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ROLE OF PHALATRAYADI CHURNA AND SVADAMSHTRADI CHURNA IN RAJONIVRUTTI WITH SPECIAL REFERENCE TO POST MENOPAUSE SYNDROME - A RANDOMIZED COMPARATIVE CLINICAL TRIAL

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ABSTRACT

Background: Rajonivrutti, the physiological cessation of menstruation, is a natural transition in a woman's life. However, the associated postmenopausal syndrome, characterized by vasomotor, psychological, and somatic symptoms, significantly impacts quality of life. Modern hormone replacement therapy (HRT) offers relief but carries potential risks, prompting the search for safer, holistic alternatives. **Aim:** To evaluate and compare the clinical efficacy of Phalatrayadi Churna and Svadamshtradi Churna in the management of Rajonivrutti Janya Lakshanas (postmenopausal syndrome). **Method:** A randomized, open-labeled, prospective controlled clinical trial will be conducted on 60 postmenopausal women aged 45-55 years. Participants will be randomized into two groups: Group A will receive Phalatrayadi Churna and Group B will receive Svadamshtradi Churna for 12 weeks. Assessment will be conducted using Menopause Rating Scale (MRS) and

Menopause-Specific Quality of Life Questionnaire (MENQOL). **Result:** Based on previous research, Rasayana Churna has shown significant improvement in vasomotor, physical, and psychological domains of MENQOL, with excellent tolerability and no adverse effects. Phalatrayadi Churna, with its Vata-Kapha balancing properties, is expected to yield comparable results. **Conclusion:** Both Phalatrayadi Churna and Svadamshtradi Churna offer safe, economical, and holistic management options for postmenopausal syndrome, potentially serving as effective alternatives to HRT.

KEYWORDS: Rajonivrutti, Postmenopausal Syndrome, Phalatrayadi Churna, Svadamshtradi Churna, Rasayana Churna, Menopause.

INTRODUCTION

Menopause, or Rajonivrutti in Ayurveda, marks the permanent cessation of menstruation due to the decline of reproductive hormones, typically occurring between 45-55 years of age. While a natural physiological event, the transition is often accompanied by a constellation of symptoms collectively termed postmenopausal syndrome. These include vasomotor symptoms (hot flushes, night sweats), psychological disturbances (anxiety, depression, mood swings), urogenital atrophy, and somatic complaints such as joint pain, fatigue, and cognitive decline.

In modern medicine, Hormone Replacement Therapy (HRT) remains the primary treatment for managing these symptoms. However, its association with increased risks of breast cancer, cardiovascular events, and thromboembolic complications has led to a search for safer, non-hormonal alternatives. Non-hormonal pharmacologic therapies have shown limited efficacy compared to hormonal therapy.

Ayurveda offers a holistic approach to managing Rajonivrutti, viewing it as a Swabhavika Vyadhi (natural condition) arising from Vata Vriddhi (increased Vata Dosha), Kapha Kshaya (depletion of Kapha Dosha), and Dhatukshaya (tissue depletion) due to aging. The approach focuses on Rasayana (rejuvenation) therapy to nourish Dhatus, balance Doshas, and restore homeostasis. This paper presents a study protocol for a randomized comparative clinical trial evaluating two classical Ayurvedic formulations — Phalatrayadi Churna and Svadamshtradi Churna —in managing postmenopausal syndrome.

AYURVEDIC PERSPECTIVE OF RAJONIVRUTTI

Conceptual Understanding

In Ayurveda, Raja (menstrual blood) is considered an Upadhatu (secondary tissue) of Rasa Dhatu. Rajonivrutti, the cessation of menstruation, is described as a natural occurrence in the Praudha Avastha (advanced age) and is categorized under Swabhavika Vyadhis (natural diseases) along with aging, hunger, thirst, sleep, and death.

Pathogenesis (Samprapti)

The pathogenesis of Rajonivrutti involves

1. Aging (Jara): Natural degeneration of Dhatus.
2. Vata Vriddhi: Aggravation of Vata Dosha, particularly its Ruksha (dry), Laghu (light), and Khara (rough) properties.
3. Kapha Kshaya: Depletion of Kapha Dosha, reducing its Snigdha (unctuous), Guru (heavy), and Drava (liquid) properties.
4. Ashayapakarsha of Pitta: Displacement of Pitta due to aggravated Vata.
5. Rasa Dhatu Kshaya: Reduced formation and nourishment of Rasa Dhatu, leading to impaired formation of Raja (Artava).
6. Srotorodha: Obstruction in Artavavaha Srotas.

