



Research Article

A CLINICAL TRIAL ON THE EFFECT OF GUDUCI (*TINOSPORA CORDIFOLIA* (WILLD) MIERS) SATVA ALONG WITH KSHEERA IN PERIMENOPAUSAL SYMPTOMS

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<p>Article info</p> <p>Article History: Received: 18-01-2022 Revised: 02-03-2022 Accepted: 26-03-2022</p> <p>KEYWORDS: <i>Rajakshaya, Guducisatva, Medhyarasayanam, vayastapana, Greene Climacteric scale.</i></p>	<p>ABSTRACT</p> <p>Perimenopause refers to the period around menopause. In Ayurveda it is considered as <i>Rajakshaya</i>, the transition period of body from predominance of <i>Pitta dosha</i> to <i>Vatadosha</i> which is characterized by aggravation of <i>Vata</i>, alteration of <i>Pitta</i> and <i>Kaphadosha</i>. It is included as a <i>Swabhavikavyadhi</i> in Ayurveda. Management of <i>Dhatukshaya, Rasayana, Balya</i> and <i>Rasa- Raktha Prasadana</i> treatments are seen beneficial in this condition. <i>Guduci</i> is one among <i>Rasayana</i> drugs mentioned in Ayurveda. The drug <i>Guducisatva</i> taken for the study is from the classic <i>Yogaratanakara</i> and has <i>Dhatukrith</i> and <i>Vayastapana</i> property. The objective of the study was to evaluate the effect of 1g <i>Guduci Satva</i> along with <i>Ksheera</i> (25ml boiled and lukewarm) in perimenopausal symptoms. Females in the age group 40-50 years with perimenopausal symptoms were selected for the study from the OPD of <i>Prasutitantra-stiroga, GAVC Hospital, Tripunithura</i> as per the inclusion criteria. Study tools are clinical case proforma and Greene Climacteric scale score above 30. Drug was given orally in the dose of 1g twice along with 25ml <i>Ksheera</i> one hour before food. Duration of administration was 30 days and assessment was taken on 0th day, 31st day and 60th day. Results were analysed statistically by Wilcoxon's signed rank test and Friedman's test. The study result is highly significant after treatment with P value <0.001 during treatment and during follow up and is found effective in reducing the symptoms in perimenopause.</p>
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INTRODUCTION

Perimenopause or transition to menopause is a physiological process that affects all women who reach midlife. It is the period of ageing process during which a woman passes from reproductive stage to non-reproductive slugs and it covers 5-10 years on either side of menopause. The perimenopausal stage is characterized by variations in the levels of hormones mainly follicle stimulating hormone, luteinizing hormone, estrogen, progesterone and androgens^[1]. The effect of varying hormonal levels during this period may be experienced as menstrual irregularities, hot flushes, night sweats, insomnia, difficulty in concentrating, depression, headache, loss of memory,

dypareunia, loss of interest in sex etc. Generally all these kind of symptoms are classified under psychological, somatic, vasomotor end urogenital symptoms. During the perimenopausal period, most women feel a general reduction in the quality of life.

Relevance of the study

Women are forced to do multiple roles often dividing their time between family and profession results in high level of stress and strain. These are contributed to alteration in the harmony of the female hormone system in the perimenopausal period. While their health issues were very often neglected, increased exposure to risk factors like lack of exercise, untimely food and sleep further vitiated the situation. These factors often result in the development in the most distressing symptoms of perimenopause such as hot flushes and night sweats. The present conservative treatment modality is being hormone replacement therapy. Thus arise in the necessity of an alternative treatment modality.

