

Open-Labeled, Randomized, Prospective Controlled Clinical Study to Assess Efficacy of *Rasayana Churna* and *Pranayama* in the Management of *Rajonivritti Lakshanas w. s. r.* to Postmenopausal Syndrome

Research Article

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Abstract

Background: In modern science, hormonal replacement therapy (HRT) is the only alternative for postmenopausal syndrome whereas non-hormonal pharmacologic therapies have been shown to be less effective than hormonal therapy. So, it was assumed that *Rasayana Churna* along with *Pranayama* would be effective in relieving postmenopausal symptoms. **Objective:** to assess the clinical efficacy of *Rasayana Churna* and *Pranayama* in the management of *Rajonivritti Lakshanas w. s. r.* to Postmenopausal Syndrome. **Methods:** The present open-labeled, randomized, prospective controlled clinical study was conducted after IEC approval. Total 60 female patients suffering from Postmenopausal Syndrome were enrolled in the study and randomized into two groups i. e. Group A & Group B. 30 patients in Group A were given *Rasayana Churna* orally with daily practice of *Pranayama* was advised. 30 Patients in Group B were advised daily practice of *Pranayama* for consecutive 12 weeks. The results were assessed by using Menopausal Rating Scale (MRS) and Menopause-Specific Quality of Life Questionnaire (MENQOL). **Results:** The significant difference was observed in MRS-Total score and MENQOL scores after treatment in both the groups. Out of four scales of MENQOL, the vasomotor, physical and psychological scales showed significant improvement in the group received regimen of *Rasayana Churna* along with *Pranayama* as compared with only *Pranayama*. Only change in sexual scale score was found to be similar in both the groups' patients. **Conclusion:** It can be inferred that regimen of *Rasayana Churna* along with *Pranayama* was more efficacious in treatment of post-menopausal syndrome as compared with only *Pranayama*.

Key Words: Hormonal replacement therapy (HRT), Postmenopausal Syndrome, *Rajonivritti*, *Rasayana Churna*, *Pranayama*.

Introduction

An estimated 80% of females experience physical or psycho-social symptoms while approaching menopause, leading to change in their quality of life.(1) These physiological and psychological changes are due to estrogen deficiency.(2) Many symptoms related to postmenopausal syndrome such as hot flushes, irritability, mood swings, insomnia, dry vagina, difficulty concentrating, mental confusion, stress incontinence, urge incontinence, osteoporotic symptoms, depression, headache, vasomotor symptoms, insomnia etc. are observed in females. In modern science, hormonal replacement therapy (HRT) is the only alternative available for postmenopausal syndrome. Non-hormonal pharmacologic therapies have

been shown to be less effective than hormonal therapy and to be associated with their own adverse events that restrict their use for many women.(3) Therefore, many menopausal women use complementary therapies to cope with their symptoms.(4) *Yoga* is among the most commonly used complementary therapies for menopausal symptoms.(5, 6) *Pranayama* was found to be effective in relieving postmenopausal symptoms in female patients in previous clinical trials. (7) *Rajonivrittijanya Lakshana* is a group of symptoms produced by degenerative changes. So, *Rasayana Chikitsa* is described by Ayurveda *Acharya* to battle the degenerative process of the body tissues. *Rasayana Churna* is a classical Ayurvedic formulation which contains dried powders of three rejuvenating drugs viz. Guduchi (*Tinospora cordifolia* Wild. Hook.), Amalaki (*Emblia officinalis* Gaertn.) and Gokshura (*Tribulus terrestris*).(8, 9) As the name suggested, it is used in Ayurveda as *Rasayana* to enhance general body resistance, promote longevity, as anti-stress and adaptogen. So, it was assumed that *Rasayana Churna* along with *Pranayama* would be effective in relieving postmenopausal symptoms. Therefore, considering it as a challengeable malady, the present study entitled

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“Open-labeled, Randomized, Prospective Controlled Clinical Study to assess Efficacy of *Rasayana Churna* and *Pranayama* in the management of *Rajonivritti Lakshanas w. s. r. to Postmenopausal Syndrome*” was undertaken to find out effective and safe management of *Rajonivritti Lakshanas w. s. r. to Postmenopausal Syndrome*.

