

REVIEW OF CLINICAL STUDIES ON RAJONIVRITTI AVASTHA & RAJO NIVRITTI VYAPAD

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Abstract

Ayurveda, the Indian System of medicine, is the medicine for the whole life. Remedy for all present day upcoming new life style raised complaints is hidden in Ayurvedic concepts. Increased lifespan, increased number of education in women and rather than everything, craving of more knowledge regarding every field of life by every woman has not spared the word 'Menopause' aside. There are special problems entering in women's life with advancing age for which they should be prepared to face. Hot flushes, the hallmark symptom of menopausal syndrome, is almost experienced by 80% of Menopausal women & 20% women are suffering with its severity. The duration of these symptoms persists for 3-4 years, but may continue for as many as 12 years in about 10% of women. On the topic Rajonivritti Avastha and its Vyapad, research work is been done under all universities in India. Compilation of their essence is been tried here. All the work were stressing towards advice for Rasayana chikita for women nearing to Menopause and after attaining Menopause.

Keywords:

*Menopausal Syndrome,
Rajonivritti Avastha,
Rasayana Chikitsa.*

INTRODUCTION

Menopausal Syndrome is one of the most important Global Gynecological problems met today. Women all over the world now have to spend almost 1/3rd of their lives in menopause years because average life expectancy is increasingⁱ. Menopause is the time of cessation of ovarian function resulting in permanent amenorrhoeaⁱⁱ. Menopause even though physiological, the deficiency of estrogen during this phase of life, results in changes in the body functions like hot flushes, insomnia, decreased strength and calcification of bones throughout the body. The management protocol for Menopause in the Allopathic science starts from Hormone Replacement Therapy, which is not free from another burning topic, carcinoma. Finding the solution for this current issue is the topic for researchers.

AIMS & OBJECTIVE

- To know various research of Ayurvedic drugs and its efficacy on Menopause and Menopausal syndrome.
- Compilation and establishment of standard treatment Ayurvedic protocol methods for Menopausal Syndrome.
- To provide the guidelines for further research works in the same.

MATERIALS AND METHOD

All the theses were collected from Department of *Prasuti tantra* and *Stree roga*, National Institute of *Ayurveda*, Jaipur, and from the Ayurvedic research data base, Jamnagar.

Hand search – The procured theses were studied in detail and scientific review was done.

Following research works have been carried out in various Post graduate research institutions throughout India on related topic-

NIA, Jaipur:

1. Study on Ayurvedic concept of pathogenesis of Perimenopausal Syndrome & Evaluation of Efficacy of a *Rasayana Compound* in its Management by Dr.Sunitha in 2001.
2. Pharmacological of *Varadadi yoga* w.s.r to Post Menopausal Syndrome by Dr.Kaushal kamini in 2002.
3. Pharmacognostic and Pharmacological Evaluation of *Gauryadi Yoga* w.s.r. to PostMenopausal Symdrome, by Dr.Usha Koli in 2005.
4. Evaluation of “AVA” Formula in the Management of *Rajonivritti Lakshana* (Post-Menopausal Syndrome) by Dr.Bharathi in 2009. (Ph.D. Thesis)
5. A Clinical Study on the Role of Menosol Compound in the Management of Menopausal Syndrome, by Dr. Mamatha Rani in 2011.
6. Clinical evaluation of *Ashokarishta*, *Ashwagandha Churna* and *Praval pishti* in the management of Menopausal syndrome by Dr. Neeta Kumari in 2012.

IPGT &RA, Jamnagar:

1. *Rajonivritti Ek Adhyayana* by Dr. Deena Raval in 1973-74.
2. A Clinical Study on *Rajonivritti* with special reference to Menopausal syndrome by Dr.Kirtidevi Gohil in 1993-95.
3. A Clinical Study on the management of climacteric stage in women with special reference to Menopausal syndrome by using certain *Ayurvedic* formulations by Dr. Kirtidevi Gohil in 1996-98 (Ph.D. Thesis).
4. Comparative study b/w *Rasayana – Kalp vati* and *Shankhapushi vati* in Clinical Study on *Rajonivritti* by Dr. Ajay Sood in 1998-2000.
5. A comparative pharmaco-clinical study of *Rasayana Kalpavati* and *Manshyadi Vati* on *Rajo-Nirvritti – Avastha Janya Lakshana* by Dr. Ami. Modi in 2002.
6. A clinical study on *Manas Bhavas* in Menopausal syndrome and its management by *Medhya Rasayanavati* and *Shirodhara* by Dr. Manju Pateria in 2002.
7. The role of *Nasya* (with *Medhya drug*) in the *Rajo Nivritti Janya Lakshana* w.s.r to Menopausal syndrome by Dr. Devangi Patel in 2004.
8. A clinical study on the role of *Satavari* in minimizing the risk of post-menopausal osteoporosis by Dr. Jasmine Jaypee in 2006.
9. An assessment of *Manasika Bhavas* in Menopausal syndrome and its management by Dr. Khyati Santavani in 2009.
10. A clinical-Experimental study of *Shatavaryadi Vati* on Menopausal Syndrome (*Rajonivrittijanya lakshana*) by Dr.Rujuta Trivedi in 2009 (Ph. D Thesis)

