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A clinical study to evaluate the combined effect of Kalyanaka Ghrita and S-GABA Churna (an indigenous formulation) on psychological symptoms in Perimenopausal Syndrome

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ABSTRACT

Introduction: Perimenopause is the physiological transitional phase, where the estrogen level decreases due to depletion in ovarian follicular activity. Even though it is a physiological condition decreased estrogen secretion in the circulating system result in group of symptoms termed as Perimenopausal syndrome, consisting of psychological, vasomotor, somatic and uro-genital symptoms. The psychological symptoms are anxiety, depression, irritability, crying spells, lack of concentration, loss of memory and sleep disturbances which needs to be handled with specific intervention. Materials & Methods: It was single group study, with pre-post test design. Study included 32 subjects between the age group 40-55-year females. Kalyanaka Ghrita was used for Nasya Karma, S-GABA Churna as Shamanaoushadhi. Result: The results obtained after completion of intervention showed statistically highly significant with p value 0.001. Conclusion: The psychological symptoms in perimenopausal syndrome was effectively managed with Kalyanaka Ghrita Nasya Karma and S-GABA Churna as Shamanoushadhi.

Key words: Perimenopausal Syndrome, Nasya Karma, Kalyanaka Ghrita, S-GABA Churna.

INTRODUCTION

Perimenopause is physiological process where the estrogen level decreases due to depletion in ovarian follicular activity. Even though it is a physiological condition, decreased estrogen secretion in the circulating system result a group of symptoms termed as Perimenopausal syndrome.

The age of Perimenopause is between 40-55 years. The symptoms are categorized in somatic, psychological,

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vasomotor and uro-genital. They are palpitations, feeling tense or nervous, forgetfulness, difficulty in sleeping, excitable, attacks of anxiety, difficulty in concentrating, feeling tired or lacking in energy, loss of interest in most of things, crying spells and irritability are psychological symptoms. Irregular menstrual cycles, feeling dizzy or faint, headaches, muscle and joint pains, breathing difficulties are somatic symptoms. Hot flashes and sweating in night are vasomotor symptoms. Sexual problems, bladder problems, dryness in vagina are uro-genital symptoms.

The severity of symptoms varies from individual to individual and from perimenopause to menopause. Anxiety, depression is more predominant in perimenopause compare to post menopause. Palpitations and headache are more prevalence in around 30-32% in perimenopause and 16-20% in post menopause.

The management includes Hormonal replacement therapy (HRT). HRT is indicated to overcome short- and long-term consequence due to estrogen deficiency

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where the estrogen alone or progesterone is prescribed. HRT is useful in treating vasomotor symptoms, sleep disturbance and genitourinary symptoms and less efficient in treating psychological symptoms, which is more prevalence in Perimenopause.

Risk of endometrium cancer, breast cancer, venous thromboembolism, coronary heart disease, dementia etc. further cause limitation of extensive uses of HRT.

In Ayurveda, the menopause is termed as Rajonivrutti. The age of Rajonivrutti is mentioned as around the age of 50 years. The classification of according Sushruta samhita, mentions 4 stages in Madhyama avastha. They are Vriddhi avastha (up to 20 years), Yauvan avastha (up to 30 years), Sampurnata (up to 40 years) and Parihani (up to 70 years).

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*.

This study was undertaken to know the efficacy of combined effect of *Kalyanaka Ghrita Nasya Karma* and *S-GABA Churna* (an indigenous formulation).

The management is designed to do *Vata Shamana* by *Bruhmana Nasya Karma* with *Kalyanaka Ghrita* for first 7 consecutive days of intervention and *Rasayana*, *Medhya* effect by *S-GABA Churna* (an indigenous formulation) in *Jara Kala* for all 60 days of intervention.

OBJECTIVE OF THE STUDY

To evaluate the combined efficacy of *Kalyanaka Ghrita Nasya Karma* and *S-GABA Churna* (an indigenous formulation) in the management of psychological symptoms of Perimenopausal syndrome.

MATERIALS AND METHODS

Source of data

Subjects were selected from the O.P.D and I.P.D of Government Ayurveda Medical College and Hospital,

Mysore and Hi-tech Panchkarma Hopsital, a teaching hospital of Government Ayurveda Medical College, Mysore.