Materials & Methods

Study design, sites

This randomized, open labeled, comparative, prospective clinical study was carried out in the OPD of Dept of Prasutitantra and Streerog, D.Y. Patil deemed to be University School of Ayurveda, Nerul, Navi-Mumbai- 400706, Maharashtra state.

Ethical considerations

Ethical clearance was obtained from Institutional Ethics Committee (IEC) of D. Y. Patil Deemed to be University School of Ayurveda, Nerul, Navi Mumbai, Maharashtra State. The written informed consent was obtained from all study subjects before any study related procedures.

Enrolment of patients

60 female patients fulfilling the inclusion criteria were selected for study by purposive sampling method and randomly divided into two groups, namely Group A and Group B.

Inclusion criteria

Females of age between 45 and 55 years with absence of menstrual period for more than or equal to 12 months (≥ 12 months), having symptoms of postmenopausal syndrome as well as willing and able to participate in the clinical trial for 3 months were enrolled in the study.

Exclusion Criteria

Women on HRT or post HRT, Surgical menopause, clinically suspected benign or malignant lesion in uterus, cervix or vagina, patients with established cases of mental illness, hypertension, hyperthyroidism or hypothyroidism, diabetes mellitus, rheumatoid arthritis, coronary artery disease, hepatic disorders, chronic obstructive pulmonary disease, etc. and any condition when the patient is not willing were excluded from the study.

Sample size

Total sixty patients with Postmenopausal Syndrome were screened, out of which 60 were recruited in the study and completed the study.

Treatment Groups:

The recruited patients were randomized into two groups i. e. Group A & Group B. 30 Patients of Group A were given *Rasayana Churna* orally and daily practice of *Pranayama* was advised.

The patients were given *Rasayana Churna* 6 gm twice a day before food with *Ghrita* orally and daily practice of *Pranayama* was advised.

Anuloma – Viloma Pranayama: The process of inhaling and exhaling breath through right nostril by closing the left nostril, the same was repeated for left nostril too. This cycle was repeated for 10 to 15 times twice a day for 12 weeks in morning and evening before food.

30 Patients in Group B were advised only daily practice of *Anuloma – Viloma Pranayama* for 12 weeks in morning and evening before food.

Study duration & Visits

The total duration of the study was 12 weeks. In each group duration of treatment was given for consecutive 12 weeks. Follow up was taken on every alternate week till 12 weeks, i. e. Day 14 (week 02), Day 28 (week 04), Day 42 (week 06), Day 56 (week 08), Day 70 (week 10) and Day 84 (week 12).

Laboratory Investigations

All selected patients were subjected to routine investigations before (Day 0) and after completion of treatment duration (Day 84), which include the following: Blood: Hemoglobin (Hb), Fasting /PP Blood Glucose Levels (BSL) and TSH (Thyroid Stimulating Hormone).

Assessment Parameters

The results were assessed with regards to improvement recorded in clinical findings and laboratory investigations, as well as changes observed in signs and symptoms. It was assessed by adopting suitable scoring methods and objective signs by using appropriate clinical tools.

Subjective Criteria

Symptoms of Postmenopausal syndrome mentioned in the text or practically observed were assessed at each follow- up and presence or absence of them were registered. Somatic and urogenital symptoms were graded based on "Menopause Rating Scale (MRS)" and Menopause Specific Quality of Life Questionnaire (MENQOL).

Menopause Rating Scale (MRS): The scoring scheme is simple, i. e. the score increases point by point with increasing severity of subjectively perceived symptoms in each of the 11 items (severity 0 [no complaints] 4 scoring points [very severe symptoms]). The respondent provides her personal perception by checking one of 5 possible boxes of "severity" for each of the items. This can be seen in the questionnaires in the additional files linked to this publication. The composite scores for each of the dimensions (sub-scales) is based on adding up the scores of the items of the respective dimensions. The composite score (total score) is the sum of the dimension scores. (10)

The MENQOL is self-administered and consists of a total of 29 items in a Likert-scale format. Each item assesses the impact of one of four domains of menopausal symptoms, as experienced over the last month: vasomotor (items 1–3), psychosocial (items 4–10), physical (items 11–26), and sexual (items 27–29). (11)

Criteria for Overall Assessment of Therapy was as Completely Cured: 100% relief, Markedly Improvement: > 75% to < 100% relief, Moderate Improvement: > 50% to 75% relief, Mild Improvement: > 25% to 50% relief and Unchanged: < 25% relief.