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The main cause of menopausal symptoms is the reduction in the level of estrogen. The menopausal changes affect different women differently, depending on the physical, mental, emotional and social condition of the woman. The endocrine, reproductive, and central nervous systems are affected by reduced estrogen levels at the time of the last menstrual period. Early symptoms of menopause includes irregular and abnormal menstrual bleeding, vasomotor symptoms mainly hot flushes and night sweats, sleep dysfunction includes inability to fall asleep, night time wakefulness, loss of sleep and psychological symptoms are mainly depressed mood, irritability, lethargy, lack of energy, sadness. Late symptoms are osteoporosis, cardiovascular diseases, decrease in concentration and memory, urogenital problems, sexual dysfunction, weight gain.^[2]

Drug Review

Guduchi (fresh stem) is used in the form of *Ghanasatva*

Botanical name: *Tinosporacordifolia* (Willd).Miers ex Hook & Thoms



Figure 1: *Guduchi* Plant

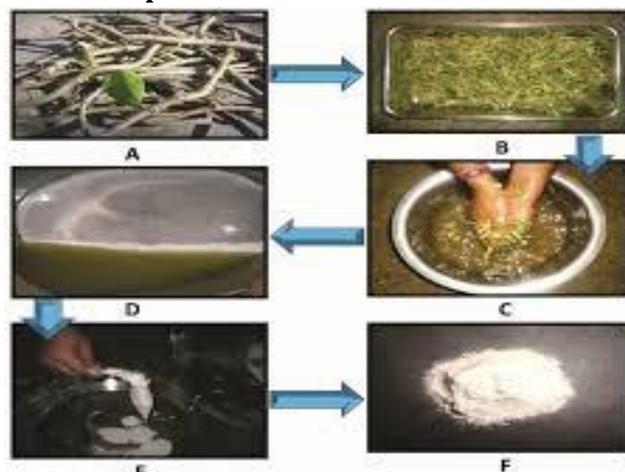


Figure 2: Fresh *Guduchi* Stem

Pharmacological properties of *Guduchi*^[3]

Rasa- As per most of the Ayurveda texts, the drug *Guduchi* has *Tiktha*, *Kashayarasas*, *Guna-* most of the *Acharyas* have stated *Laghuguna* of *Guduchi*, *Veerya-* Almost all the *Nighantus* have enumerated *Ushnaveerya* for *Guduchi*. *Acharya Vagbhata* mentioned that *Guduchi* has *Sheetaveerya*, *Vipaka-* *Acharya Vagbhata* enumerates *Katuvipaka* for *Guduchi*. However most of the *Nighantus* opine that *Guduchi* has *Madhuravipaka*.

Mode of Preparation



A- Guduci stem, B- pounded coarse slimy mass, C- maceration, D- removal of supernatant liquid, E- scraping of white sediment, F- dried Guduci Satva.

Guducisatva was prepared according to the reference in *Yogaratanakara*. Fresh *Guduci* stems were collected and chopped. These were washed well crushed into coarse slimy mass and 4 parts of water was added. Stems were macerated well manually in the water and then filtered through a clean cloth. The filtrate was kept aside whole night and next day the supernatant water was removed. *Satva* settled at the bottom of the container was collected and dried and packed in 1g in air tight plastic covers -Dosage: 1gm, Anupana: cow's milk

AIM- To assess the effect of *Guduci Satva* along with *Ksheera* in perimenopausal symptoms.

OBJECTIVE OF THE STUDY- To evaluate the effect of *Guduci Satva* along with *Ksheera* in the somatic, vasomotor and psychological symptoms of perimenopausal symptoms.

MATERIALS AND METHODS

Study design was single group Pre and post interventional study. The patient's status after treatment is compared with the status before treatment. Study setting was the clinical study conducted in OPD of Prasuti Tantra & Striroga in Govt. Ayurveda collage, Tripunithura.

Study population includes 27 females of age group 40-50 years who are diagnosed as having perimenopausal symptoms fulfilling inclusion criteria, attending Outpatient Department of Prasutitantra Striroga, Govt. Ayurveda College & Hospital, Tripunithura are taken for study. Inclusion criteria-females in the age group 40-50 years diagnosed to have perimenopausal symptoms according to Greene climacteric scale score above 30. Exclusion criteria-surgical menopause, any known case of malignancy, psychiatric disorders, Patients with systemic and chronic illness and pregnancy. Sample technique: 27 females and sampling procedure is convenience sampling.

Study tools were assessment of perimenopausal symptoms as per Greene climacteric scale by case proforma and changes were noted. (before treatment, after treatment and after follow up).