11. Clinical evaluation of *Ashokarishta*, *Ashwagandha Churna* and *Pravala Pishti* in the management of Menopausal syndrome by Dr. Mansi Modi in 2012.

12. Role of *Ashwagandha –Arjuna Ksheerapaka* and Soya Seeds in the management of *Vata* predominant features of Menopausal Syndrome by Dr. Dipika Gupta in 2013.

13. A clinical study to evaluate the efficacy of *Ayurvedic* formulations and procedures in *Pitta* predominant Menopausal Syndrome by Dr. Shraavan Kamble in 2014.

14. A clinical study on Menopausal Syndrome and its Management by Vayasthapana Gana and Rasayanakalpa Vati by Dr. Krutika in 2015.

Pune University

1. To study the relationship between *Vandhyatta vikara*, *Shastra karma* and *Rajonivrutti* by Dr. Kiran Kumar Devare in 2003 in pune.

2. A clinical study of *Rajonivrutti kalaja Lakshna* and its management with Shatavari by Dr. Arun Chavan in 2004 in Pune.

Raipur - Rajonivritti Kalin Samasyao per Gugglu Rasayanaka Prayogika Adhyayana by Dr. Sheena Agrawal in 1988.

BHU, Varanasi - Effect of *Vacha*, *Ashwagandha*, *Ulatakambala* and *Jatamansi* on Menopausal Syndrome by Dr. Shipra Dhar in 1999.

RGPGAYC, Paprola (H.P.) - Clinical evaluation of *Ashokarishta*, *Ashwagandha Churna* and *Praval Pishti* in the management of Menopausal Syndrome by Dr. Charulata in 2012.

Nagpur University - Doshaja Prakruti Anusara Rajjo-Pravrutti va Rajonivrutti kala – Ek Adhyayan by Dr. Mudhal Dhanashree in 2001.

Delhi University - A Clinical study on onset of Menopause (*Rajonivrutti*) in reference to *Deha Prakruti* by Dr. Arora Jasvindre in 2006.

At SDMCA Hassan, Karnataka - Effect of *Pranayama* on *Arthavanivritti* W.S.R. to Climatic features. RGUHS – Hassan by Dr. Kavitha M B in 2006.

At Trivendrum - Study on the effect of *Shatavari* in *Rajonivrutti Lakshana* (Perimenopausal and Menopausal Symptoms) Kerala University by Dr. Agarwane UK in 2002.

OBSERVATION

1. **Dr. Sunithaⁱⁱⁱ (2001)** - The study was conducted in 3 three groups, Group A was given ***Rasayana Compound (Ashwagandha, madhuyasti mula, bala and chandrashura beeja)*** 2gm three times a day with milk. For Group B ***Soybean powder*** 25-30 gm/day was advised to consume in the form of chapattis **along with *Rasayana compound*** was also given. And in Group C placebo therapy of glucose powder filled capsule 500mg two times a day was given along with it special consideration was given to the psychological assurance & advice of *pathya* and *apathya*.

Clinical improvement was judged assessing the severity of symptoms before and after treatment. In somatic symptoms like headache, backache, flatulence, decreased libido, dyspepsia, constipation, palpitation, fatigue, more than 70% results were noted, whereas, more than 50% results were observed in hot flushes, sensation and pins and needles, joint pains, *asthi toda*, *daurbalya* and noises in ear in group A with *Rasayana* compound. Relief in the dryness of vagina, dryness of skin, recurrent vaginal infections, *yonivedana* and *kasha prapatana* was only 30-35% but it was statistically significant. With *Rasayana* compound no effect was observed in *timira darshana* & *artava*

alpata (Oligomenorrhoea). In psychological symptoms like *vyathitendriya and shabda asahishnuta* more than 70% result was observed, whereas, more than 50% result was observed in the symptoms like lack of concentration, forgetfulness, irritability, depression, *bhrama, bhaya, krodha*, sleep disturbances in group A, which were statistically highly significant.