Results

Total 60 female patients were enrolled in the study. 30 patients in Group A received *Rasayana Churna* and practised Pranayama for consecutive 12 weeks whereas 30 patients in Group B practised Pranayama for consecutive 12 weeks. All patients

completed the study period. The average age of 30 patients in Group A was 49.97 ± 3.36 years whereas in Group B was 50.57 ± 3.18 years with no statistically significant difference.

Out of total 60 patients, majority of patients, i. e. 30 (50%) patients had *Vata – Pitta Prakriti*, 05 (8.33%) patients *Vata – Kapha Prakriti*, 06 (10%) patients had *Pitta – Vata Prakriti*, 05 (8.33%) patients *Pitta – Kapha Prakriti*, 05 (8.33%) patients *Kapha – Vata Prakriti* whereas 09 (15%) patients had *Kapha – Pitta Prakriti*.

The assessment of efficacy parameters is given below:

Table 1 :- Menopausal Rating Scale (MRS)

Parameter	Group		Mean \pm SD	Median (Range)	Intra-Group Comparison	Inter-Group Comparison
MRS – Total Score	Group A (n = 30)	BT	6.80 ± 1.61	06 (05 – 11)	Sum of all signed ranks (W) = 435.00 Number of pairs = 29 The two-tailed P value is < 0.0001, considered extremely significant.	Mann-Whitney U-statistic = 267.50 U' = 632.50 The two-tailed P value is 0.0070, considered very significant.
		AT	4.13 ± 1.25	04 (02 – 07)		
	Group B (n = 30)	BT	6.73 ± 2.13	07 (02 – 11)		
		AT	4.93 ± 1.05	05 (02 – 07)		
MENOPAUSE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE (MENQOL)	Group A (n = 30)	BT	22.97 ± 4.00	22 (17 – 33)	Sum of all signed ranks (W) = 462.00 Number of pairs = 30 The two-tailed P value is < 0.0001, considered extremely significant.	Mann-Whitney U-statistic = 186.00 U' = 714.00 The two-tailed P value is < 0.0001, considered extremely significant.
		AT	13.37 ± 1.87	13 (11 – 18)		
	Group B (n = 30)	BT	21.77 ± 3.79	22 (12 – 30)		
		AT	15.97 ± 2.41	16.5 (12 – 21)		
MENQOL – Vasomotor	Group A (n = 30)	BT	2.67 ± 1.37	08 (06 – 18)	Sum of all signed ranks (W) = 190.00 Number of pairs = 19 The two-tailed P value is < 0.0001, considered extremely significant.	Mann-Whitney U-statistic = 357.00 U' = 543.00 The two-tailed P value is 0.1671, considered not significant.
		AT	1.77 ± 0.77	02 (00 – 03)		
	Group B (n = 30)	BT	2.07 ± 1.87	2.5 (00 – 06)		
		AT	1.30 ± 1.15	02 (00 – 03)		

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Parameter	Group		Mean ± SD	Median (Range)	Intra-Group Comparison	Inter-Group Comparison
MENQOL – Psychological	Group A (n = 30)	BT	7.43 ± 1.91	7.5 (04 – 11)	Sum of all signed ranks (W) = 465.00 Number of pairs = 30 The two-tailed P value is < 0.0001, considered extremely significant.	Mann-Whitney U-statistic = 119.50 U' = 780.50 The two-tailed P value is < 0.0001, considered extremely significant.
		AT	4.50 ± 1.11	4.5 (02 – 07)		
	Group B (n = 30)	BT	4.17 ± 1.78	04 (02 – 08)		
		AT	2.73 ± 1.05	03 (01 – 05)		
MENQOL – Physical	Group A (n = 30)	BT	15.43 ± 4.06	15.5 (04 – 24)	The two-tailed P value is < 0.0001, considered extremely significant. t = 14.903 with 29 degrees of freedom.	Mann-Whitney U-statistic = 293.00 U' = 607.00 The two-tailed P value is 0.0205, considered extremely significant.
		AT	8.93 ± 2.26	09 (04 – 14)		
	Group B (n = 30)	BT	13.4 ± 2.62	12 (08 – 21)		
		AT	7.83 ± 1.44	07 (06 – 11)		
MENQOL – Sexual	Group A (n = 30)	BT	2.03 ± 1.90	02 (00 – 06)	Sum of all signed ranks (W) = 190.00 Number of pairs = 19 The two-tailed P value is < 0.0001, considered extremely significant.	Mann-Whitney U-statistic = 361.50 U' = 538.50 The two-tailed P value is < 0.1907, considered not significant.
		AT	1.13 ± 1.07	01 (00 – 03)		
	Group B	BT	2.13 ± 1.59	02 (00 – 06)		
		AT	1.50 ± 1.08	01 (00 – 03)		