Sample Size: 32 subjects

Inclusion Criteria

Female subjects of age group between 40-55 years were selected.

Exclusion Criteria

- Subjects with comorbidity of other psychiatric illness, such as depression, generalized anxiety disorders and other anxiety disorders such as obsessive-compulsive disorder and phobias were excluded.
- Subjects with history of amenorrhea more than 12 months were excluded.
- Subjects who attained surgical menopause were excluded.
- Subjects having major organic pathology of reproductive system like carcinoma, fibroid, ovarian cysts were excluded.
- Subjects who were having other systemic diseases such as Diabetes mellitus (>250mg/dl), Hypertension having blood pressure >150/100mmHg and sexually transmitted diseases which interrupt the intervention were excluded.

Diagnostic Criteria

Menopausal Rating Scale (Annexure 1) was used to diagnose Psychological symptoms in Perimenopausal syndrome.

Assessment

Assessment schedule

In this study, totally four assessments were done.

- Pre-test assessment 0th day before the intervention
- Mid test assessment I 8th day after completion of Nasya Karma
- 3. Mid test assessment II 30th day

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4. Post-test assessment - 61st day after completion of intervention

Assessment criteria (Annexure 2)

Greene Climacteric Scale was used to assess the symptoms before and after the intervention.

Statistical Methods

The data obtained were analyzed by using Descriptive statistics, Cramer's V test, Chi-square test, paired 't' test, Repeated measure ANOVA statistical methods and results were analyzed using SSPS windows.

Intervention

Duration of intervention: 60 days

All subjects of the study received the following intervention.

Nasya Karma with Kalyanka Ghrita for first 7 consecutive days of intervention.

Dose - 8 *bindu* (4ml) 2ml in each nostril in the morning (9am to 11am) on empty stomach.

S-GABA Churna (an indigenous formulation, consisting *Shatavari, Guduchi, Ashwagandha, Brahmi, Amalaki*) - all ingredients in equal quantity.

Dose - 12gms in 2 equally divided doses after food, with warm milk as *Anupana* for all 60 days of intervention.

OBSERVATION AND RESULTS

Observation and result section consists two divisions i.e., the demographical profile and results of the clinical trial.

Demographical profile

- 1. Age: In the present study among 33 subjects, maximum 19 (57.6%) subjects belonged to the age group of 46-50 years.11 subjects (33.3%) belonged to the age group of 40-45 years and 3(9.1 %) subjects belonged to the age group of 51-55years.
- Occupation: In the present study, among 33 subjects 19 (57.6%) subjects were homemakers, 5 (15.2%) subjects were tailor, 6 (18.2%) subjects

were for office worker, and 3 (9.1%) subjects were teachers.

- Vyayama: In the present study, majority of the 18 (54.5%) individuals used not do any exercises, 9 (27.3%) subjects used to go for walk, and 6 (18.2%) subjects used to practice Yoga.
- 4. Status of *Satva*: In the present study, majority of the subjects 18(54.4%) had *Madhyama Satva*, 15 (45.5%) subjects had *Avara Satva*.
- Age of Menarche: In the present study, 12 (36.4%) subjects attained menarche in between the age 11-13 years, and 21 (63.6%) subjects in age group 14-16 years.
- Co-Morbidity: In the present study, 10 (30.30%) subjects had Osteoarthritis, 1 (3.03%) subject had rheumatoid arthritis, 4 (12.12%) subjects had Hypothyroidism, 5 (15.15%) subjects had Cervical spondylosis and 13 (39.39%) subjects had no comorbidity.
- Haemoglobin: In the present study, maximum subjects 22 (66.6%) had Hb% in range 10-11gm%,
 (24.24%) subjects had in range 8-9gm% and 3 subjects had Hb% in the range 11-12g%.
- 8. Body Mass Index: In the present study, among 33 subjects maximum 22 (66.7%) subjects were having BMI in between 25 to 30, 7 (21.2%) subjects having BMI below 25 and 4 (12.1%) subjects having more than 30.

