

COMPARATIVE CLINICAL STUDY OF THE EFFICACY OF SHATAVARYADI CHURNA AND BRAHMI GHRITA NASHYA IN THE MANAGEMENT OF RAJONIVRITTI JANYA LAKSHANA

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ABSTRACT

Acharyas mentioned the *Rajonivritti Awastha* as a *Swabhavik awastha* of women life and occur due to *jara-pakwa awastha* of female. Acharyas mentioned fifty years as an age of *Rajonivritti*. Basically, in *Rajonivritti*, *Vata dosha* is most aggravated with *madhyam pitta* and *kapha kshaya* and also there is *kshaya* of various *dhatu*s and *upadhatu*s. Incidence and prevalence rate of postmenopausal syndrome is 78% of population, but only 19.5% of the symptomatic women take treatment, its outcomes effecting the Quality of life (QoL). After analysis, this topic was taken up for present study. *Rasayana chikitsa*, *Medhya aushadhi*, *Vata-pitta shamak*, *kapha vardhak*^[16] *ausadhi*, *dhatu*s, *upadhatu*s regulating *ausadhi* are found to be helpful in

managing the *Rajonivritti janya lakshana*. By keeping in mind, the properties, a combination of drugs ie *Shatavaryadi churna* was prepared for this trial and along with *Brahmi ghruta* for *pratimarsha nasya*, which pacify dosha by acting in *Shringataka marma*. And thus, evaluate the efficacy in the management of *Rajonivritti janya lakshana*. **Methodology:** This research was a randomized comparative clinical study of 40 patients, whose *Rajonivritti* was established, cases was randomly divided into 2 groups of 20 patients in each group. Group A was given *Shatavaryadi churna* orally Group B *Shatavaryadi churna* with *Brahmi ghruta nasya* for (three consecutive months with drug and one month for drug free follow). **Result:** Clinically parameter was assessed in each group was statistically. Highly significant result was found in symptoms of Hot flushes, night sweats, sweat, palpitation, fatigue, weakness. Psychological symptoms like depression, insomnia, irritability, mood swings, anxiety. **Interpretation and Conclusion:** Thus, group B (*Shatavaryadi churna* along with *Brahmi*

ghrita nasya) shows higher response as compared to Group A (*Shatavaryadi churna*) in management of *Rajonivritti janya lakshana*.

KEYWORDS: *Rajonivritti janya lakshana Shatavaryadi churna, Brahmi ghrita, Pratimarsha nasya, Menopause.*

INTRODUCTION

Women are the pioneer of family, society and Nations. Woman have heap of responsibilities on her, therefore it becomes so important for a woman to remain healthy in every phase of her life, so that she becomes able justify with her every role.

There is no brief description of *Rajonivritti* in *Ayurvedic* classics. All *Acharyas* mentioned the *Rajo-nivritti Awastha* as a *Swabhavik awastha* of women life and occur due to *jara-pakwa awastha* of female.^[1] *Acharya Sushruta* and various other *acharya* mentioned fifty years as an age of *Rajonivritt*.^[2]

In *Vridhdha awastha* (50 years) i.e., *Rajo-nivritti*, *Vata dosha* is most aggravated with *madhyam pitta* and *kapha kshaya*, also there is *kshaya* of various *dhatus* and *upadhatu*s. Due to various dosha imbalances, various symptoms arouse in a female.

Menopause is generally defined as cessation of periods for 12 months, time of cessation of ovarian function resulting in permanent amenorrhea.^[3] During reproductive years, women are protected by female hormones i.e., Estrogen and Progesterone. By the start of menopause, women enter in estrogen deficient phase, which accelerates her ageing process results in appearance of various psychosomatic problems.

Incidence and prevalence rate of postmenopausal syndrome is 78% of population, but only 19.5% of the symptomatic women take treatment. Hence there is a need for definitive management during the Menopausal stage, to improve the quality of life of individuals.

In *Ayurveda* to slow down these degenerative process of the body tissue *acharyas* have described the various protective measurement in form of *Aahar, dincharya, Ratricharya, yoga, Aashana, Rasayana chikitsa, Medhya aushadhi, Vata-pitta shamak, kapha vardhak, aushadhi, dhatus, updhatus* regulating *aushadhi* are found to be helpful in managing the *Rajonivritti janya lakshana*.

So, so choosen trial drug Shatavaryadi churna combination of three drugs Shatavari, Arjun, Ashwagandha^[4] and Brahmi ghrita nasya^[5] (Brahmi and GO ghrita) had properties of Vata pitta shamak and kapha vardhaak

OBJECTIVES OF STUDY

1. To assess the efficacy of *Shatavaryadi churna* in management of *Rajonivritti janya lakshana*.
2. To evaluate the efficacy of *Shatavaryadi churna* with *Brahmi ghrita nasya* improvement of *Rajonivritti janya lakshana*.