The study proves the efficacy of *Rasayana* compound, in perimenopausal syndrome. The addition of Soybean along with this drug has synergistic effect in improving only a few symptoms & beneficial effect on S.HDL & S.triglyceride levels.

2. Dr.Usha Koli^{iv} (2005) - It is a randomized comparative study, conducted 20 patients in two groups, Group A was given with *Gauryadi Yoga, (Haridra, shatavari and shankhapushpi* in equal parts) 3gm twice a day with water. Group B was on **placebo therapy, arrowroot powder** filled capsule 500mg two capsules twice daily was given along with it special consideration was given to the psychological assurance & advice of *pathya* and *apathya*.

Clinical improvement was judged assessing the severity of symptoms before and after treatment. After statically analysis, in symptoms like hot flushes, palpitation, lack of concentration, sleep disturbances, forgetfulness, joint pain, backache, dyspepsia more than 70% results were noted, whereas, between 60-70% results were observed in headache, excessive sweating, depression, irritability, burning micturation, flatulence and constipation. And more than 50% results were observed in sensation of pins and needles and noises in ear. Only 30-35% results were observed in symptoms like vaginal infections, dryness of vagina and dryness of skin. Psychological symptoms along with some somatic symptoms pacified in placebo group. The study was concluded as *Gauryadi Yoga* is very effective in treating short term distressing symptoms.

3. Dr.Bharathi^v (2009) – It was a single and open trial, study was conducted on 90 patients using **AVA compound** (*Amalaki churna, Vidari kandha churna and Ashwagandha churna*) 2gm each trice a day with milk for three months.

Study showed highly significant results on all parameters, 19 (21.11%) patients showed good response, 36(40%) had showed fair response, 16(17.78%) patients showed poor response and 19(21.11%) patients did not show any response to AVA herbal formula. Total 61.11% people got benefitted with this treatment.

4. Dr. Mamatha Rani^{vi} (2011) - It is a randomized single blind, placebo controlled study. Study was done on 30 patients in two groups, Group A was given with **Menosol compound** (Each 500gm capsule containing of *Shatavari, Madhuyasti, Guduchi, Amalaki, Haritaki, Bala, Ashoka, Ashwagandha and Suddha shataka Yoga*). And Group B was given **Placebo capsules** of 500mg each filled with **starch powder**. The drugs were given as 2 capsules twice a day with milk for two months.

On Kupperman's Index Menosol compound showed extremely significant results on almost all symptoms. Vasomotor irritability (82.85%), Insomnia (81.25%), Excessive sweating (79.98%), Headache (80.64%), Nervousness (88.4%), Dizziness (86.36%), Joint pain(47.73%), Tremor (73.63%), Tachycardia (83.89%), Irritability (80.78%), Lack of concentration (55.55%) except Depression (30.43%) on which results were only significant statistically as compared to placebo which had not significant results on all symptoms.

CCRAS Conducted Multi-centric Open Ayurvedic Clinical Trial at IPGT & RA-Jamnagar, NIA-Jaipur and RGGPGAYC- Paprola during 2012.

5. Dr.Neeta Kumari^{vii} (2012) -This is a research study conducted under the Ayurvedic Clinical Trial (ACT) project of the Ayurvedic pharmacopeia committee(APC) by Central Council for Research in Ayurveda and Siddha (CCRAS), Department of AYUSH, Ministry of Health & Family Welfare, Government of India, involving administration of **Ashokarishta** (25ml with water), **Ashvagandha Churna** (3gm) **And Praval Pishti** (250mg) was given twice a day for 12 weeks, with a view to scientifically document the clinical efficacy and safety of the said Ayurvedic formulation that have been in use since thousands of years for the Management of Menopausal Syndrome. The trial was completed in 48 patients,

Effect of “*Ashokarishta, Ashvagandha Churna And Pravala Pishti*” was assessed on Menopausal Rating Scale (MSR) Score and MENQOL Score, and Hematological and biochemical investigations. The study showed highly significant Result to decrease in Serum Cholesterol (6.7078%). Decrease in Triglycerides (5.9184 %). Decrease in LDL (8.4722 %). In HDL (3.2652%) and 7.4545 % Decrease in VLDL. The study also showed 12.495 % Decrease in S.Alkaline Phosphatase , 16.99 % Decrease in SGOT. 2.9596 % Decrease in Total protein, all of the above shows highly significant results. Somatic Subscale (36.239%), Psychological Subscale(33.52%), Urogenital Subscale(21.942%), and Overall total effect on MRS score is 31.721% gets Decrease up to followups .other most of successive visits also showed highly significant after treatment.

