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Role of Ashwagandha - Arjuna Ksheerapaka in the management of Vata predominant features of Menopausal Syndrome

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ABSTRACT

Menopause is a normal, natural event - defined as the final menstrual period and usually confirmed when a woman has missed her periods for 12 consecutive months at age 45 to 55 years. Some women may have troublesome symptoms. Also Menopause is supposed to be a sign of aging to others which may cause distress in a woman in society that values youth and fertility. In *Ayurveda*, Menopause (*Rajonivritti*) is manifested due to progressive reduction in the functional ability of *Srotas* and *Agni*, which results into an inadequate tissue nutrition. This nutritional imbalance triggers the irreversible degenerative changes in various “*Dhatus*” leading to *Vata Prakopa*. Most of the menopausal symptoms are results of vitiation of *Vata*. To understand menopause in the light of *Ayurvedic* principles of *Doshas* theory and to evaluate the effect of an *Ayurvedic* regime, *Ashwagandha-Arjuna Ksheerapaka* has selected as drug of choice. In this study 17 patients were treated with *Ashwagandha-Arjuna Ksheerapaka* 53.33% improvement was observed in *Vata* predominant menopausal symptoms. Hence it can be concluded that this drug can manage menopausal symptoms.

Keywords: Menopause, *Rajonivritti*, *Ashwagandha-Arjuna ksheerapaka*, *Dhatu*, *Vata*

INTRODUCTION:

Menopause is defined as the culmination of women's reproductive life in which ovulation function of ovaries cease and clinically it is confirmed when a woman has missed her periods for 12 consecutive months at the age of 45 to 55 yearsⁱ. As per *Ayurvedic* classics menopause is considered as a natural transition instead of a disease.ⁱⁱ In some women this natural phenomenon when reflected with problems like hot flashes, sweating, skin changes, night sweating, alteration of menstrual function, abnormal bleeding and psychic disorders including sleep disturbances, paresthesia, headache, noises in ears, irritability, anger, depression, anxiety, reduced sexual urge, vaginal dryness, pruritis vulva, lower BMR, etc. commonly it is termed as menopausal syndromeⁱⁱⁱ. These problems are supposed due to hormonal deficiency in modern medical science. On the other side, in *Ayurveda Jara* and *Rajonivritti* are said to be manifested due to progressive reduction in the functional ability of *Srotas* and *Agni*^{iv}, which results into an inadequate tissue nutrition. This nutritional imbalance triggers irreversible degenerative changes in "*Dhatu*" leading to *Artavakshaya*. Concept of '*Aajasrik Rasayana*'^v (general rejuvenation) deals with food products that can be consumed daily by offering protection from external and internal stressors for improvement of quality of life. Hence to evaluate the role of *Ashwagandha -Arjuna Ksheerapaka* the study was undertaken.

MATERIALS & METHODS:

Patients & Drugs:-

Patients were selected from the O.P.D. of the department of the *Stree Roga* &

Prasooti Tantra of I.P.G.T. & R.A. Jamnagar, fulfilling the criteria for selection. All the raw Drug were procured from the Pharmacy of the institute which were authenticated by the Pharmacognosy laboratory and Physico-chemical parameters assessed in Pharmaceutical laboratory of the institute.

Inclusion criteria:-

Age group between 35-55 years having Cardinal Symptom i.e. Cessation of menses for 12 months and only *Vata* predominated symptoms were taken among symptomatology commonly associated with menopause and on the basis of Menopausal rating scale (MRS) and Menopause specific quality of life questionnaire's (MENQOL)

Exclusion criteria:-

Women who were Pregnant, breast-feeding, with uncontrolled medical conditions e.g. Hypertension, Heart disease, Diabetes mellitus etc., who were undergoing treatment for cancer or were in remission, who had the history of Hormone replacement therapy (HRT) and hysterectomy and having history of excessive and/or irregular bleeding per vaginally were excluded from the study.

Criteria for diagnosis:-

The diagnostic criteria based on symptomatology commonly associated with menopause and on the basis of Menopausal rating scale (MRS) and Menopause specific quality of life questionnaire's (MENQOL) out of which symptoms of *Vata* predominance according to *Ayurvedic*-classics has taken.