RESULTS

The results obtained regarding the psychological symptoms heart beating quickly or strongly, feeling tense or nervous, difficulty in sleep, excitable, attacks of anxiety, difficulty in concentrating, feeling tired or lacking in energy, loss of interest in most of things, feeling unhappy or depressed, crying spells, irritability showed statistically highly significant with p value 0.000.

Additional effect was also seen on the somatic parameters like headache, muscle and joints pain and vasomotor symptom hot flushes showed statistically highly significant with p value 0.000.

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DISCUSSION

Age of Perimenopause: *Parihani Avastha* is age from 5th decade to 7th decade of life. During this phase there is gradual decline of *Dhatu*, *Indriya*, *Bala* and *Virya*. Perimenopause is the stage prior to *Vriddhaavastha* that is in between later part of *Rajaswala* and commencement of *Vriddhaavastha*.^[1] Hence, *Parihani* stage can be considered as perimenopausal age.

Perimenopausal syndrome is somatopsychic condition, where in the individual is affected both physically and psychologically. Somatopsychic condition can be understood in *Ayurveda* by knowing the relationship between *Sharira* and *Manas*. Through the process of decline in ovarian follicles and decrease in the levels of estrogen levels happens, psychological symptoms are produced. The *Sharirika Vyadhi* in due course of time involves *Manas*. The diseases manifested by somatic origin do have impact on mind and vice-versa.^[2]

Psychological symptoms in perimenopausal syndrome in can be considered under *Kupita Vata Lakshana*^[3] and *Raja* and *Tama Dosha Vikara*.

Disturbances given in physiology of <i>Vata</i>	Disturbances observed in Rajonivrutti
Niyanta Praneta Cha Mana, Sarvendriya Audhyojaka, Sarvendriyaarthanam Abhivodha, Harsha Utshah Yoni	Psychological disturbances like anxiety, irritability, depression, mood swings
Sarva Sharir Dhatu Vyuhakara	Circulatory disturbances resulting palpitations, vasomotor symptoms like hot flushes
Prakriti Shabdha Sparshayoh	Sensory motor problems
Pravartaka Chestanam	Difficulty in initiating activities

Vitiation of Manas Dosha Raja and Tama leads to Vikara like Kama (passion), Krodha (anger), Lobha (greed), Moha (attachment), Irsha (envy), Abhimana (ego), Mada (pride), Shoka (grief), Chinta (worry), Udvega (anxiety), Bhaya (fear), Harsha (excitement). [4]

Chikitsa: Vata Shamana by Bruhmana Chikitsa, Medhya Rasayana and Vayasthapaka.

Bruhmana Chikitsa in the form the Bruhmana Nasya Karma with Kalayanka Ghrita was carried out in the study.

Bruhmana Nasya Karma provides nourishment to nervous system. On its administration, it reaches Shirngata Marma spreads all over head, channels of eyes, ears, throat and causes Vata Shamana and Bruhmana effect.

In this study, as *Shamanoushadhi S-GABA Chruna* (an indigenous formulation) was used. It includes five drugs. They are *Shatavari*, *Guduchi*, *Aswagandha*, *Brahmi* and *Amalaki*.

Probable mode of action of *S-GABA Churna* (an indigenous formulation)

Shatavari - The properties of Shatavari are Rasayana, Medhya, Agni Bala Vardhaka, Balya.

Guduchi - Guduchi is Vata Shamaka, possess Guru, Snigdha Guna and Ushna Virya. Properties of Guduchi are Medhya and Rasayana.

Ashwagandha - The properties Ashwagandha are Rasayana and Bala Pushtiprada.

Brahmi - The properties of Brahmi are - Rasayana, Medhya, Smrutiprada, Vayasthapana, Buddhi, Prajna, Medha Karaka.

Amalaki - The properties of Amalaki are Rasayana, Medhya, Smriti, Balya and Vayasthapana

CONCLUSION

Bruhmana Nasya Karma with Kalyanaka Ghrita pacifies Vata, benefits as Medhya, Balya, Smriti Karaka. Nasya Karma gives strength to all Indriya and produces Laghuta of the body. S-GABA Churna: all drugs are Rasayana, Medhya, Balya, Vayasthapana, helps in relieving the psychological symptoms in Perimenopausal syndrome.

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