There was highly significant decrease in MENQOL (Vasomotor symptoms decrease up to 42.885%, Psychosocial score (26.667%), Physical (31.369%), and sexual (28.764%). Score all these things that the drug **Ashokarista, Ashvagandha Churna and Praval Pishti** showed positive response on various parameters which indicates that it helped in reducing the symptoms of Menopausal syndrome.

6. Dr. Deepika Gupta^{viii} (2013) – The Research study is randomized open clinical trial conducted in two groups. Group A is given with *Ashwagandha-Arjuna Ksheerpaka* and Group B is given with **Soya seeds granules** (5gm) for patients diagnosed with *Vata* predominant symptoms of Menopausal Syndrome for a period of 3 months. Statistically highly significant ($P < 0.001$) relief was found in *Shirahshoola* (Headache), *Anidra/Alpanidra* (Sleeplessness), *Bhrama* (Vertigo), *Anavasthitachitvatam* (Mood swing), *Vaichitya* (Loss of concentration), *Chinta* (Anxiety) in group A, may be due to *Mashtishka Shamak* property of *Ashwagandha*, *Raktavahini Shothohara* property of *Arjuna* with *Jeevniya* and *Tarpana* properties of milk which provide better *Rasa Samvahana* to brain tissues and in group B in *Shirahshoola* (Headache) and *Bhrama* (Vertigo) as it has effect in frontal lobe of brain. Statistically highly significant ($P < 0.001$) relief was observed in *Hrid spandana* (Palpitation), *HastaPadaSupti* (Numbness), *Shabda-Asahishnuta* (Noise-Intolerance), *BalaKshaya* (Weakness) and *Angamarda* (Body ache) in group A, which may be due to *Raktabhar Shamak* property of *Ashwagandha*; *Medohara* & *Hridya* properties of *Arjuna* along with *Pushtikara* property of milk which collectively acts on body and enhance the functioning of heart and ensures adequate nourishment and in group B in *Hasta-Pada Supti* (Numbness) and *SandhiVedana* (Joint pain) as it contains all the essential amino acid along with Omega-3 fatty acid and other nutrients² which helps in blood circulation so enhance nourishment of body tissues.

The study shows that trial drugs give better results in *Vata* dominated somatic Complaints as well as psychological disturbances. Hence, it can be concluded that in women with mild to moderate symptoms of Menopausal Syndrome, *Ashwagandha-Arjuna Ksheerapaka* and Soya seeds are proved as rejuvenating drugs as well as specific food products (*Ajasrika Rasayanas*) which fulfil the requirement of body at his particular phase of life by supplementing *Rasadi Dhatus*, Thus pacifying the provoked *Vata*, but due to *Vishtambhi* nature of Soya seeds, a *Shimbi Dhanya* it produces flatus and indigestion so it must be cooked with "wet" heat (to destroy the trypsin inhibitors (serine protease inhibitors) for better absorption.

7. Dr. Shrawan N. Kamble^{ix} (2014) - For Group A Patients *Shamana Yoga* (*Anubhuta dravya – Shatavari churna, Amalaki churna, Yastimadhu churna* – 1gm each, *Mukthashukti bhasma* -500gm) was given, For Group B Patients *Virechana Karma* (Classical *virechana* by *Trivritta Avaleha* – 100gm) and *Shamana yoga* was given, and for Group C Patients *Shirodhara (Ksheera dhara)* and *Shamana yoga* was given. For all the groups shaman yoga was given for 30 days.

All the three groups showed highly significant statistical results in Parameters like *Ushnanubhuti*, *Daha*, *Svedaadhikyata*, *mutradaha*, *Yoni daha*, *Glani*, *Santapa*, *Krodha*, sexual sub score, Psychological sub scale score, Urogenital sub scale score, Hot flushes, Night sweats, Sweating, being dissatisfied with personal life, Feeling anxious or nervous, Experiencing poor memory, Feelings of wanting to be alone, Change in sexual desire, Vaginal dryness during intercourse, Avoiding intimacy, *Shirashula*, *Balakshaya*, *Vibandha*, *Anidra*, *Krichhra vyavayata* and *Yoni shushkta*. The study was concluded that in women with mild to moderate symptoms of Menopausal syndrome, *Shamana yoga*, *Virechana karma* and *Shirodhara* are proved as rejuvenating drugs as well as *Rasayana* therapy, which fulfill the requirement of body.