MATERIAL AND METHOD

Sources of Data

Patient – Patient with symptoms of *Rajonivritti* were selected from OPD/IPD of *Prasuti Tantra evam Stri Roga* department of State Ayurvedic College and Hospital, Lucknow.

Source of drugs

The trial drugs were prepared in the pharmacy of State Ayurvedic college, Lucknow by experts and under the supervision of department of *Rasa shastra* and *Bashiq Kalpana*. Therefore, all the necessary measures regarding the drugs preparation were taken by the experts.

Preparation of drug

The trial drugs were prepared in the pharmacy of State Ayurvedic college, Lucknow by experts and under the supervision of department of *Rasa shastra* and *Bhaishajya kalpana*.

Method of data collection

40 patients were having Menopause were selected based on diagnostic, Inclusion criteria.

Sample size – 40 patients in two groups were registered.

Group Allocation

1. **Group A-** The trial drug *Shatavaryadi churna* - 5 gm orally for 3 consecutive months was given to the patient of group A.
2. **Group B-** The trial drug *Shatavaryadi churna* 5 gm with *Brahmi ghrita pratimarsha nasya*-2 drops each nostril for consecutive three months was given to group B.

Period of study

Total duration of clinical study was 4 consecutive cycle (3 months with drugs and 1 month drug free follow up).

DIAGNOSTIC CRITERIA

Diagnosis of each patient was made with help of detailed history in respect to disease, family history, previous similar episodes, physical and systemic examination as well as the investigation.

1. Physiological symptoms like hot flushes, night sweat, palpitation, fatigue, weakness.
2. Psychological symptoms like depression, insomnia, irritability, mood swings, anxiety.

INCLUSION CRITERIA

1. Amenorrhea for 12 months or more.
2. Women age group 45-60 years.
3. Women is not undergoing any estrogen replacement therapy presently and also not for last months for menopausal symptoms.
4. Subjects willing to participate in this trial.

EXCLUSION CRITERIA

1. Women with Surgical menopause.
2. Patient with evidence of Malignancy.
3. Patient who had past history of any systemic illness i.e., Heart disease, Diabetes mellitus, Hypertension, Hepatic disorders, Renal pathology, Pulmonary dysfunction.
4. Patient undergoing any kind of Chemotherapy, Radiotherapy.
5. Patient on prolonged medication (>6 months) with Hormone Replacement
6. Therapy (HRT) corticosteroids, Antidepressant, etc.

INVESTIGATION

1. Blood - Hemoglobin (Hb), Total count (TC), Differentiate count (DC), Erythrocyte sedimentation rate (ESR), Random blood sugar (RBS).
2. Urine – Routine and Microscopic examination.
3. Serum T₃, T₄, TSH
4. USG of whole abdomen.

ASSESSMENT CRITERIA

The effect of therapy was analysed on certain parameters before and after treatment.

SUBJECTIVE PARAMETERS

1. Hot flushes (*Swedadhikyata*)
2. Nights sweats (*Ratri sweda*)
3. Fatigue (*Glani*)
4. Palpitation (*Hrid Spandanadhikya*)
5. Weakness (*Bala kshaya*)
6. Insomnia (*Anidra /Alpanidra*)
7. Irritability (*Ashatwa*)
8. Anxiety (*Tanaao yuktata*)
9. Mood swings (*Asthir manobhava*)
10. Depression (*Aaoshaad*)

RESULT AND OBSERVATIONS

Most of the cases (55%) was age group 45-99 years, was of mixed society, 92.5% was housemakers, about 40 % were educated up to primary level, 55 % of cases was of Vata pitta prakriti, Age of menopause was 46 years in about 40% of cases, 13 years is age of menarche in 40 % of cases.

Table .1

Characteristic	Group A				Group B			
	Mean		% Relief	P value	Mean		% Relief	P value
	BT	AT			BT	AT		
Hot flushes	2.40	1.10	54.16	<0.001	2.35	0.70	70.21	<0.001
Night sweats	2.15	1.25	41.86	<0.001	1.80	0.75	58.33	<0.001
Fatigue	2.80	1.30	53.57	<0.001	2.25	0.55	75.56	<0.001
Palpitation	2.65	0.95	64.15	<0.001	2.25	0.75	66.64	<0.001
Weakness	2.45	0.60	75.5	<0.001	2.35	0.60	74.47	<0.001
Insomnia	2.40	1.0	58.33	<0.001	2.45	0.45	79.07	<0.001
Irritability	2.45	1.10	55.10	<0.001	2.25	0.75	68.8	<0.001
Anxiety	2.15	0.95	55.81	<0.001	1.90	0.40	78.95	<0.001
Mood swings	0.90	0.45	50.00	0.003	0.75	0.20	73.33	0.001
Depression	0.65	0.3	46.15	0.008	0.75	0.25	66.67	0.002

aStatistically and clinically significant effect of the treatment was observed in both the groups.

