

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SAPTHAVIMSHATI GUGGULU AND SOUBHAGYA VATI AFTER VIRECHANA IN PERIMENOPAUSAL SYNDROME

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ABSTRACT

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Perimenopausal syndrome is the transitional phase from reproductive to non-reproductive age characterized by somatic, psychological, and urogenital symptoms, which interfere with daily activities. In Ayurveda, this phase corresponds to *Rajonivrutti*, a *Jara-kalaja Swabhavika avastha*, where *Pitta* and *Vata vriddhi* lead to vitiation of *Raja* and involvement of *Tama* as a *Manasika dosha*. **Objectives:** To compare the efficacy of *Sapthavimshathi Guggulu* and *Soubhagya Vati* after *Virechana* in Perimenopausal syndrome. To evaluate the efficacy of *Saptavimshathi Guggulu* after *Virechana* in Perimenopausal syndrome. To evaluate the efficacy of *Soubhagya Vati* after *Virechana* in Perimenopausal syndrome. **Materials and Methods:** Total 40 subjects with 20 in each group. The interventions were as follows, Group A *Virecana* followed by *Sapthavimshati guggulu* as *Shamanoushadhi*. Group B *Virecana* followed by *Soubhagya vati* as

Shamanoushadhi in the management of Perimenopausal syndrome. The data was collected on 0th day, after *samsarjana krama* and after the completion of follow-up period i.e. on 30th day. **Results:** Both the groups showed improvement from pretest to post-test. Group A

demonstrated an overall improvement of 37.45% at mid-test and 66.50% at post-test, while Group B showed comparatively higher improvement of 40.16% at mid-test and 88.86% at post-test. Thus, *Soubhagya Vati* administered after *Virechana* was more effective than *Sapthavimshati Guggulu* in reducing Perimenopausal symptoms.

KEYWORDS: *Rajonivrutti*, Perimenopausal syndrome, *Virechana*, *Sapthavimshati guggulu*, *Soubhagya vati*.

INTRODUCTION

In Ayurveda, the menopause is termed as *Rajonivrutti*. The age of *Rajonivrutti* is mentioned as around the age of 50 years. The classification of *vaya* according to *Sushruta samhita*, mentions 4 stages in *Madhyama avastha*. They are *Vriddhi avastha* (up to 20 years), *Yauvana avastha* (up to 30 years), *Sampurnata* (up to 40 years) and *Parihani* (up to 70 years)¹. This last stage of *Parihani* can be considered as Perimenopausal stage that is transition from *Pitta pradhana kala* to *Vata pradhana kala*. *Jara* is *Vata pradhana kala*. In this transition due to *Vata vriddhi* and vitiation to *Manasika dosha* (*Rajah* and *Tama*) by *Vata* leads to development of symptoms like *Vishadha*, *Krodha*, *Bhaya*, *Harsha*, *Smrutihani*, *Chinta*, *Dainya* and *Shoka*². This study was undertaken to evaluate and compare the efficacy of *Sapthavimshati guggulu*³ and *Soubhagya vati*⁴ after *Virechana* in Perimenopausal Syndrome. The management is designed to eliminate *pitta* and *vata* by *Virechana* (for Normalizing HPO axis) with *Trivrut lehya* followed by *shamanoushadhis* *Sapthavimshati guggulu* and *Soubhagya vati* for 30 consecutive days.

OBJECTIVES

To compare the efficacy of *Sapthavimshathi Guggulu* and *Soubhagya Vati* after *Virechana* in Perimenopausal syndrome. To evaluate the efficacy of *Saptavimshathi Guggulu* after *Virechana* in Perimenopausal syndrome. To evaluate the efficacy of *Soubhagya Vati* after *Virechana* in Perimenopausal syndrome.

MATERIALS AND METHODS

Source of data

- Subjects were incidentally selected from OPD & IPD of Government Ayurveda Medical College and Hospital, Mysuru and Government Hi-Tech Panchakarma Hospital, Mysuru.

Source of drug

- *Kalyanaka ghritha, Ksheerabala taila, Trivrut lehya* was specially prepared & procured for the study from a GMP certified pharmacy, Kottakal arya vaidyashala Mysore.
- *Sapthavimshati guggulu* was procured for the study from a Shree Dootapapeshwar pvt Ltd, a GMP certified pharmacy.
- *Soubhagya vati* was specially prepared & procured for the study from a GMP certified pharmacy, *Agnivesha rasashala* Puttur.

Study design

It is a comparative clinical trial with pre, mid and post-test design.

Sample size: A minimum of 40 subjects, 20 in each group.