Laboratory investigation:

General investigations like Haematological (Hb%, T.L.C., D.L.C., ESR), Urine

(Routine and microscopic), Liver function test (Serum Bilirubin, Alkaline Phosphate, S.G.O.T, S.G.P.T.), Renal function test (S. Uric acid, Blood Urea, Serum Creatinine, Total Protein, Albumin, Globulin, A/G ratio), RBS, Serum Calcium, Lipid Profile and Special investigations to see the effect of therapy like Ultrasonography (TVS/TAS), Hormonal assessment (Serum FSH, Serum TSH, and Serum estradiol), ECG were done before and after treatment.

Study design:

This study was randomized open clinical trial to evaluate the efficacy of trial drug on menopausal syndrome.

Ethics: Study was approved by institutional ethics committee, wide letter no. PGT/7-A /Ethics/2011-12/2087 dated 5/9/11.

Treatment protocol:

Preparatory phase - In all the patients Tablet *Aampachana* [containing *Haritaki* (*Terminalia chebula*), *Sunthi* (*Zingiber officinale*), *Maricha* (*Piper nigrum*), *Pippali* (*Piper longum*), *Hingu* (*Foetida nerifolia*), *Saindhav* (Rock Salt) etc.] was given for 7 days to stimulate appetite prior to treatment.

Method of drug administration, Dosage and Duration of treatment -

Patients were advised to make *Ksheerapaka* themselves by 3 gm. coarse powder (sieve No. 10) of each drug and soaked it in 100 ml of portable water for overnight (12 hrs.). Next day, 100ml of milk poured in it and then cook it in mild heat with continuous stirring without covering with lid. Reduction was done to reduce until the quantity of 100ml out of the total volume of 200ml. Then filtered

the *Ksheerapaka* and it was advised to take after meal two times a day for 3 months^{vi}.

Follow up:

The duration of treatment was 3 months and then follow up study was done for 2 months at the interval of 15 days.

Criteria of assessment:

To assess the effect of therapy, *Vata* predominant symptoms i.e. subjective criteria (TABLE 1) were given scoring depending upon their severity and objective criteria like Serum Cholesterol, Serum Triglyceride, HDL, Serum Cholesterol/HDL ratio, Serum Calcium, Serum Estradiol, Serum FSH, USG (TVS / TAS) , ECG by comparing the values before and after treatment

Assessment of overall effect of therapy:

No change- Less than 25% changes in the sign and symptoms.

Mild improvement - 26-50% relief in the signs and symptoms.

Moderate improvement - 51-75% relief in the signs and symptoms.

Complete cure - 76-100% relief in the signs and symptoms.

Statistical analysis:

The information collected on the basis of observations were subjected to statistical analysis by the use of student paired 't' test.

Observation & results:

17 patients were registered out of which 15 patients have completed the treatment while 2 patients left the treatment against medical advice. Observations and results have been shown under the GRAPH 1 and TABLE 1.

DISCUSSION:

Maximum i.e. 35.29% patients were belonging to age group of 45-50 years and 55.88% of patients had Menopause for last 1- 4 years which indicates Various somatic and psychological complaints of menopause are more troublesome during perimenopause which brings the women for treatment^{vii}.

Improper dietary habits like *Viruddha Ahara*, *Ruksha Ahara* (low calorie rich foods) were found in 67.65% of patients and disturbed digestion was found in 47.06% of patients it leads to *Agnimandhya* and *Ama* production which results in to various symptoms by producing insufficient *Rasa Dhatu* and *Srotorodha* too as a result; *Vata Dosha* get aggravated and all troublesome symptoms arise.

Chinta, *Tanava*, *Bhaya*, and *Krodha* was found in 97.06%, 73.53%, 67.65%, and 29.41% of the patients respectively i.e. worry and stress. 44.12% of females were observed to have supple mental state. 85.29% belongs to nuclear family. In small families' women are found alone herself and cannot share their problems so depression and anxiety problem are more^{viii}. These psychological status vitiate *Vata Dosha* and then vitiate *Agni*^{ix}. Stress weakens adrenal glands affects the production of oestrogen and aggravate menopausal symptoms^x.

52.94% of patients were doing moderate exercise irregularly in the form of house hold work. Sedentary life is also a cause of musculoskeletal symptom of menopause^{xi}. Night awakening, controlling of natural urges were found in almost all patients i.e. 100 %.