Table. 2

Grade	group A		group B	
	No.	%	No.	%
Marked improvement (76%-100%)	2	10.0%	10	50.0%
Moderate improvement (51 % -75 %)	12	60.0%	8	40.0%
Mild improvement (26 % - 50%)	6	30.0%	2	10.0%
No improvement (0 % - 25%)	0	0.0%	0	0.0%
Total	20	100.0%	20	100.0%

Out of total 40 patient 12 patient shows showed marked improvement, 20 cases showed moderate improvement and 8 cases showed mild improvement was noticed.

DISCUSSION

Menopause is natural occurring physiological phenomenon which is sure to occur in every women life. Although it is a milestone process, still in some women it becomes troublesome, which in turn halt their day-to-day activities by various physical and mental agony. To overcome from menopausal symptoms, contemporary science has got many drugs, therapies like Hormone replacement therapy (HRT) etc. these physical replacements of hormones which may help in reducing the symptoms are usually accompanied by various serious hazardous complications like endometrial cancer on long term use.

Ayurveda considered *Rajonivritti* as *Swabhavik awastha* of woman general physiology, it occurs due to *jara pakwa awastha* of body. There is no brief description of *Rajonivritti* in *Ayurvedic* classics and mentioned 50 years as the age of *Rajonivritti*. In *Rajonivritti kala*, *Vata dosha* is most aggravated with *Madhyam pitta* and *kapha Kshaya* and also there is *kshaya* of various *dhatu*s and *Upadhatus*.

Because of imbalancing of *doshas*, various symptoms occur as due to *Vata dosha* Insomnia, anxiety, mood swings etc. *Pitta dosha* causes hot flushes, irritability, night sweats, etc. *Kapha dosha* primarily cause Palpitation, Weakness etc, vitiation of *Manas doshas* also causes symptoms like *Krodha*, *Bhaya*, *Smriti Hras*, *Swesha* etc, and due to *Rasa dhatu kshaya* symptoms like *Shula*, *Shosha*, *Trishna* etc may occur, *Rakta dhatu kshaya* causes *Twak parushya* and due to other *dhatukshaya* various *lakshana* occurs.

In *Ayurveda classics* to combat this degenerative process of the body tissue *Acharyas* have described the *Rasayana chikitsa*, *Medhya Aushadi*, *Jivaniye aushadi*, *Vaya Stapak gana*

Aushadhi, Vata-pitta Shamak and kapha Vardhak drugs, these are found to be helpful in overcoming from Menopausal symptoms.

By analysing the *Rajonivritti* symptoms pacifying properties combination of drugs is prepared ie *Shatavaryadi churna*, which has over all effect of *Vata pitta shamak* and *kapha vardhak*.

Brahmi ghrita nasya, drugs reache the *shringataka marma*, and it pacifies doshas in *urdwajatru gata* and hence *manas dosha* which leads to subside psychological symptoms.

CONCLUSIONS

- ❖ On the symptoms of Hot flushes, both groups are statistically significant, where Group B showed 16.05% more effective than Group A.
- ❖ On the symptoms of Night sweats, both groups are highly significant, where Group B showed 16.47% more effective than Group A.
- ❖ On the symptoms of Fatigue, both groups are highly significant, where Group B showed 21.99% more effective than Group A.
- ❖ On the symptoms of Palpitation, both groups are significant, where Group B showed 2.49% more effective than Group A.
- ❖ On the symptoms of Weakness, both groups are significant, where Group A showed 1.03% more effective than Group B.
- ❖ On the symptoms of Insomnia, both groups are highly significant, where Group B showed 20.74% more effective than Group A.
- ❖ On the symptoms of Irritability, both groups are highly significant, where Group B showed 13.7% more effective than Group A.
- ❖ On the symptoms of Anxiety, both groups are highly significant, where Group B showed 23.14% more effective than Group A.
- ❖ On the symptoms of Palpitation, both groups are significant, where Group B showed 2.49% more effective than Group A.
- ❖ On the symptoms of Mood swings, both groups are statistically highly significant, where Group B showed 20.52% more effective than Group A.
- ❖ On the symptoms of Depression, both groups are statistically highly significant, where Group B showed 12.82% more effective than Group A.
- ❖ *The Shatavariyadi churna* is its *Vata-pitta shamak and kapha vardhak, Rasayana, Medha* properties, so effective in subsiding symptoms of *Rajonivritti*.

- ❖ In *Nashya* drug administered through nose reaches the *Shringataka Marma*, *Sira Marma*. The drug spreads, pacify the morbid *doshas* of *Urdhwajatru*
- ❖ Hence, it is concluded that Group B (*Shatavariyadi churna* along with *Brahmi ghrita*) is showing more response to treatment than Group A.

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