A total 40 subjects having the signs and symptoms of Perimenopausal syndrome fulfilling the inclusion criteria were registered for the study with the help of a Proforma designed for the purpose of study. Study was completed in 40 subjects, 20 in each group. Informed consent was taken at the time of registration.

Subjects will be assigned into two groups viz. group A and group B using Simple random sampling method.

Duration of the intervention- 30 days after *Samsarjana krama*.

Inclusion criteria

- Female subjects of age group 40-50 years.
- Subjects diagnosed based on diagnostic criteria.

Exclusion criteria

- Subjects who have attained surgical menopause were excluded.
- Subjects who are having uncontrolled DM (RBS>250mg/dl) HbA1c>9 and Hypertension (BP>160/100mmhg) which interfere with the course of treatment were excluded.
- Subjects who are suffering from any other systemic disorders which interfere with the course of disease and treatment were excluded.
- Subjects who are unfit for *Virechana* were excluded.

Diagnostic Criteria

Diagnosis will be based on Menopausal Rating Scale

The MRS scale consists a list of 11 items in three dimensions.

Score- None-0, Mild-1, Moderate-2, Severe -3, Very severe-4

Total score from 0 to 44

0-4: No complaints

5-8: Mild

9-15: Moderate

16+: Severe.

Assessment criteria

Assessment was done using GREEN CLIMACTERIC SCALE Scoring for each symptom will be graded as,

- Not at all - 0
- A little – 1
- Quite a bit - 2
- Extremely - 3.

Assessment schedule

In both the groups assessment will be done on-

Pretest assessment – 0th day before intervention.

Mid test assessment - After *Samsarjana krama*.

Post test assessment - After completion of *Shamanoushadhi*.

Statistical methods

The result was compared and analysed statistically by using the following statistical methods:

Descriptive statistics, Mann Whitney U test, independent t test, Wilcoxon matched pairs tests were done using SPSS windows.

RESULTS

Table no. 1: Shows Overall changes from pretest to post-test in Group A and Group B.

Groups	Changes from	Overall changes
Group A	Pretest - mid test	37.45
	Pretest – post-test	66.50
Group B	Pretest - mid test	40.16
	Pretest – post-test	88.86

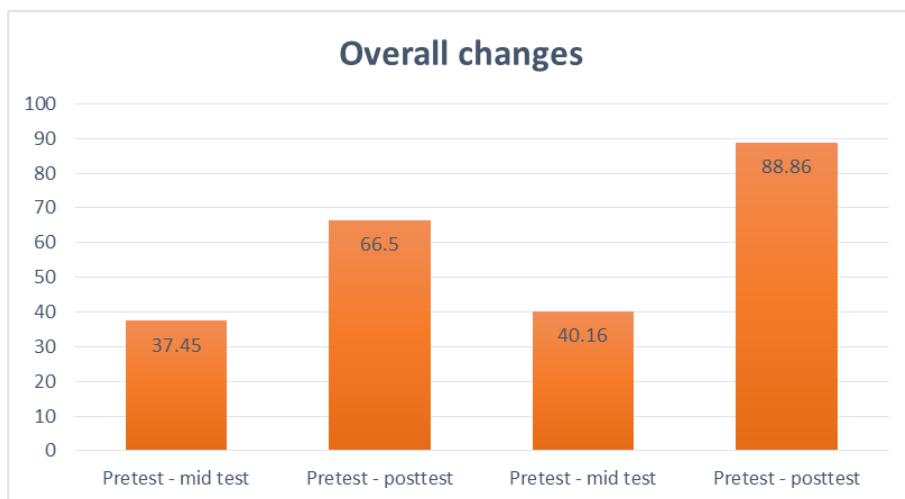


Illustration showing the final results of perimenopausal syndrome from pre to post-test in Group A and Group B.

The Overall changes from pretest to post-test is more in Group B as compared to Group A.

The comparison of overall changes between Group A and Group B revealed that both groups showed improvement from pretest to post-test; however, the magnitude of improvement was higher in Group B. From pretest to mid-test, Group A demonstrated an overall change of 37.45%, while Group B showed a slightly greater change of 40.16%. At post-test, the difference became more pronounced, with Group A achieving an overall change of 66.50%, whereas Group B achieved a substantially higher change of 88.86%. This indicates that although both interventions were effective in reducing symptoms, Group B exhibited a greater degree of improvement compared to Group A over the entire treatment period.

