Evaluation of the Effect of Ashwagandhadi Ksheerbasti on Peri-menopausal Psychological and Vasomotor Conditions Through Serum Estradiol Estimations

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ABSTRACT

Introduction: Perimenopause is the time between the onset of waning ovarian function associated with menstrual irregularity and vasomotor symptoms and the year after the last menses. This period is characterized by irregularities of menses; lengthy and heavy menses with episodes of amenorrhea, sub-fertility, hot flushes which falls under vasomotor symptoms, a psychological symptom like insomnia.

Objectives: To evaluate the effect of Ashwagandhadi ksheerbasti on psychological symptoms, vasomotor symptoms and serum estradiol fluctuations in perimenopause with the administration of Ashwagandhadi ksheer Basti along with counselling in one group and only with counselling in other groups.

Methods: In age group ranging of 41-50 years, women suffering from perimenopausal psychological and vasomotor symptoms meeting the criteria mentioned in standard score scale included in the study.

Expected Results: Recent studies show bone marrow transplantation restores follicular maturation and steroid production in mouse models for primary ovarian failure. Follicular recruitment occurs in the bone marrow before ovaries. We postulate a theory based on Ayurveda principle stating, the base of the reproductive system is in the bone marrow. The female reproductive component is generated and derived from the bone marrow and its treatment leads to improve folliculogenesis, estradiol levels and symptoms like hot flush, depression, insomnia and panic disorder.

Conclusion: It will be drawn after obtaining the results of the study.

Key Words: Ashwagandhadi ksheerbasti, Perimenopausal, Estradiol

INTRODUCTION

Menopausal transition, or 'perimenopause', is a defined period beginning with the onset of irregular menstrual cycles until the last menstrual period and is marked by fluctuations in reproductive hormones.¹ This period is characterized by irregularities of menses; lengthy and heavy menses with episodes of amenorrhea, sub-fertility, hot flushes which falls under vasomotor symptoms, a psychological symptom like insomnia. 4 years is an average span during which these symptoms appear prior menopause.² Primary source of sex

hormones like estrogen, progesterone and androgens in the ovary. Menopause resulting in infertility secondary to oocyte depletion is the major event. The woman holds her at high risk for endometrial hyperplasia and carcinoma when exposed to endogenous or exogenous estrogen in form of unopposed administration. According to a study, perimenopausal women showed greater symptoms as compared to menopausal women. The perimenopausal period has been considered a peak phase for the menopausal symptoms.³ Also, the period of post menopause showed declining symptoms in same women.⁴ An Indian study found that the perimenopausal

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group included more prevalent vasomotor symptoms while postmenopausal age group were suffering from musculoskeletal symptoms in the majority. Greater prevalence of biological and psychological symptoms have been recorded in women with low socioeconomic status.⁵

Women all over the world now have to spend almost 1/3rd of their lives in menopause years because average life expectancy is increasing. The Collaborative Group on Hormonal Factors in Breast Cancer showed a significant increase in breast cancer risk in 52,000 women using HRT-Estrogen replacement therapy for >5 years.⁶⁻⁸ The WHI findings have drawn attention to non-hormonal treatments of hot flushes and other menopausal symptoms. Use of HRT, Bisphosphonates, SERMs and anabolic steroids are not devoid of adverse effect.⁹ It is need of the hour to carry researches for finding efficient, economic, natural and safer formulations to manage peri-menopausal symptoms. Present Pilot Study considers the four disorders a patient is suffering from, in

perimenopause and aims to observe and record the serum estradiol fluctuations while receiving Ashwagandhadi Ksheerbasti (administration of medicated regime per rectum) along with counselling in one group and counselling only in other group (Table 1-3).

OBJECTIVES

1. To evaluate the effect of Ashwagandhadi ksheerbasti on psychological symptoms and vasomotor symptoms during perimenopause.
2. To evaluate serum estradiol fluctuations in perimenopause with the administration of Ashwagandhadi ksheer Basti.
3. To observe the efficacy of duration of basti administration.
4. To observe the effect of counselling in symptoms of perimenopause.

MATERIAL AND METHODS

Table 1: Inclusion and Exclusion Criteria

Place of the Study	MGACH & RC, Wardha
Inclusion criteria	Patient of age group - 41-50 years Patient suffering from peri menopausal psychological and vasomotor symptoms. (Meeting the criteria mentioned in standard score Scales)
Exclusion criteria	Patient on hormone replacement therapy (H.R.T.) Patient with severe menorrhagia. Patients with any organic lesions of reproductive tract like tuberculosis, carcinoma and congenital deformities, or any other pelvic pathology. Patients with Known case of adrenal hyperplasia, androgen secreting neoplasm, thyroid abnormalities, Cushing's syndrome, cardiac diseases. Patient with hemoglobin < 7. Patients with Known case of DM. Patients who are unwilling to become subject for study
Withdrawal Criteria	In case of an acute or severe illness. In case, patient leaves against medical advice.

