

CLINICAL EVALUATION OF ASHWAGANDHADI COMPOUND IN THE MANAGEMENT OF PERIMENOPAUSAL SYMPTOMS

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ABSTRACT :

Menopause is an important phase in every woman's life. Perimenopause is menopause transition -al period around menopause (40 – 55years) presenting with psychological and somatic symptoms. Prevalence of psychological and somatic symptoms is seen in 80% of women at perimenopausal period. The present clinical trial was designed as per *Ayurveda* clinical trials protocol to evaluate the efficacy of *Ashwagandhadi* compound which contains *Ashwagandha Shatavari* and *Brahmi* in equal quantity, to evaluate the effect of placebo and Comparison of the effects of *Ashwagandhadi* compound with placebo group to ascertain its effect in the management of perimenopause symptoms. In the present clinical study, 40 patients of Perimenopausal symptoms were treated in two group, total 40 patients completed the study plan. Highly significant reduction value is found in the *Ashwagandhadi* group ($p < .001$). It can be stated that *Ashwagandhadi* group gives better result in both somatic and psychological complaints in women with mild to moderate symptoms of perimenopausal symptoms.

Key words: Menopause, *Ashwagandha* Compound, Placebo, Perimenopausal Symptoms

INTRODUCTION : Menopause is the 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 and adjustments. Some of the women may be asymptomatic¹ or some may have very minimum symptoms which go unnoticed; many may have symptomatic condition which alarms her and her family. 1/3rd of life span women suffers from psychological symptoms like mood disturbance, insomnia, cognitive difficulty, anxiety, depression, memory loss, irritability and somatic symptoms like hot flushes, sexual disturbance etc. The psychosomatic constitution of an individual can also become a genetically transmitted trait which can also predispose a person to certain stress disorder. Though, *Rajonivritti*¹ as a

diseased condition is not described separately in the classic Ayurveda texts, *Rajonivritti kala*² is mentioned by almost all the acharyas without any controversy. According to Sushruta and various other references too^{3,4,5}. 50 years was mentioned as the age of *Rajonivritti*, when the body is fully in grip of senility. In the modern science HRT being the choice of treatment but its effect is limited to physical symptoms only, but it has a wider health hazards like vaginal bleeding, breast cancer, endometrial cancer, gall bladder disease etc. on the other hand this therapy is not much effective in psychological manifestation of this stage. Other symptoms is managed by the long term use of sedatives, hypnotics and anxiolytics, drugs which may lead to various side effects like drowsiness, impaired motor function, loss of memory, drug dependence etc. In

today's era, horizons of the *Ayurvedic* treatment in regard to *Stri-roga* have increased tremendously. For Almost all Gynecological Problems, patients are turning to the *Ayurvedic* treatment modality. Therefore, considering it's a challengeable malady, 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 perimenopausal symptoms.

AIMS AND OBJECTIVES:

1. To evaluate the effect of *Ashv gandhadi* compound on perimenopausal symptoms
2. To evaluate the effect of placebo on perimenopausal symptoms
3. Comparison of the effects of *Ashv gandhadi* compound with placebo group to ascertain its effect on perimenopausal symptoms.

MATERIALS AND METHODS

Distribution of patients:

40 patients were randomly selected from O.P.D of *StreeRoga* and *PrasutiTantra* Department of GangasheelAyurvedic Medical College and hospital.

Inclusion criteria:

- Age group of 40-55 yrs
- Vaginal dryness
- Hot flushes
- Night sweat
- Sleep disturbance
- Irritability
- Depression
- Decrease libido
- Painful intercourse

Exclusion criteria:

- Any pre-existing psychological disorder
- Diabetes mellitus
- Age > 55 yrs.

- Post-menopausal women

Drugs:

Ashwagandha, Shatavari and *Brahmichurna* were obtained from pharmacy of Gangasheelayurvedic college.

Investigation:

All the selected patients were subjected to routine investigation, which included the following

- Blood haemoglobin(Hb%)
- Urine routine and microscopic examination
- Biochemical examination Fasting blood glucose
- Hormonal assessment FSH and serum Estradiol
- Ultra-sonography- pelvis and abdomen to exclude any organic pathology

Study design

Grouping: In the present study, all the selected patients were given *Ashwagandhadi* compound 4 g tid with luke warm water half an hour after food and placebo 2 capsule (1 capsule of 250mg) tid with luke warm water half an hour after food.

Follow up study: After completion of the treatment the patients were asked to attend the OPD at interval of 15 days for one month to ascertain whether the relief provided was sustained.

Criteria of assessment:

- Detailed history was taken through various physical examinations
- The result was assessed on the basis of improvement in the symptoms of perimenopause.

Criteria for overall assessment of therapy:

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

- Complete remission: 100% relief
- Marked improvement : >75%-<100%

- Moderate improvement : >50%-75 %
- Mild improvement : >25%-50%
- Unchanged : Up to 25%

Statistical analysis: The values were expressed as percentage of relief and mean, data were analyzed by student “t test”.

