $P < 0.001$ in Ushnaanubhuti Daha, Mutradaha, Yonidaha, Santapa, Krodha and significant result i.e. $P < 0.05$ in Trushna kshudhadikyata. Where as insignificant results i.e. $P > 0.05$ in, Svedaadikyata and Gani. [Table 3]. Therapy has shown Highly significant result i.e. $P < 0.001$ in, Shirashoola (Headache), Balakshaya (Weakness), Vibandha (Constipation), Anidra/Alpanidra (Sleeplessness), Anavasthita chitavvam (Mood swing), Chinta (Anxiety), Krichchhra Vyavayata (Loss of libido), Maithuna asahishnuta (Dyspareunia), Sandhivedana (Joint pain), Yoni Shushkata (Vaginal dryness). [Table 4].

Effect on hematological/biochemical values has shown S. Triglyceride, S. Calcium & S. Estrodiol there was a decrease of about 2.15%, 1.37 %, 36.51% respectively, However, S. Cholesterol, HDL, S. Cholesterol/HDL & S.FSH were found to be increased by 10.74%, 8.73% 1.85%, 13.79 & 2.25% respectively which is found statistically insignificant except S. cholesterol which is highly significant ($p < 0.001$) and HDL, S. Estrodiol which were found statistically significant ($p < 0.05$). No other significant change in the hematological and biochemical values after treatment was observed in any patient. [Table 5].

Total effect of therapy On the basis of criteria of assessment allotted, the total effect of therapy has been carried out, which has shown that maximum i.e. 60% patients reported mild improvement followed by 40% patients reported moderately improved, none of the patients reported unchanged, markedly improved & complete cured respectively in this group [Table 6].

Table 1: Effect On Menopausal Rating Scale Symptoms.

Symptoms	Total no. of patient n=	Mean B.T.	Mean A.T.	S.D. ±	S.E. ±	't'	'P'
1. Sexual subscale score	10	5.25	3.37	1.24	0.39	4.75	<0.001
2. Psychological subscale score	10	5.4	3.1	1.56	0.49	4.64	<0.001
3. Urogenital subscale score	10	5.12	2.87	0.70	0.22	10.06	<0.001

Table 2: Effect On Menqol Symptoms.

Symptoms	Total no. of patient n=	Mean B.T.	Mean A.T.	S.D. ±	S.E. ±	't'	'P'
1. Hot flushes	10	1.87	0.87	--	--	--	--
2. Night sweats	10	2.12	0.87	0.46	0.14	8.53	<0.001
3. Sweating	10	2.12	0.5	0.51	0.16	9.92	<0.001
Being dissatisfied with personal life	3	1	0.66	0.57	0.33	2	>0.05
Feeling anxious or nervous	10	1.12	0.25	0.35	0.11	7.82	<0.001
Experiencing poor memory	9	1.14	0.42	0.48	0.16	4.39	<0.001
Feelings of wanting to be alone	6	1.16	0.16	0.63	0.25	3.87	>0.05
Change in sexual desire	10	1.87	0.87	--	--	--	--
Vaginal dryness during intercourse	10	1.75	0.87	0.35	0.11	7.82	<0.001
10. Avoiding intimacy	1	1	--	--	--	--	--

Table 3: Effect On Pitta Predominant Menopausal Symptoms.

Symptoms	Total no. of patient n=	Mean B.T.	Mean A.T.	S.D. ±	S.E. ±	't'	'P'
1. Ushnaanubhuti	10	2.12	1.12	0.53	0.16	5.91	<0.001
2. Daha	10	2.62	1	0.51	0.18	9.9	<0.001
3. Svedadikyata	10	1.87	0.87	--	--	--	--
4. Trushna kshudhadikyata	10	1.37	1	0.51	0.16	2.29	<0.05
5. Mutradaha	10	2.37	0.87	0.53	0.16	8.8	<0.001
6. Yonidaha	10	2.25	0.87	0.51	0.16	8.40	<0.001
7. Glani	10	1.37	0.37	--	--	--	--
8. Santapa	10	2.12	0.75	0.51	0.16	8.40	<0.001
9. Krodha	10	1.87	0.5	0.51	0.16	8.4	<0.001

Table 4: Effect On Important Vata Predominant Menopausal Symptoms.

Symptoms	Total no. of patient n=	Mean B.T.	Mean A.T.	% relief	S.D. ±	S.E. ±	't'	'P'
Shirashoola (Headache)	10	2	0.87	0.35	0.11	10.06	<0.001	10
Bala- Kshaya (Weakness)	10	2	0.87	0.35	0.11	10.06	<0.001	10
Vibandha (Constipation)	10	1.71	0.85	0.37	0.12	6.80	<0.001	10
Anidra/Alpanidra (Sleeplessness)	10	2.87	1	0.35	0.11	16.77	<0.001	10
Anavasthita chitavam (Mood swing)	10	2	1	0.53	0.16	5.91	<0.001	10
Chinta (Anxiety)	10	2.62	1	0.51	0.16	9.92	<0.001	10
Krichchhra Vyavayata (Loss of libido)	10	2.12	1.12	0.53	0.17	5.61	<0.001	10
Maithuna asahishnuta (Dyspareunia)	10	2.25	1.12	0.64	0.20	5.55	<0.001	10
Sandhivedana	10	2.25	1	0.46	0.14	8.53	<0.001	10
Yoni Shushkata (Vaginal dryness)	10	2.25	1	0.70	0.22	5.5	<0.001	10

Table 5: Effect Of Therapy On Biochemical Parameters.

Investigations	Mean		Mean Diff.	% Change	S.D.±	S.E. ±	t	n	P
	B.T.	A.T.							
S. Cholesterol	181.5	201	-19.5	10.74↑	6.29	1.99	-9.79	10	<0.001
S. Triglyceride	134.3	131.4	2.9	2.15↓	25.57	8.08	0.35	10	0.0728
HDL	50.40	54.80	-4.4	8.73 ↑	5.5	1.74	-2.52	10	<0.05
S.Cholesterol/HDL	3.64	3.73	-0.08	1.85↑	0.47	0.15	-0.56	10	0.58
S. Calcium	9.45	9.32	0.13	1.37 ↓	0.67	0.21	0.61	10	0.55
S FSH	69.72	75.90	-6.18	13.79 ↑	12.37	5.53	-	10	0.32

							1.17		
S. Estrodiol	103.64	61.46	42.18	36.51↓	34.92	15.61	2.70	10	<0.05

Table 6: Total Effect Of Therapy In Group A.

Effect of therapy	No. of patients	%
Unchanged - □ 25% relief	0	0
Mild Improvement -26-50% relief	6	60
Moderate improvement -51-75%	4	40
Markedly improved -76-99% relief	0	0
Complete cure -100% relief	0	0

CONCLUSION

Shirodhara and Shaman Yoga combined is better in various psychological disturbances mainly include headache, irritability, depression, mood swings, sleep disturbances, etc., So, it can be concluded that in women with mild to moderate symptoms of menopausal syndrome, a Shaman Yoga gives better result in both somatic as well as psychological complaints. No any adverse effect was noted during the study. Therefore it could be a safe alternative therapy of HRT. It is found to be an effective therapy in psychological and somatic problems related with menopausal syndrome.

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