

Clinical Research

Clinical evaluation of *Ashokarishta*, *Ashwagandha Churna* and *Praval Pishti* in the management of menopausal syndromeMansi B. Modi, Shilpa B. Donga¹, Laxmipriya Dei²

Ayurvedic Practitioner, Vadodara, ¹Assistant Professor, ²Associate Professor, Department of Stree Roga and Prasuti Tantra, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India

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Abstract

Menopause is a gradual and natural transitional phase of adjustment between the active and inactive ovarian function and occupies several years of a women's life and involves biological and psychological changes adjustments. The present clinical trial was designed as per Ayurveda clinical trials protocol to evaluate the efficacy of *Ashokarishta*, *Ashwagandha Churna* and *Praval Pishti* in the management of menopausal syndrome. It was directed by Central Council for Research in Ayurvedic Sciences as randomized open clinical trial. Total 52 patients were registered in the study, out of which 51 patients completed the study. Specialized rating scales like Kupperman Index Score as well as 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 Wilcoxon matched paired test and 't' test. Highly significant ($P < 0.01$) reduction was found in the symptoms of MRS as well as MENQOL. Finally, it can be stated that combined treatment of above drugs gives better result in both somatic as well as psychological complaints in women with mild to moderate symptoms of menopausal syndrome.

Key words: *Ashokarishta*, *Ashwagandha Churna*, menopausal syndrome, *Praval Pishti*

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." Menopause is generally defined as cessation of periods for 12 months or a period equivalent to 3 previous cycles or as time of cessation of ovarian function resulting in permanent amenorrhea.^[1] The menopause is thus a gradual and natural transitional phase of adjustment between the active and inactive ovarian function and occupies several years of a women's life and involves biological and psychological changes adjustments. This period is usually associated with unavoidable manifestation of aging process in women.^[2] Most women experience near complete loss of production of estrogen by their mid-fifties.^[3] During reproductive years, women are protected by female hormones, i.e. estrogen and progesterone. With menopause, women enter an estrogen deficient phase in their lives, which accelerates the ageing process resulting into greater vulnerability to psychosomatic

problems. 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.^[4]

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*^[5] and various other references too^[6-8] 50 years is mentioned as the age of *Rajonivritti*, when the body is fully in grip of senility.^[9]

Currently, the number of menopausal women is about 43 million and projected figures in 2026 have estimated to be 103 million.^[10] So, menopausal health demands even higher priority in Indian scenario.^[11] In modern science, hormone replacement therapy is one and only alternative for these health hazards, but it has a wider range of secondary health complications like vaginal bleeding, breast cancer, endometrial cancer, gallbladder diseases, etc.^[12-15] On the other hand, this therapy is not much effective in the psychological manifestations of this stage. Allopath manages them by the long-term use of sedative, hypnotics, and anxiolytic drugs, which may lead to various side effects like drowsiness, impaired motor function, loss of memory, allergic reactions, non-social behaviors, drug dependence, etc.

Address for correspondence: Dr. Mansi B. Modi,
69, Swami Narayan Nagar, Nizampura,
Vadodara - 390 002, India.
E-mail: mansi.modi1@gmail.com

Therefore, considering it as a challengeable melody, this project has been undertaken in order to find out a safe and effective medicament in Ayurveda without creating any adverse effect and for the management of menopausal syndrome.

Aims and Objectives

The present study was aimed to evaluate efficacy of *Ashokarishta* (ASK), *Ashwagandha Churna* (ASW) and *Praval Pishti* (PP) on menopausal syndrome.

Materials and Methods

Distribution of patients

Fifty-two patients were randomly selected from O.P.D. of Stree Roga and Prasooti Tantra Department [Table 1].

Inclusion criteria

1. Females of age between 40 and 55 years
2. Amenorrhea for ≥ 12 months
3. Kupperman menopausal index score ≥ 15
4. Follicle Stimulating Hormone (FSH) ≥ 20 IU/L
5. Thickness of endometrium ≤ 5 mm
6. Willing and able to participate for 16 weeks.

Exclusion criteria

1. Patients with evidence of malignancy
2. Surgical menopause
3. Established cases of mental illness, hyper tension, diabetes mellitus, rheumatoid arthritis, coronary artery disease, hepatic disorders, chronic obstructive pulmonary disease, etc.