As the age advances, generalized *Shosha* and *Rukshata* take place in *Rasa-vahi srotas* which hampers the nourishment of *Rasadhatu*, and further *Dhatu*s also. This qualitatively and quantitatively reduce *Rasa Dhatu* and increasing degrees of *Srotorodha* resulting into oligomenorrhoea & if it is severe – amenorrhoea and ultimately in to *Rajonivritti*; a sign of *Dhatu Kshaya*. In menopause, almost all the body *Dhatu*s are involved in pathogenesis. The majority of the Symptoms of Menopause are due to *Vata Vriddhi*, *Kapha Kshaya*, *Ashayapakarshit Pitta* along with vitiation of *Manovaha srotas*; and *Dhatukshaya* because of all improper life style and food habits.

Urinary complaints, atrophic changes in genital organs, weakness, palpitations, noise intolerance, mood swings, loss of concentration, disturbed sleep etc. are due to increased *Vata* and *Dhatukshaya*.

Ashwagandha -Arjuna Ksheerapaka act as a general rejuvenation (*Aajasrik Rasayana*). In this study Statistically highly significant ($P < 0.001$) relief was found in Headache (*Shirahshoola*), Sleeplessness (*Anidra/Alpanidra*), Vertigo (*Bhrama*), Mood swing (*Anavasthitachitvatvam*), Loss of concentration (*Vaichitya*), Anxiety (*Chinta*), may be due to CNS depressant (*Mashtishka Shamak*) property of *Ashwagandha*^{xii}, anti-atherosclerotic (*Raktavahini Shothohara*) property of *Arjuna*^{xiii} with rejuvenating (*Jeevniya*) and nourishing (*Tarpana*) properties of milk^{xiv} which provide better circulation of nutrients (*Rasa Samvahana*) to brain tissues. Also Statistically highly significant ($P < 0.001$) relief was observed in Palpitation (*Hrid spandana*), Numbness (*Hasta PadaSupti*), Noise-Intolerance

(*Shabda-Asahishnuta*), Weakness (*BalaKshaya*) and Body ache (*Angamarda*) which may be due to anti-hypertensive property of *Ashwagandha*^{xv}, lipolytic (*Medohara*) and cardio-protective (*Hridya*) properties of *Arjuna*^{xvi} along with nourishing (*Pushtikara*) property of milk^{xvii} which collectively act on body and enhance the functioning of heart and ensures adequate nourishment. On the other hand *Ashwagandha* has appetizer (*Dipana*), carminative (*Anulomana*), aphrodisiac (*Vajikarana*), uterine anti-inflammatory (*Garbhashaya shotha-hara*), vaginal analgesia (*Yoni shoolahara*), diuretics (*Mutral*)^{xviii}, strengthening (*Balya*), Weight promoting (*Brimhnaiya*), and antioxidant (*Rasayana*) properties. *Arjuna* has blood-coagulant (*Rakta-stambhana*), cell regenerating (*Sandhaniya*), preventing urine disorder (*Mutra-sangrahaniya-shamaka*), skin invigorating (*Tvak prasadana*), antitoxic effect (*Vishaghana*), and strengthening (*Balya*) properties^{xix}. Milk has *Alpabhishtyanda* i.e. not obstructs the channels of circulation (*srotas*) carrying Rasa (plasma), antioxidant (*Rasayana*), intellect promoting (*Medhya*), strengthening (*Balya*), regulated diet (*Pathya*), tasty (*Ruchya*), aphrodisiac (*Vrishya*), skin lustre (*Kanti*) promoting, intellect (*Buddhi*) promoting, memory (*Medha*) boosting properties^{xx}. By these properties combination of these drugs helps in channel transportation (*Sroto Vahana*) and enhancement of tissue plasma production (*Rasa Nirmana*). Proper nourishment pacifies *Vata* this helps in break the pathogenesis and ultimately suppresses the symptoms. On the other hand by making *Ksheerapaka* of these drugs the heaviness (*Kaphakaritva*) of milk is decreased and dryness

(*Rookshata*) of *Arjuna* and *Ashwagandha* is removed and by its sweet (*Madhura*), heavy (*Guru*), unctuous (*Snigdha*), hot (*Ushna*), smooth (*Shalakshana*), mild (*Manda*) properties it also pacifies *Vata*, also milk is rich in Calcium which acts as a bone supplement.

Conclusion:

The study shows that menopausal symptoms, somatic as well as psychological are mostly due to dominancy of *Vata Dosha*. Hence, it can be concluded that *Ashwagandha-Arjuna Ksheerapaka* works better in both somatic and psychological complaints in women with mild to moderate symptoms of Menopausal Syndrome; In short, stage of menopause requires a careful early attention. This period may manifest short term symptoms and long term complications. Short term symptoms must be treated while the long term complications must be prevented.