Result: Rukshata (dryness) and Shosha (atrophy) of Artavavaha Srotas, leading to Artavanasha (cessation of menstrual flow) and manifestation of Rajonivritti Lakshanas.

Etiological Factors (Nidana)

- Kala: Natural aging process
- Ahara: Dietary factors causing Vatavriddhi and Dhatukshaya
- Vihara: Lifestyle factors like excessive exercise, sleep deprivation, stress
- Manasika Nidana: Psychological stress, anxiety

Symptoms Correlated with Postmenopausal Syndrome

Rajonivrutti Lakshana Postmenopausal Syndrome Kampa Tremors

Shula Pain Bhrama Dizziness Anidra Insomnia

Shosha Vaginal dryness, Atrophy Asukla Pravritti Loss of libido Bhaya Anxiety

Vishada Depression Sandhi Shula Joint pain

MODERN PERSPECTIVE: POSTMENOPAUSAL SYNDROME

Postmenopausal syndrome encompasses a wide range of symptoms resulting from estrogen deficiency.

Clinical Features

1. Vasomotor Symptoms: Hot flushes, night sweats, palpitations
2. Psychological Symptoms: Depression, anxiety, irritability, mood swings, cognitive decline
3. Urogenital Symptoms: Vaginal dryness, dyspareunia, urinary frequency, recurrent UTIs
4. Somatic Symptoms: Joint pain, muscle aches, fatigue, headache, weight gain
5. Long-term Complications: Osteoporosis, cardiovascular disease

Diagnostic Assessment

- Clinical history of amenorrhea for ≥12 months
- Menopause Rating Scale (MRS)
- Menopause-Specific Quality of Life Questionnaire

(MENQOL)

REVIEW OF INTERVENTIONS

1. Phalatrayadi Churna

Synonyms & Classical Reference: Phalatrikadi Churna

Ingredients

Sanskrit Name Botanical Name Common Name Properties

Haritaki Terminalia chebula Chebulic Myrobalan Vata-Kaphahara, Deepana, Rasayana Amalaki Phyllanthus emblica Indian Gooseberry Rasayana, Tridoshahara, Vrishya Bibhitaki Terminalia bellirica Belliric Myrobalan Kaphahara, Netrya, Keshya Shunthi Zingiber officinale Ginger Deepana, Pachana, Vatanulomana.

Pharmacological Properties (Rasadi Panchaka)

- Rasa: Kashaya (astringent) pradhana, Katu (pungent), Tikta (bitter)
- Guna: Ruksha (dry), Laghu (light)
- Virya: Ushna (hot)
- Vipaka: Madhura (sweet)

Therapeutic Actions

- Vata-Kaphahara (pacifies Vata and Kapha)
- Deepana-Pachana (stimulates digestion, burns Ama)
- Srotoshodhana (clears channels)
- Lekhana (scraping) and Shoshana (drying) properties
- Rasayana (rejuvenating)

Probable Mode of Action in Rajonivrutti:

1. Vata Pacification: The Ushna and Snigdha properties counteract Vata Vriddhi.
2. Kapha Balancing: Kashaya and Katu Rasa help balance Kapha Kshaya.
3. Dhatu Nourishment: Rasayana action nourishes Rasa Dhatu, improving Artava formation.
4. Ama Elimination: Deepana-Pachana action enhances Agni, preventing Ama formation and obstruction.

Dose: 3-5 grams twice daily with warm water or honey.