8. Dr. Krutika K. Chaudhary^x (2015)

It is an open randomized clinical trial done in 30 patients totally in two groups. The intervention was done using **Vayahsthapana-gana ghana vati and Rasayana-kalpa Ghana vati** in two Groups. 500mg medicine was given twice a day with milk for 60 days.

After Statistical Analysis, Group A *VayasthapanaGana Ghanavati* showed better result in hot flushes, bladder problems, anxiety, depressive mood, sleep problems and palpitation and Group B *Rasayanakalpa Vati* showed better result in hot flushes, irritation, joint and muscle discomfort and mental exhaustion. In bladder problems *VayasthapanaGana Ghanavati* had shown better result and *Rasayanakalpa Vati* shown better result in joint and muscle discomfort.

The overall effect from the present study in Group A (*VayasthapanaGana Ghanavati*), 13 patients reported mild improvement (81.25%) and 3 patients (18.75%) moderate and in Group B (*Rasayanakalpa Vati*), 10 patients reported mild improvement (71.43%), 4 patients (28.57%) moderate and no any patients reported unchanged, marked improvement or complete cured in both the groups.

So from the present study it has been concluded that both the trial drugs are equally effective to reducing Menopausal syndrome i.e. Group-A *Vayasthapangana Ghanavati* group more effective in urinary problem involvement and cardiac problem where as Group-B *Rasayanakalpa Vati* group shown better result in muscular and joint problems, where as in psychological involvement both groups had shown similar effect.

DISCUSSION

The Observational Study of previous works done on the subject helps the researcher to know the current status of the Problem and avoids repetition of study; problems faced during previous research could be nullified.

On reviewing the theses works, the following points can be understood. Dr.Sunitha got significant result by using Rasayana compound and soybean powder combined therapy. Dr.Usha koli explains efficacy of Gauryadi Yoga (Haridra, shatavari and shankhapushpi) in Postmenopausal syndrome. Dr.Bharati explains the efficacy of AVA compound (Amalaki churna, Vidari kandha churna and Ashwagandha churna). Dr. Mamatha Rani concludes her work by establishing significant result of Menosol compound (Shatavari, Madhuyasti, Guduchi, Amalaki, Haritaki, Bala, Ashoka, Ashwagandha and Suddha shataka Yoga) in treating Menopausal syndrome. Multicentre trial done under CCRAS (IPGT & RA, Paprola and NIA) concludes by proving efficacy of Ashokarista, Ashwagandha churna and Pravala pisti in the management of Menopausal Syndrome. Dr.Deepika Gupta writes in her summary the effectiveness of the Ashwagandha arjuna ksheera paka and soya seeds granules in Vata dominant Menopausal Syndrome. Dr.Shrawan N. Kamble concludes the benefit of Shodhana therapy followed by shamana therapy and Shirodhara with Shamana therapy in the management of Pitta predominant Menopausal syndrome. Dr.Kritika K.Chaudhary concludes her research by confirming the effect of Vayahsthapana gana Ghana vati and Rasayana kalpa vati on Menopausal Syndrome.

The extensive research works on the topic establishes the need of the management protocol for the Menopausal women suffering with Menopausal Syndrome. Each women is unique, there is variation in her deha prakruti, vaya, dosha variation, dietic and life style of every woman. Considering all these treatment should be advised. All the above works are the result of such extensive hard effort. The significant result found in above research work as they were with the additional advice of dietic lifestyle, pathya and apathy included in the research group. The clinical works concludes the importance of Rasayana therapy given in different formulation.

CONCLUSION

Menopausal Syndrome, one of the current issues, is as important as Infertility or any other Gynecological problems. The topic needs extensive research and updates in the field of *Ayurveda*. All the research done is explaining one common base of treatment of *Rasayana therapy*. It is even more effective when followed after *mridu shodhana karma* and treatment associated with palliative therapy like *shirodhara* and additional calcium rich *sudha varga dravya*. All works mostly supports, their efficacy towards short term menopausal syndrome. Research work on

complete management of Syndrome and avoiding complication is the need for further study for the well being of Women.

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