Drugs

All the drugs, i.e. ASK,^[16] ASW,^[17] and PP were prepared in the Arya Vaidhya Shala, Kottakkal, Kerala, India according to the Ayurvedic Formulary of India.

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.
- Urine: Routine and microscopic examination
- Biochemical examination: Fasting blood glucose, total serum proteins, lipid profile, alkaline phosphatase, liver function tests, renal function tests, Serum calcium, HbA1C, etc.
- Hormonal assessment: FSH, LH (Luteinizing Hormone) and S. T₃, T₄, TSH (Thyroid Stimulating Hormone).
- Ultra Sonography - TVS (Trance Vaginal Sonography/ Abdomen.), ECG and pap smear

Table 1: Data of patients

Trial group	Total no. of the patients
Registered	52
Completed	51
Discontinued	01

Study design

Present study was designed as per Ayurveda clinical trial protocol. It was directed by Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi as randomized open clinical trial to evaluate the efficacy of trail drugs on menopausal syndrome.

Grouping: Open trial

In the present study, all the selected patients were given ASK (25 ml twice daily with equal quantity of water, after food, orally), ASW (3 g twice daily with milk, half an hour before food, orally) and PP (1 capsule of 250 mg twice daily with milk, half an hour before food, orally) for 3 months.

Follow-up study

All patients were followed up for 1 month.

Criteria for assessment

- Detailed history was taken thorough various physical examinations with the data being recorded in a special proforma that was specifically designed by CCRAS for this study.
- The result was assessed on the basis of menopause rating scale (MRS)^[18] and menopause specific quality of life (MENQOL).^[19] The improvement in the patients was assessed mainly on the basis of relief in the signs and symptoms of the disease.

Criteria for overall assessment of therapy

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

1. Completely cured: 100% relief
2. Marked improvement: $>75\%$ - $<100\%$ relief
3. Moderate improvement: $>50\%$ - 75% relief
4. Mild improvement: $>25\%$ - 50% relief
5. Unchanged: Up to 25% relief

Statistical analysis

The values were expressed as percentage of relief and mean, SEM; MRS and MENQOL data were analyzed by Wilcoxon matched paired test, while other parameters were analyzed by students paired 't' test.

Observations and Results

In the present study, maximum 61.53% of patients were from the age group of 50-55 years; 98.08% were married; 96.15% of patients were housewives; 73.08% of patients had disturbed sleep; 76.92% of patients had irregular bowel habit followed by 61.54% had constipation, while 82.69% of patients had frequent urination; 32.69% of the patients had menopause for 2-4 years; 92.31% of patients were having normal BMI (Body Mass Index); 73.08% of patients were not using any contraceptive; 86.54% patients were vegetarian; *Nidana Sevana*, i.e. *Vishamashana* and *Ratrijagarana* were found in maximum patients, i.e. 88.46% and 90.38% respectively; 86.54% of patients were suffering from *Chinta*; 57.69% of patients had *Vatapitta Prakriti*; *Mandagni* was found in 51.92% of the patients. Looking to the sign and symptoms, maximum, i.e. 100% patients were having *Artavavaha* and *Raktavaha Srotodushti*; In K.I., melancholia was found in 94.23% of patients; In MRS, joint and muscular

discomfort was found in 88.46% of patients; 55.77% of patients were having past irregular menstrual history; 57.69% of patients were having moderate quantity of menses, while 59.62% of patients had painless menses.

Effect of Therapy

Effect on menopause rating scale

The effect of therapy on MRS has shown that statistically highly significant ($P < 0.01$) decrease was found in hot flushes by 40.56% relief, in heart discomfort by 84%, in sleep problems by 53.78%, in depressive mood by 41.41%, in irritability by 44.88%, in anxiety by 42.62%, in physical and mental exhaustion by 39.29%, in sexual problems by 18.18%, in bladder problems by 42.42%, in dryness of the vagina by 42.22% and in joint and muscular discomfort by 45.89% relief [Table 2].