Study Procedure: 27 female patients of age group 40–50 years with perimenopausal symptoms attending the OPD of Govt. Ayurveda college Hospital, Tripunithura were selected for study as per inclusion and exclusion criteria. Necessary lab investigation had done. Perimenopausal symptoms were assessed as per Green Climacteric Scale (by case perfoma was assessed before treatment). Informed consent was obtained from the patients included in the study. The medicine *Guduchisatwa*, which is in the form of fine powder was taken in equal quantity, and given in packets of 1gm. Mode of preparation and administration were explained to the patients along with written advice in local language. 1g of medicine is taken with 25ml of boiled and lukewarm milk 1 hour before food twice

Psychological (1-11), 2. Physical (12-18), 3. Vasomotor (19-21)

daily for one month. Follow up was done after 1 month without medication. A general *Pathya–Apathya* chart is given to each patient. The patients were asked to report on 0th day, 31th day, 60th day for assessment, after treatment and after follow up as per Greene Climacteric Scale.

Duration of Drug Administration: Internal administration of drug was continued for 30 days.

Follow up: Further follow up was done after completing 30 days of drug administration.

Study Period: 2 months.

Assessment: Assessment was taken on 0th day, 31st and 60th day as per Greene Climacteric scale.

Greene Climacteric Scale^[4]

The Greene Climacteric Scale provides a brief measure of menopausal symptoms. It can be used to assess changes in different subjective symptoms before and after treatment. Three main areas are measured:

Symptoms	Not at All 0	A Little 1	Quite a Bit 2	Extremely 3
1. Heart beating quickly or strongly				
2. Feeling tense or nervous				
3. Difficulty in sleeping				
4. Excitable				
5. Attacks of anxiety, panic				
6. Difficulty in concentrating				
7. Feeling tired or lacking in energy				
8. Loss of interest in most things				
9. Feeling unhappy or depressed				
10. Crying spells				
11. Irritability				
12. Feeling dizzy or faint				
13. Pressure or tightness in head				
14. Parts of body feel numb				
15. Head aches				
16. Muscle and joint pains				
17. Loss of feeling in hands and Feet				
18. Breathing difficulties				
19. Hot flushes				
20. Sweating at night				
21. Loss of interest in sex				
SCORE				

The Greene Climacteric Scale provides a brief measure of menopausal symptoms. It can be used to assess changes in different symptoms before and after treatment. Three main areas are measured:

- Psychological symptoms (1-10)- Heart beating quickly or strongly, feeling tense or nervous, difficulty in sleeping, excitable, attacks of anxiety, panic, difficulty in concentrating, feeling tired or

lacking in energy, loss of interest in most things, feeling unhappy or depressed, crying spells, irritability

- Physical symptoms (11-18)- Feeling dizzy or faint, Pressure or tightness in head, parts of body feel numb, headaches, muscle and joint pains, loss of feeling in hands and feet, breathing difficulties
- Vasomotor symptoms (19-21)- hot flushes, night sweats and loss of interest in sex.

These symptoms were scored from 0 to 3 according to the severity of symptoms.

Statistical Analysis: Data were statistically analysed using Wilcoxon Signed Rank test and Friedman's test, after study period. Three pairs of data- Before treatment (BT) - After treatment (AT) - After follow up (AFU) and the results were evaluated further.

Ethical clearance: Ethical clearance had been obtained from the Institutional Ethical Committee Govt. Ayurveda College, Tripunithura, dated 25/04/2018. Ethical committee reference number was 02/PTSR/IEC/2018.

RESULTS AND DISCUSSION

The main aim of the treatment is the symptomatic relief to the discomfort during the menopausal transitional period and to achieve optimal health which will last comparatively for a long period of life. Ayurvedic system of medicine focuses on strengthening the female body by encouraging it to balance, regulate and normalize itself during this transitional period.

The description of this condition as such is not available in Ayurvedic classical literatures. Only a mention about the age of *Rajakshaya* as 50 years is the reference available. As per Ayurvedic concepts, *Rajonivrutti* is considered as sign of *Jara* or aging process due to *Swabhavikalaparinama* that occurs in a female body. *Rajonivrutti* is a very early stage of *Jaravasta* (aging). From the division of a woman's life span, it occurs at the *Sandhikala* of *Madyamavasta* and *Vridhdhavasta*. *Jara* is a *Swabhavikavyadhi* and it is *Nishprathyaneeka*. Though *Rajonivrutti* is a physiological phenomenon, due to stressful lifestyles and unhealthy, irregular food habits it becomes a state of pathology. Ayurveda classifies different phases of women's life time according to the status of *Doshas*, *Dhatu*s and *Agni*. Hence *Rajapravrutti* and *Rajonivrutti* are also dependent on condition of these factors.