Table 2: Study Groups and Sample Size

2-Groups	Group A-Intervention with Basti along with counselling Group B - Intervention with Counselling only
Total Sample size	20 female (10 in each group)
Standard Pattern for basti instillation	Yogabasti - Alternate Ksheer (medicated milk) and medicated oil
Dose	Ksheer (Medicated milk)-364 ml, Medicated Oil- 64 ml
Comparison	Counselling /No other intervention
Ingredients of Ashwagandhadi oil (3 days Siddhi)	Ashwagandha Erandamool Rocksalt sesame oil
Ingredients of Ashwagandhadi ksheer (Freshly prepared)	Ashwaganshada oil Rock salt Bruhat pachmool Laghu pachmool Makshika/Honey Godugdha/milk (fresh for each patient)

Table 3: Screening and Investigations

Screening Investigation	BSL HB%
Parameters -1	Hot flush-Hot flush behavioral scale (HFBS) will be used for analysis.(vasomotor) Insomnia - Athens insomnia scale (SIS) will be used for analysis.(Psychological) Depression - Hamilton depression rating scale (HAM-D)will be used for analysis. (Psychological) Panicking - Panic disorder severity scale (PDSS) will be used for analysis.(Psychological)
Parameter -2	Serum estradiol level (o day , 10th day of basti and 18th day of basti) Above timings for group B without basti. o day- Follicular phase,10th and 16th day- luteal phase
Timings of Basti in intervention group	Post menstrual 9th to 16th day
Intervention protocol-(Group A)	Counselling 3 days -Panchakol powder - 3 gm BID 1 day - Whole body abhyanga and Svedan 8 days -Basti
Group B	Counselling

Evaluation endpoints

Following symptoms will be evaluated,

Vasomotor symptom: Hot flush

Psychological symptoms: Depression, Cognition, Insomnia

Psychiatric disorders: Schizophrenia, Bipolar disorders, Panic disorders,

the receptivity of follicles for FSH to enhance folliculogenesis and thereby more estrogen secretion.

To observe the estrogen fluctuations in serum by recording three samples at certain intervals of each patient, we tried to show the relationship of the drug, its route and serum estradiol levels, hypothesizing the intervention affects through bone marrow and folliculogenesis for enhancing or at least fluctuating serum estradiol levels.

EXPECTED RESULTS

Statistical analysis will be performed with Paired and unpaired t-test and the result will be drawn. HRT which is an estrogen replacement therapy in the deficient or lesser estrogen conditions like peri and post-menopause. We postulate a theory based on Ayurveda principle stating, the base of the reproductive system is in bonemarrow/female reproductive component are generated and derived from the bone marrow (Majja-Shukra concept-Charak) The intervention category of drug (Tikta) and route of administration is an exclusive bone-bone -marrow treatment as per Ayurveda texts (Charak-Vagbhat) which can enhance the folliculogenesis and thereby estrogen secretions.

Recent studies showing bone marrow transplantation experiments in poor ovarian reserve to increase folliculogenesis and thereby ovarian hormone levels can be taken into consideration for supporting the postulated theory. (Mohasen Ghadi et al-2012)The estrogen is secreted from ovarian follicles which are said to be originated from bone marrow as per Ayurveda principle as well as recent animal studies. The more active and healthy bone marrow is, the more efficient is the folliculogenesis and estrogen secretion. Intervention possibly increases the rate of folliculogenesis or might increase

DISCUSSION

Symptoms of perimenopause (Zeffcoat's PG) in general and subjective parameters of present study fall in the criteria of Vata pitta disorders and hence abnormal perimenopause is an abnormal Vata-Pitta condition. The Basti (per rectal instillation of drugs) as the route itself is effective and indicated in Vata disorders and drug (Ashwagandhadi ksheer) itself is indicated in Pitta disorders. Vata resides in Asti (Bone)and its vitiation leads to athikshaya(degeneration of bones) and Basti is the key route of management for abnormal Asthi (Ayu). Bone marrow(Majja) is closely related to pitta and rakta and hence tikta drugs are advised as tikta normalizes pitta.

The principle treatment for bone-related disorders is Tikta-ksheer basti (Ashwagandha-Tikta). On 8th day Basti reaches to Asthi (Sushrut). Interrelationship of Asthi-majja -Shukra/ Artava in female (Bone - Bone marrow and ovaries/follicles) Basti works in the bone, Bone marrow-majja- Neurological functions. Recent studies show bone marrow transplantation restores follicular maturation and steroid production in mouse models for primary ovarian failure. (Mohasen Ghadi et al.-2012)Follicular recruitment occurs in the bone marrow before ovaries. Shukra/Artava/ Female-reproductive

component-(HPO) is the product of Bone marrow (Ayu) Menopause-transition-hampering normal life-shukra/Artava malfunctioning.

CONCLUSION

It will be drawn after obtaining the results of the study.

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