Effect on menopause specific quality of life

The MENQOL comprises of four sub scales. These are vasomotor, psychosocial, physical and sexual. The effect of therapy on MENQOL has shown that statistically highly significant ($P < 0.01$) decrease was observed on all above four sub scales. On vasomotor, psychosocial, physical and sexual sub scales, 22.95%, 12.59%, 19.91%, and 2.70% improvement was observed respectively [Figure 1].

Effect on hematological/biochemical values

S. calcium was increased by 2.62% upto statistically significant level ($P < 0.01$). No other significant change in the hematological and biochemical values after treatment was observed in any patient.

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 nine patients were moderately improved (17.65%) and 40 patients (78.43%) were mildly improved, while none of the patients were completely improved [Figure 2].

Discussion

The slogan “Healthy Women, Healthy World” embodies the fact that as custodians of family health, women play a

critical role in maintaining the health and well-being of their communities.

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

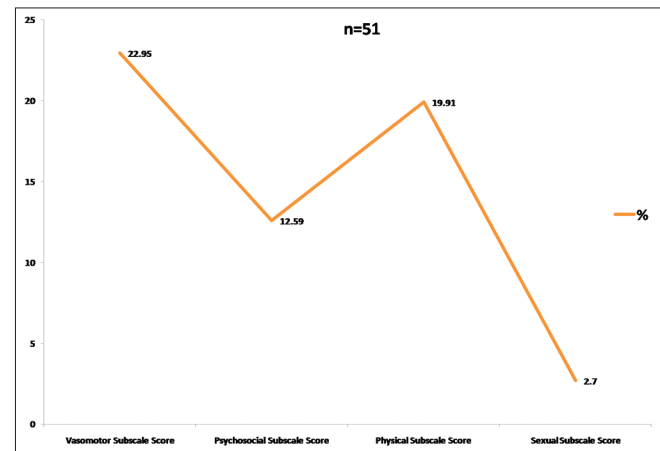


Figure 1: Effect on menopause specific quality of life

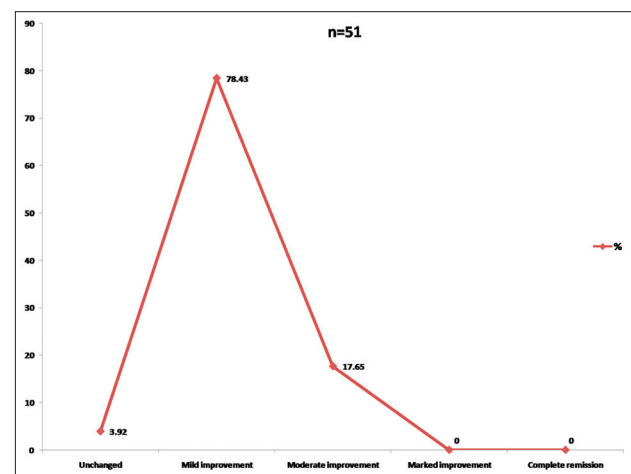


Figure 2: Total effect of therapy

Table 2: Effect of therapy on menopause rating scale

Symptoms	Mean B.T.	Mean A.T.	Mean diff.	% Change	'W'	'N'	'P'
Hot flushes (n=51)	2.80	1.67	1.14	40.56↓	1225	49	<0.01
Heart discomfort (n=25)	0.49	0.08	0.41	84↓	231	21	<0.01
Sleep problems (n=51)	2.33	1.08	1.25	53.78↓	1128	47	<0.01
Depressive mood (n=51)	2.51	1.47	1.04	41.41↓	1035	45	<0.01
Irritability (n=51)	2.49	1.37	1.12	44.88↓	990	44	<0.01
Anxiety (n=51)	2.39	1.37	1.02	42.62↓	903	42	<0.01
Physical and mental exhaustion (n=51)	2.20	1.33	0.86	39.29↓	820	40	<0.01
Sexual problems (n=50)	1.94	1.59	0.35	18.18↓	171	18	<0.01
Bladder problems (n=51)	1.94	1.12	1.12	42.42↓	741	38	<0.01
Dryness of vagina (n=51)	2.65	1.53	1.12	42.22↓	903	42	<0.01
Joint and muscular discomfort (n=51)	2.86	1.55	1.31	45.89↓	1225	49	<0.01

↓: Decrease; BT: Before treatment; AT: After treatment

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. The Table 3 clarifies this interrelationship.