2. Svadamshtradi Churna (Rasayana Churna)

Synonyms: Gokshurakadinama Churna, Rasayana Churna

Ingredients

Sanskrit Name Botanical Name Common Name Properties

Guduchi Tinospora cordifolia Giloy Rasayana, Tridoshahara, Deepana, Medhya

Gokshura Tribulus terrestris Gokshura Vrishya, Balya, Mutrala, Tridoshahara

Amalaki Phyllanthus emblica Indian Gooseberry Rasayana, Tridoshahara, Vrishya

Pharmacological Properties (Rasadi Panchaka)

- Rasa: Kashaya pradhana, Madhura, Tikta, Katu
- Guna: Laghu (light), Snigdha (unctuous)
- Virya: Ushna (hot) predominantly
- Vipaka: Madhura (sweet)

Therapeutic Actions

- Rasayana (rejuvenation)- enhances general body resistance, promotes longevity
- Tridoshahara (balances all three Doshas)
- Medhya (improves intellect and memory)

- Vrishya (aphrodisiac, reproductive tonic)
- Deepana-Pachana (digestive stimulant)
- Balya (strengthening)
- Antidepressant and anxiolytic activity (experimentally proven)

Probable Mode of Action in Rajonivrutti

1. Rasayana Effect: Nourishes all Dhatus, countering Dhatukshaya associated with aging.
2. Vata-Kapha Balance: Snigdha and Ushna properties pacify Vata; Kashaya and Tikta balance Kapha.
3. Neuro-endocrine Regulation: Modulates the hypothalamic-pituitary-ovarian axis, potentially offering phytoestrogenic effects.
4. Stress Reduction: Adaptogenic properties reduce Manasika Nidana (psychological stress, anxiety).
5. Srotoshodhana: Clears microchannels (Srotas), improving tissue perfusion and nutrition.

Dose: 3-5 grams twice daily with warm water, honey, or ghee.

Anupana: Ghrita (ghee) and Madhu (honey) are mentioned as vehicles in classical texts.

MATERIALS AND METHODS

Study Design

- Type: Open-labeled, Randomized, Prospective Controlled

Clinical Trial

- Duration: 12 weeks
- Sample Size: 60 postmenopausal women (30 per group)

Study Setting

Outpatient Department of Prasuti Tantra Evam Stree Roga, Mahaveer College of Ayurvedic Science, Sundra, Rajnandgaon (C.G.)

Selection Criteria

Inclusion Criteria

1. Women aged 45-55 years
2. Amenorrhea for ≥12 months
3. Presenting with classical symptoms of postmenopausal syndrome
4. Willing to provide informed written consent

5. MRS score ≥ 8 at baseline

Exclusion Criteria

1. Women on HRT in the last 6 months
2. History of breast or endometrial cancer
3. Known hypersensitivity to trial drugs
4. Severe systemic illness (uncontrolled diabetes, hypertension, renal/hepatic disease)
5. Pregnant or lactating women

Intervention

Group A (Phalatrayadi Churna)

- Drug: Phalatrayadi Churna
- Dose: 3 grams twice daily
- Anupana: Warm water
- Duration: 12 weeks

Group B (Svadamshtradi Churna / Rasayana Churna):

- Drug: Svadamshtradi Churna
- Dose: 3 grams twice daily
- Anupana: Warm water with honey/ghee
- Duration: 12 weeks

Assessment Tools

Primary Outcome Measure

1. Menopause Rating Scale (MRS): Assesses severity of menopausal symptoms in three domains—somatic, psychological, and urogenital.
2. Menopause-Specific Quality of Life Questionnaire (MENQOL): Evaluates quality of life across four domains—vasomotor, physical, psychological, and sexual.

Secondary Outcome Measures

1. Laboratory Parameters: Hemoglobin (Hb), Fasting and Postprandial Blood Sugar, TSH.
2. Overall Assessment of Therapy (OAT): Complete remission, marked/moderate/mild improvement, no change.
3. Safety Assessment: Tolerability and adverse effects monitoring.

Assessment Schedule

Time Point Assessment

Baseline (Day 0) Demographics, MRS, MENQOL, Lab parameters

Week 4 MRS, MENQOL Week 8 MRS, MENQOL

Week 12 (End of Treatment) MRS, MENQOL, Lab parameters, OAT, Safety

Week 24 (Follow-up) MRS, MENQOL

EXPECTED RESULTS AND DISCUSSION

Based on previous clinical research, both formulations are expected to show significant improvement in postmenopausal symptoms.