DISCUSSION

Chitrakadi vati

Chitrakadi Vati primarily acts on *Agni*, *Ama pachana*, and *Vata-Kapha* pacification, which indirectly improves hormonal balance and reduces associated symptoms in perimenopause such as bloating, indigestion, mood swings, irritability, and fatigue. *Chitraka* – Contains plumbagin, a potent digestive stimulant that enhances metabolic fire and clears Ama, reducing heaviness and lethargy. *Pippalimoola* and *Trikatu* (*Shunti*, *Maricha*, *Pippali*) – Rich in piperine, gingerols, which act as bioavailability enhancers, improve metabolism, and support thermogenesis to combat weight gain and sluggishness common in perimenopause. *Matulunga* (*Citrus medica*) & *Dadima* (*Punica granatum*) – Provide flavonoids and antioxidants, which improve digestion, reduce oxidative stress, and stabilize mood.^[6]

Kalyanaka ghrita

Hormonal Modulation: Herbs like *Amalaki* (*Emblica officinalis*), *Dadima* (*Punica granatum*), *Manjistha* (*Rubia cordifolia*), and *Nagakesara* (*Mesua ferrea*) are rich in phytoestrogens, plant compounds that mimic estrogen and help balance hormonal fluctuations during perimenopause. Nervine and Sedative Effects: *Tagara* (*Valeriana wallichii*), *Vishala* (*Citrullus colocynthis*), *Malati* (*Jasminum sambac*), and *Utpala* (*Nymphaea caerulea*) possess sedative properties that alleviate stress, anxiety, and insomnia.^[7]

Sapthavimshati guggulu

Sapthavimshati Guggulu acts through a multi-dimensional pharmacological approach in the management of perimenopausal syndrome. The formulation exhibits hormonal modulation due to the presence of phytoestrogen-rich constituents such as gallic acid, ellagic acid, and lignans in *Amalaki* (*Emblica officinalis*), *Haritaki* (*Terminalia chebula*), *Vibhitaki* (*Terminalia bellirica*), and *Guduchi* (*Tinospora cordifolia*), which mimic estrogen activity and alleviate vasomotor symptoms and bone loss. Nervine and adaptogenic herbs like *Ela* (*Elettaria cardamomum*) and *Dhanyaka* (*Coriandrum sativum*) contain volatile oils such as cineole and linalool, providing mild CNS depressant and anxiolytic effects, beneficial in mood disturbances and insomnia.^[8]

Soubhagya vati

Soubhagya Vati is an Ayurvedic polyherbal-herbo-mineral formulation used to support women's health during the perimenopausal phase. Herbs like *Shunti* (*Zingiber officinale*), *Maricha* (*Piper nigrum*), and *Pippali* (*Piper longum*) contain gingerol and piperine, providing anti-inflammatory, digestive stimulant, and bioavailability enhancing effects. *Haritaki* (*Terminalia chebula*), *Vibhitaki* (*Terminalia bellirica*), and *Amalaki* (*Emblica officinalis*) are rich in tannins, flavonoids, and vitamin C, offering antioxidant, anti-inflammatory, and immune-modulating properties. *Bhringaraja* (*Eclipta alba*), *Nirgundi* (*Vitex negundo*), and *Vasa* (*Adhatoda vasica*) provide hepatoprotective, anti-inflammatory, and respiratory-supportive effects. Herbo minerals like *Shuddha Gandhaka*, *Shuddha Parada*, and *Shuddha Tankana* act as *Rasayanas*, supporting rejuvenation and hormonal balance.^[9]

CONCLUSION

The majority of participants belonged to the 46–50 years age group (65%), which corresponds to the typical perimenopausal transition period. Demographically, most subjects were Hindu (75%), married, had primary education (57.5%), and belonged to the lower

middle socioeconomic class (70%). Regarding lifestyle and habits, a large proportion were homemakers (82.5%), followed moderate dietary habits (62.5%), and predominantly consumed caffeine, especially coffee (72.5%), which may have contributed to stress levels and sleep disturbances. In terms of constitutional profile, *Pittakapha Prakriti* was most common (50%), followed by *Vatapitta* (35%), and *Vishamagni* was observed in 45% of participants, indicating unstable digestion during this phase. Sleep disturbance was reported by 72.5% of subjects, while the majority exhibited *Madhyama Satva* (97.5%). With respect to intervention outcomes, both Group A and Group B showed clinical improvement; however, Group B treated with *Saubhagya Vati* demonstrated greater overall efficacy. Group B showed significant improvement in symptoms such as anxiety, irritability, difficulty in concentration, hot flushes, and night sweats, whereas Group A treated with *Sapthavimshati Guggulu* was more effective in alleviating tiredness and lack of energy. Overall, Group B achieved an 88.86% improvement compared to 66.50% in Group A, indicating a superior therapeutic effect.

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