Observation and Results : Out of 40 patients registered Maximum patients 82.5% were between age group of 40 to 50 years, religion wise 90% were Hindu, occupation wise 82.5% were housewives 87.5% were middle class, 17.5% were having higher secondary education, 35% high school, 100% were married. 82.5% belonging to *AnoopSadharanaDesha*, 77.5% were mixed diet, 17.5% of patients had increased frequency of urine, 65% patients had disturbed sleep, only 10 % patient had Regular Menstruation, 72.5% of female had menarche at age between 11-13yr & 27.5% of female had had menarche at age between 14-16yr, 75% Of patients had Gradual Onset , 22.5% were of *VatapittaPrakruti*, 60% of the subjects were of *RajasikaPrakriti*, maximum patients having *MadhyamaSaara*, *Samhanana*, *Saatmya* and *Pramana*, 85% had *Samagni* and 72.5% patients not at all doing any exercise.

Effect of therapy

Effect of Ashvagandhadi compound: In the 20 patients who were given the *Ashvagandhadi* compound showed the reduction in the symptoms after 3 month of treatment, Hot flushes shown improvement of 86.34%, 88.88% in night sweat, sleep disturbance 94.24% with p

value <.001, depression 87.12% improvement with p value < .001 is significant, irritability shown 82.3% of improvement with p value< .001, whereas vaginal dryness, decrease libido and painful intercourse did not show any improvement.

Effect of Placebo: In the 20 patients who were advised to consume Placebo, for 3 months considerable reduction was found in symptoms like Hot flushes shown improvement of 6.1%, 4.54% in night sweat, sleep disturbance 6.1% with p value <.001, depression 4.54% improvement with p value < .001 is significant, irritability shown 10.76% of improvement with p value< .001, whereas vaginal dryness, decrease libido and painful intercourse did not show any improvement

In comparison Group *AshwagandhadiCompound* had shown better results than Placebo Group.

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 *Prudhavastha* which lies in a *Sandhikakala*(a mid- period between *Yuvavastha* and *Vridhdhavastha*). During this period there is increased level of pitta, during *Jarakala*, *Vata* remains in aggravated condition along with vitiated *Pitta* creates hot flushes, excessive sweating , sleep disturbance, irritability, vaginal dryness etc.

Probable mode of action of AshwagandhadīChurna:

Drugs	Rasa	Guna	Virya	Vipaka	DoshaKarma	DhatuKarma
Ashwagandha ⁶	Kashaya, Tikta, Madhura	Laghu, Snigdha	Usna	Madhura	KaphaVataShamaka	SaptaDhatuVardhaka, AtiShukrala
Shatavri ⁷	Madhura, Tikta	Guru, Snigdha	Sheeta	Madhura	Vatapittahara,	Rasayan
Brahmi ⁸	TiktaMadhura	Laghu	Sheeta	Madhura	Kapha Pitta Hara,	MedhyaRasayan

Ashwagandha :

- Tikta, KashayaRasa and UshnaVeerya of Ashwagandha act on the Hot flush, which may be occurring due to involvement of these two doshas, hence pacifying this Lakshana. It probably acts on thermogenic center in the hypothalamus and hence regulates the hot flushes.
- Withanolides, withaferin A and withanolide D also helps in reducing depression⁹
- It is immuno-modulatory, immuno-stimulatory, immuno-suppressive, radio sensitizing, respiratory stimulating, nervine, psychotropic, rejuvenative, sedative, tonic actions on our body which gives Rasayanaeffect
- It is sedative and nervine tonic, it helps in atonic nerves, fainting, giddiness, and insomnia
- It improves the function of HPO (hypothalamic-pituitary-ovarian) axis.
- Glycosides (saponin) was also found to have cardiotoxic action.
- Improves learning, memory, and reaction time

Shatavri:

- HOT FLASHES: Phytoestrogens are plant-derived estrogens. Phytoestrogens are natural "selective estrogen receptor modulators" (SERMs) and they have a diphenolic ring in their structure similar to human estrogens. Phytoestrogens bind to the estrogen receptors, acting either as "partial agonists" or "antagonists", depending on the levels of endogenous estrogens. Phytoestrogens are known to strengthen bones and heart, control weight, lessen hot flashes, improve sleep, boost energy.
- Shatavrin¹⁰ is known to increase nonspecific resistance and hence it can be used as adaptogen.
- Adaptogens are useful agents and may offer some positive benefits as a general tonic for improved stamina and overall health, especially for stressful conditions, fatigue, concentration, and recovery from illness.
- Major bioactive constituents of Asparagus are a group of steroidal saponins, it has vitamins A, B₁, B₂, C, E, Mg, P, Ca, Fe, and folic acid¹¹.