Probable mode of action of Ashokarishta

The drug ASK is having mainly *Madhura*, *Tikta*, *Kashaya*, *Katu Rasa*, *Sheeta Virya*, *Madhura Vipaka*, *Laghu Guna*, and *Tridoshashamaka* properties.^[16] The ingredients are also having *Rasayana*, *Vayahsthapana*, *Balya*, *Medhya*, *Manasdosahara*, *Vedanasthapana*, etc., properties.

As in *Rajonivritti*, as the *Vata Dosha* is dominant, majority of symptoms occur due to *Vatavridhi*. ASK by its *Snigdha Guna* acts against *Ruksha Guna* of *Vata Dosha* and pacifies it. So, the majority of symptoms of *Rajonivritti* may subside. Moreover, *Agnimandhya* is also, being the common manifestation of *Rajonivritti*. The drug ASK by its *Deepana-Pachana* action, acts on *Jatharagni* and relieves the symptom of GIT (Gastro Intestinal Tract) effectively like dyspepsia, decreased appetite, flatulence, constipation, etc.

So, the drug ASK, when administered to the patients through oral route, the probable mode of action is as follows: *Ashoka*, *Shunthi*, *Haritaki*, *Vasa*, and *Chandana* are *Hridya* and *Balya* and act as *Rasayana Karma* may cause *Dhatu Pushti*, which results in *Samprapti Vighatana* and ultimately leads to *Lakshanopshamana*.

Haritaki, *Amalaki*, and *Utpala* directly act as *Rasayana Karma* and further course of action same as discussed above.

Musta, *Ajaji*, *Sunthi* and *Haritaki* do *Dipana* and *Pachana Karma*, which can lead to *Agni Pradipti* and do *Dhatu Pushti* by doing *Prasasta Dhatu Nirmana*, which results in *Samprapti Vighatana* and ultimately lead to *Lakshanopshamana*.

Finally, *Utpala*, *Haritaki* and *Bibhitaki* are *Medhya* and act as *Manasa* and *Indriya Tarpaka*, which decreases *Chinta*, *Shoka* and sleep disturbances and ultimately lead to *Lakshanopshamana* [Chart 1].

Probable mode of action of Ashwagandha Churna and Praval Pishti

Due to *Balya* and *Vaya-Sthapana* properties of *Ashwagandha* (*Withania somnifera* Dunal.), it directly acts as

Rasayana and causes *Dhatu Pushti*, which results in *Samprapti Vighatana* and ultimately leads to *Lakshanopshamana*. In case of *Manasa Tarpana*, it supports sound sleep and anti-stress effect due to alcohol, alkaloids and glycosides, which results in *Samprapti Vighatana* and ultimately leads to *Lakshanopshamana*, while in case of *Vajikarana*, it nourishes the reproductive system by improving the sexual dysfunction and further course of action same as discussed above.

Along with this, *Ashwagandha* improves the degenerative changes by effect on chondroplasts in cartilage as well as it creates hemopoetic effect by cyclophosphamide and reduces leukopenia [Chart 2].

Ashwagandha can affect elements of the central nervous system and the immune system; it might be useful in reducing hot flushes.^[20]

Effect on the inflammatory response

Prostaglandins cause inflammation and are implicated in the generation of hot flashes. Enzymes such as cyclooxygenase-2 (COX-2), synthesize prostaglandins from cellular lipids. Vanisree Mulabagal and co-workers at Michigan State University showed that *Ashwagandha* inhibited the enzyme activity of COX-2 in laboratory tests.^[20]

Effect on the immune system

IL-8 (Interleukin-8) is a potent vasodilator released by macrophages under stressful conditions. According to study conducted at the University of Tokushima, IL-8 was significantly increased in 179 women with hot flashes and it suggests that macrophages sense the decline in estrogen and respond by secreting IL-8. Working with cultured cells, researchers at the University of Buffalo found that *Ashwagandha* decreased the genetic expression of IL-8.^[20]

A withanolide-free aqueous fraction isolated from the roots of *Withania somnifera* exhibited anti-stress activity^[21] in a dose-dependent manner in mice.^[22]

Praval is used to treat disorders like *Pitta* aggravation and calcium deficiency because it has got properties like cooling and soothing effect. *Praval* is used with herbal phytoestrogen for better and early result.^[23]