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TABLE: 1 Vata predominant menopausal symptoms and effect of therapy on these symptoms

Symptoms	Mean		B.T.- A.T.	%	S.D.	S.E.	‘t’	N	‘P’
	B.T.	A.T.							
1.Shirahshoola (Headache) n=14	1.80	0.27	1.53	85.19	0.99	0.26	6.0	13	0.001
2.HridSpandana (Palpitation) n=15	1.73	0.80	0.93	53.85	0.88	0.23	4.09	14	0.001
3.HastaPadaSupti (Numbness) n=14	1.27	0.53	0.73	57.89	0.59	0.15	4.79	13	0.001
4.ShabdaAsahishnuta (Noise-Intolerance) n=14	2.07	1.07	1.00	48.39	0.85	0.22	4.58	13	0.001
5.Bala-Kshaya (Weakness) n=15	1.67	0.80	0.87	52	0.74	0.19	4.52	14	0.001
6.Adhmana (Abdominal Distension) n=15	2.33	1.40	0.93	40	1.16	0.30	3.11	14	0.008
7.Vibandha (Constipation)n=14	1.33	0.80	0.53	40	0.92	0.24	2.26	13	0.041
8.Anidra/Alpanidra (Sleeplessness) n=14	1.67	0.60	1.07	64	0.88	0.23	4.68	13	0.001
9.Bhrama (Vertigo) n=14	1.53	0.53	1.00	65.22	0.54	0.14	7.25	13	0.001
10.Anavasthitachit atvam (Mood swing) n=14	0.80	0.27	0.53	66.67	0.52	0.13	4.00	13	0.001

Symptoms	Mean		B.T.- A.T.	%	S.D.	S.E.	't'	N	'P'
	B.T.	A.T.							
11.Vaichitya (Loss of concentration) n=14	1.47	0.47	1.00	68.18	0.54	0.14	7.24	13	0.001
12.Vishaada (Depression) n=13	1.20	0.53	0.67	55.56	0.82	0.21	3.16	12	0.007
13.Chinta (Anxiety) n=14	2.00	0.80	1.20	60	0.86	0.22	5.39	13	0.001
14.Smritimandhya (Decreased memory) n=15	1.53	1.40	0.13	8.70	0.99	0.26	0.52	14	0.610
15.Krichchhra Vyavayata (Loss of libido) n=15	3.20	2.53	0.67	20.83	1.29	0.33	2.00	14	0.065
16.Maithuna asahishnuta (Dyspareunia) n=9	1.07	0.60	0.47	43.75	0.64	0.17	2.82	8	0.014
17.Vaksang (Change in voice) n=14	1.40	1.27	0.13	9.52	0.35	0.09	1.47	13	0.164
18.Vali (Wrinkling of skin) n=14	2.07	1.93	0.13	6.45	0.35	0.09	1.47	13	0.164
19.Asthivedana (Pain in bones) n=15	2.13	0.80	1.33	62.5	0.98	0.25	5.29	14	0.001
20.Katishool (Low backache) n=15	1.67	1.07	0.60	36	0.74	0.19	3.15	14	0.007
21.SandhiVedana (Joint pain) n=15	1.60	0.53	1.07	62.5	0.80	0.21	5.17	14	0.001
22. Vamanatvam (Loss of ht.) n=15	1.13	0.67	0.47	41.18	0.52	0.13	3.50	14	0.004
23.Angamarda (Body ache) n=15	1.93	0.87	1.07	55.17	0.80	0.21	5.18	14	0.001

Symptoms	Mean		B.T.- A.T.	%	S.D.	S.E.	‘t’	N	‘P’
	B.T.	A.T.							
24.Yonivedana (Pain in vagina) n=10	0.93	0.47	0.47	50	0.64	0.17	2.82	9	0.014
25.Yoni shushkta (Vaginal dryness) n=14	1.33	0.33	1.00	75	0.66	0.17	5.92	13	0.001
26.Prabhuta mutrata (Frequency in micturition) n=14	1.40	0.73	0.67	46.15	0.82	0.21	3.16	13	0.007
27.Urge incontinence n=11	1.33	0.87	0.47	35	0.52	0.13	3.50	10	0.004
28.Mutrakrichhrat a(Pain during micturition) n=15	2.00	0.60	1.40	70	1.12	0.29	4.84	14	0.001

GRAPH I: Percentage improvement