MRS – Total Score

Both the groups exhibited efficacy of respective treatments on intra-group comparison. This signifies that, both were effective. Also, inter-group comparison was also significant. It shows that the regimen of *Rasayana Churna* along with *Pranayama* was more efficacious in treatment of post-menopausal syndrome compared to only *Pranayama*.

The MENQOL comprises of 4 sub scales. These are Vasomotor, Psychosocial, Physical and Sexual scales. The effect of therapy on MENQOL has shown that statistically highly significant improvement was observed on 3 sub scales, viz., Vasomotor, Psychosocial and Physical sub scales. This efficacy was observed in both intra and inter group comparison. However, on Sexual sub scale, only intra-group comparison in both groups was significant. The inter-group comparison was not significant.

Out of 30 patients in Group A, 24 (80%) patients got mild improvement whereas 06 (20%) patients got moderate improvement after treatment. Out of 30 patients in Group B, 17 (56.67%) patients got mild improvement whereas 13 (43.33%) patients remained unchanged after treatment. Chi – Square Value = 20.195 (P value < 0.0001). There was statistically significant difference between the overall assessments of therapy between two groups.

Discussion

Intake of *Rasayana Churna* along with practicing *Anuloma – Viloma Pranayama* for consecutive 12 weeks showed significant improvement in all patients. It was observed in MRS Total score and MENQOL score. Out of four scales of MENQOL, the vasomotor, physical, and psychological scales showed significant improvement in the group received regimen of

RasayanaChurna along with *Pranayama* treatment of post-menopausal syndrome, as compared with only *Pranayama*. Only change in sexual scale score was found to be similar in both the groups' patients. No adverse events were noticed during or after the study.

As *Rajonivritti* is a naturally occurring condition in female body; it can be categorized under *Swabhavika Vyadhis* as that of *Jara* (aging); *Kshudha* (Hunger); *Pipasa* (thirst); *Nidra* (sleep) and *Mriyayu* (death) as described in the classics. Thus, due to various factors including *Kala*, along with generalized *Vatavridhi* (increased *Laghu*, *Ruksha*, *Khara Guna*) and *Kaphakshaya* (decreased *Gura*, *Snigdha*, *Drava Guna*); *Rukshata* and *Shosha* of *Artavavaha Srotas* take place and all these things will lead to *Artavanasha* and manifest as *Rajonivritti*. Considering this stage as a generalized *Kshaya Avastha*, *Rasayana* therapy seems to be a choice treatment, to nourish the *Dhatus*. Thus, it was taken as a control intervention. Even the women in intervention group also received *Pranayama* as add on therapy. *Pranayama* strengthens the mental concentration and *Dhyana* aims at mental clarity. Specifically, *Anuloma Viloma Pranayama* helps in *Nadi Shodhana* (purification of channels) which leads to eliminate the *Dosha* from the blood, leads to reduction in stress and anxiety (psychological illness), thus helpful in maintaining the quality of life in Post Menstrual Phase. *Rasayana Churna* is a poly herbal formulation mentioned by *Ashtanga Hridaya*, in *Rasayana* chapter. Other names given to this preparation in text are '*Gokshurakadinama Churna*' and '*Swandanstradi Churna*'.(12) It is not described in any other classical texts. It is a unique combination of three well known rejuvenating herbs, viz, *Guduchi*, *Gokshura* and *Amalaki* equal quantity. This formulation can be used in prevention and treatment of depression and anxiety as the medicine can act on *Tamasika Guna* also.

Conclusion

It can be concluded that the regimen of *Rasayana Churna* along with *Pranayama* was more efficacious as compared with only *Pranayama* in treatment of post-menopausal syndrome

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