Conclusion

The study shows that formulation of these three drugs: ASK,

Table 3: Interrelationship between Vata and Rajonivritti

Disturbance in given physiology of Vata	Disturbances observed in Rajonivritti phase
<i>Niyanta Praneta Cha Manas Sarvendriyarthanam, Sarvendriyanam Udhoyjaka</i>	Physiological disturbances like anxiety, irritability, depression, mood swing, etc.,
<i>Sameerane Agni</i>	Digestive troubles like <i>Aruchi</i> , <i>Hrillasa</i> , <i>Ajeerna</i> , etc.,
<i>Sarvasharir Dhatu Vyuhkar</i>	Circulatory disturbances resulting in cardiovascular problems like palpitation and vasomotor problems like hot flushes
<i>Sandhankar Sharirasya</i>	Menopausal arthropathies
<i>Kshepta Bahirmalanam</i>	Disturbances related to waste products like stool, urine, sweat, menses, etc., For example, constipation, dysuria, excessive sweating, etc.,
<i>Prakritti Shabda Sparshyoh</i>	Sensory motor problems
<i>Pravartak Chestanam Uchhaavachanam</i>	Difficulty in initiating activities, fatigue, weakness, etc.,
<i>Pravartako Vacha</i>	<i>Swarabhanga</i>