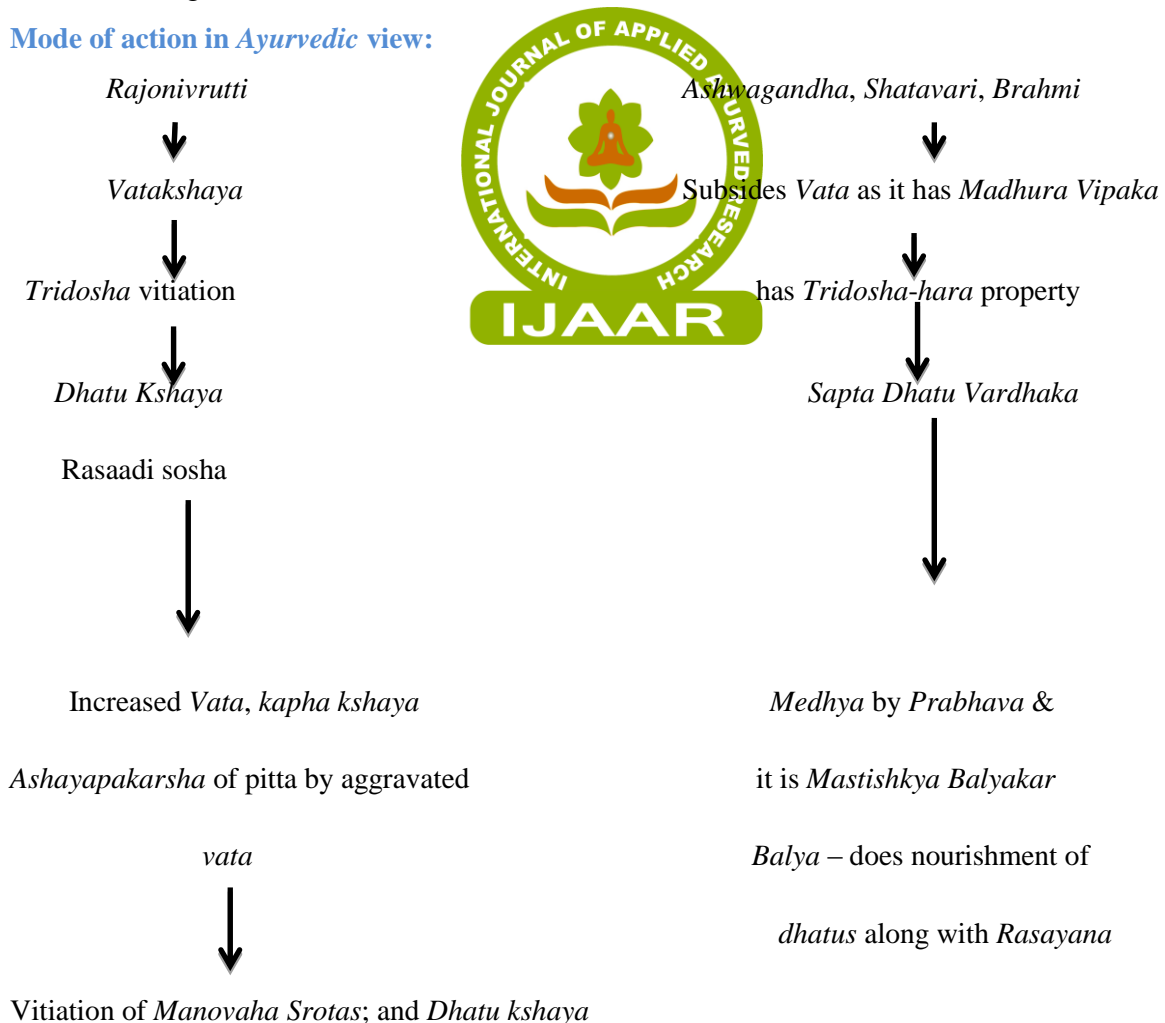
Brahmi :

- Bacosides 12 A and B component responsible for sedative and antidepressant due to cholinomimetic effect.
- Stigmasterol (also known as anti-stiffness factor) is one of a group of plant sterols, or phytosterols, that include β -sitosterol, campesterol, ergosterol (provitamin D2), brassicasterol.
- It is semisynthetic progesterone, a valuable human hormone that plays an important physiological role in the regulatory and tissue rebuilding mechanisms related to estrogen effects, as well as acting as an intermediate in the

biosynthesis of androgens, estrogens, and corticoids.

- It is also used as the precursor of vitamin D3.
- It improves the function of HPA (hypothalamic-pituitary-adrenal) axis
- The sulfhydryl and polyphenol components of Brahmi extract have also been shown to impact the oxidative stress cascade by scavenging reactive oxygen species, Brahmi, can enhance immune function by increasing immunoglobulin production.

Mode of action in Ayurvedic view:



CONCLUSION : This study shows that combination of these 3 drugs is better in somatic as well as in psychological complaints mainly includes irritability, sleep disturbance, depression, mood swings etc. So it can be concluded that in women with mild to moderate perimenopausal symptoms a combined treatment of these three drugs gives better result in both somatic as well as In psychological symptoms. No adverse effect was noted during study. Therefore it could be safe alternative to the modern drugs. It is found to be an effective therapy in somatic and psychological problems related to perimenopause.

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