Svadamshtradi Churna Evidence

A randomized controlled trial by Ramugade & Shitre (2023) on 60 postmenopausal women found that Rasayana Churna (Svadamshtradi Churna) along with Pranayama demonstrated significant improvement compared to Pranayama alone. Key findings include:

- Significant reduction in MRS total score
- Significant improvement in vasomotor, physical, and psychological domains of MENQOL
- No adverse effects reported
- Excellent tolerability

Demographic analysis from the study revealed

- Maximum patients (46.67%) were in the 51-55 year age group
- Majority (66.67%) were housewives
- 50% had Vata-Pitta Prakriti
- 46.67% had Manda Agni

Phalatrayadi Churna Evidence

Studies on Phalatrikadi Churna have shown efficacy in Vata-Kapha disorders through its:

- Deepana-Pachana action improving Agni
- Srotoshodhana clearing channels
- Vata-Kapha balancing properties

Rationale for Comparative Study

1. Similar Indications: Both formulations are indicated for Dhatukshaya and Vata-Kapha

imbalance.

2. Different Mechanisms: Phalatrayadi Churna emphasizes Srotoshodhana and Lekhana (scraping), while Svadamshtradi Churna emphasizes Rasayana (nourishment) and Medhya (cognitive support).
3. Safety Profile: Both formulations have demonstrated excellent safety and tolerability in previous studies.
4. Cost-Effectiveness: Both are economical, widely available, and culturally acceptable alternatives to HRT.

Expected Outcomes

Domain Phalatrayadi Churna Svadamshtradi Churna Vasomotor symptoms Moderate improvement Significant improvement Psychological symptoms Mild-moderate improvement Significant improvement Somatic symptoms Significant improvement Significant improvement Urogenital symptoms Mild improvement Mild-moderate improvement Quality of Life Moderate improvement Significant improvement.

PROBABLE MODE OF ACTION

Ayurvedic Pharmacodynamics

Phalatrayadi Churna

- Dosha Action: Vata-Kaphahara
- Dhatu Action: Rasavaha and Asthivaha Srotas
- Agni Action: Deepana-Pachana, improves Jatharagni and Dhatvagni
- Sroto Action: Srotoshodhana, clears Artavavaha Srotas

Svadamshtradi Churna

- Dosha Action: Tridoshahara
- Dhatu Action: Rasayana effect on all Dhatus
- Agni Action: Deepana, improves metabolic functions
- Sroto Action: Clears microchannels, improves Rasa circulation

Neuro-endocrine Modulation

Both formulations are believed to exert phytoestrogenic effects:

- Phytoestrogens bind to estrogen receptors, providing mild estrogenic activity without the risks of HRT
- Guduchi and Amalaki in Svadamshtradi Churna have immunomodulatory and

adaptogenic properties

- Shunthi in Phalatrayadi Churna improves circulation and reduces inflammation

Psychosomatic Benefits

- Rasayana therapy improves mental clarity and reduces stress
- Medhya action of Guduchi and Amalaki supports cognitive function
- Vata-pacifying action reduces anxiety and mood swings

CONCLUSION

Rajonivrutti (menopause) is a natural physiological transition that, due to modern lifestyle factors, manifests with significant symptomatology requiring intervention. While HRT remains the standard modern treatment, its limitations have prompted the exploration of safer alternatives.

Ayurveda offers a comprehensive approach through Rasayana therapy, addressing the root pathology of Vata Vriddhi, Kapha Kshaya, and Dhatukshaya. Phalatrayadi Churna and Svadamshtradi Churna (Rasayana Churna) represent two classical formulations with differing therapeutic emphases:

- Phalatrayadi Churna focuses on Srotoshodhana, Deepana-Pachana, and Vata-Kapha balance.
- Svadamshtradi Churna emphasizes Rasayana, Medhya, and comprehensive Tridoshahara action.

This proposed randomized comparative clinical trial aims to provide evidence for the efficacy, safety, and comparative effectiveness of these two interventions. Based on previous research, the regimen of Rasayana Churna along with Pranayama has shown promising results in vasomotor, physical, and psychological domains. Phalatrayadi Churna, with its established Vata-Kapha balancing properties, is expected to yield comparable results.

Both formulations offer safe, economical, and holistic management options for postmenopausal syndrome, potentially serving as effective alternatives to HRT, without associated adverse effects. Further research with larger sample sizes and longer follow-up periods is warranted to validate these findings and establish these formulations as standard therapies for Rajonivrutti.

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