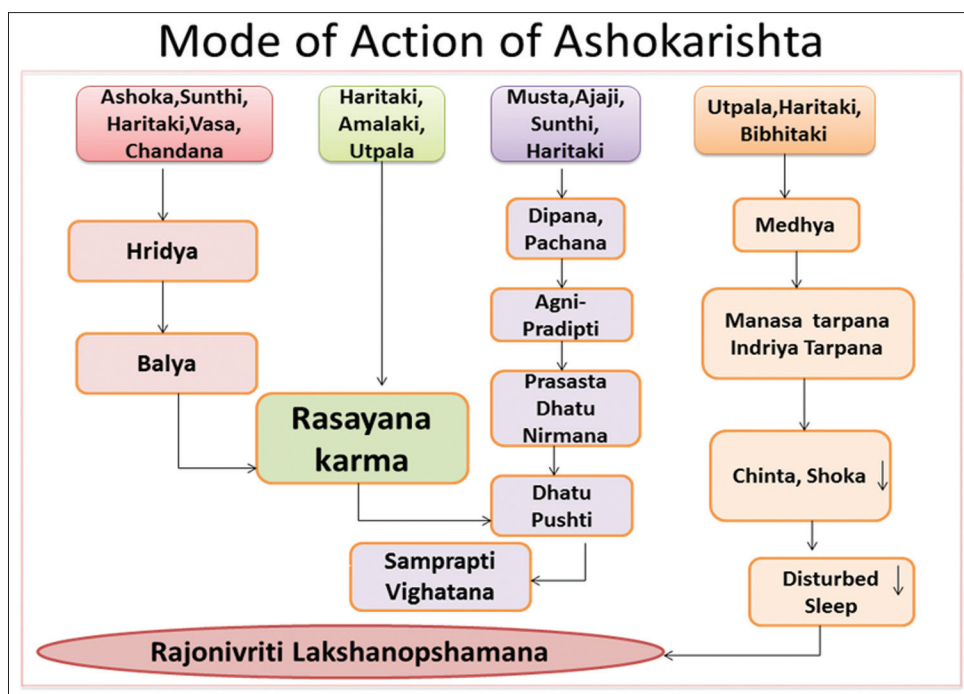


Chart 1: Action of the Ashokarishta on disease mechanism

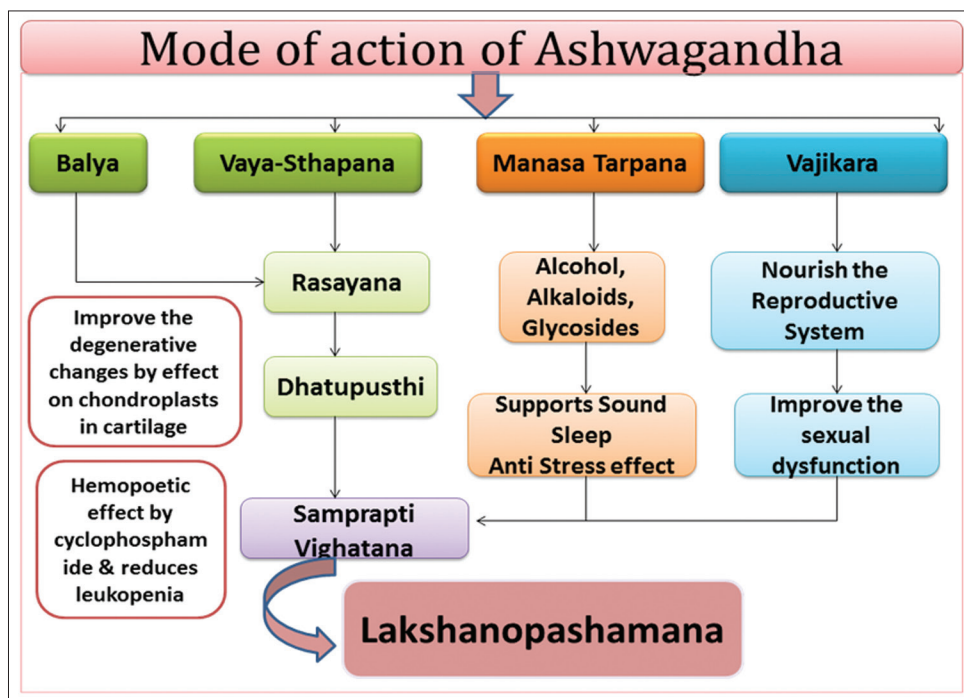


Chart 2: Action of the Ashwagandha Churna on disease mechanism

ASW, and PP is better in somatic complaints including GIT disturbances as well as white discharge and hot flushes, etc., It 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 combined treatment (ASK + ASW + PP) 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 to the modern drugs. It is found to be an effective therapy in psychological and somatic problems related with menopausal syndrome.

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हिन्दी सारांश

मेनोपॉइज़ल सिन्ड्रोम में अशोकारिष्ट, अश्वगन्धा चूर्ण और प्रवाल पिष्टी का प्रभाव और नैदानिक मूल्यांकन

मानसी बी. मोदी, शिल्पा बी. दोंगा, लक्ष्मीप्रिया देई

मेनोपॉइज़ एक सक्रिय से निष्क्रिय बीजाशय ग्रन्थि में रुपांतरित होने का प्राकृतिक क्रम है और यह अवस्था स्त्री के जीवन में कई वर्षों तक महत्वपूर्ण बनी रहती है। मेनोपॉइज़ के समय स्त्री में शारीरिक और मानसिक परिवर्तन होते हैं। जिस पर ध्यान देने की आवश्यकता रहती है। मेनोपॉइज़ल सिन्ड्रोम में अशोकारिष्ट, अश्वगन्धा चूर्ण और प्रवाल पिष्टी के प्रभाव का आंकलन करने हेतु वर्तमान अध्ययन में कुल ५२ रुग्णाओं को पंजीकृत किया गया जिसमें से ५१ रुग्णाओं ने चिकित्सा पूर्ण की। चिकित्सा का प्रभाव देखने हेतु विशिष्ट क्रमांक सारणी जैसे कुपरमेन इन्डेक्स स्कोर, मेनक्वोल और मेनोपॉइज़ रेटिंग स्केल को अपनाया गया। चिकित्सा परिणाम को मेनोपॉइज़ रेटिंग स्केल के आधार पर देखा गया। चिकित्सा परिणामों का 'टी' टेस्ट और 'वील्कोक्सन' टेस्ट द्वारा सांख्यिकी विश्लेषण किया गया। सांख्यिकीय रूप से मेनोपॉइज़ रेटिंग स्केल और मेनक्वोल में अतिसार्थक परिणाम प्राप्त हुआ। इस चिकित्सीय अध्ययन से यह निष्कर्ष निकाला जा सकता है कि मंद से उग्र मेनोपॉइज़ल सिन्ड्रोम युक्त स्त्री में इन तीनों औषधियों की संयुक्त चिकित्सा शारीरिक और मानसिक लक्षणों में उत्तम प्रभावी है।