In Ayurvedic classics, *Dhatuparipurnata* at *Youvanavasta* is mentioned as responsible factor for *Rajotpatti*. It marks the female to be capable to start her reproductive life. With the advancement of age, the quality of *Dhatu*s declines day by day. So that it can neither nourish nor hold the body. From these facts it is clear that *Dhatukshaya* ultimately ends up with *Arthavakshaya* or *Raja kshaya*. It may be the main

cause of *Rajonivrutti* that occur in *Rarapakwasareera* of females.

Thus the condition is considered as a *Swabhavabalapravruttha vyadhi*, further classified into *Kalaja* and *Akalaja*. Generalized degradation in the quality of *Dhatu*, *Vatavridhi*, *Kaphakshaya*, *Agnimandya* and *Jaravasta* leads to *Rasadi dhatukshaya* and finally *Arthavakshaya*. In addition *Rukshata* and *Sosha* of takes place at *Arthavavahasrotas* and all these changes result in *Arthavakshaya* in *Kalaja Rajonivrutti*.

Discussion on data related to clinical picture and response to treatment

Perimenopause is the period around menopause and it is the time period during which the women's body makes its natural transition towards menopause. The transition period is characterized by various signs and symptoms, classified as vasomotor, somatic, psychological and urogenital symptoms. Classical descriptions of *Rajonivrutti* lakshanas are not available except the age of *Rajakshaya* as 50 years. *Rajonivrutti* is a *Jarapakwaavasta* of body and it is considered as a *Swabhavabala pravruttha vyadhi*. In perimenopause *Paithika* nature of body changes to *Vathika*, ultimately results in *Vatavruddhi* and *Pittakopa*. Hence line of management includes *Vata Pitta samaka* and *Rasa rakthaprasadaka*.

The perimenopausal symptoms complained with more severity were hot flushes, night sweats, anxiety and loss of interest in sex in the present study. After the administration of drug, the following results were obtained.

Vasomotor Symptoms: The main vasomotor symptoms experienced by perimenopausal women are hot flushes and night sweats as per Greene climacteric scale. As per Paired t test, there is statistically significant result after treatment and after follow up period with P value <0.05. This shows the drug is effective in reducing vasomotor symptoms. The most likely reason for the symptoms that can occur in perimenopause is that hormonal fluctuations affect the mechanisms that control blood pressure and temperature control. The hot flashes in perimenopausal are due to *Prakupitha Pitta* and *Vata*. *Santhapasamaka* property of *Guduchi* is widely accepted in Ayurvedic practice. *Snigdha guna madhura rasa* and *Madhura vipaka* can act as *Vata pitta hara*, *Dahaprasamaka* and attributes *Rakthaprasadaka* property to *Guduchisatva*. *Guduchi* has *Rakthasodhaka karma* on *Rakthadhatu*. This helps to reduce the excess body heat formation.

Psychological symptoms: Here all the paired comparisons are highly significant with P value <0.001. This shows the effectiveness of drug in the treatment of psychological symptoms. Psychological symptoms in perimenopause are mainly caused by *Vatavruddhi* and *Pitta kopa*. *Guduchi* is one among the *Vata pitta samana* and it also has *Medhya* property. *Snigdha guna* of

Guduchisatva can attribute *Vatasamaka* action of *Guduchi*. *Medhya* properties can enhance the concentration and memory in this period. Numerous antioxidants present in *Guduchi* can act against the free radical formation by reducing oxidative stress in this degenerative phase.

Somatic symptoms: After treatment there is reduction in somatic symptoms score of Greene climacteric scale. As per paired t test, P value <0.001 after treatment and after follow up period. This shows the drug *Guduchisatva* along with *Ksheera* is highly significant in reducing somatic symptoms. The somatic symptoms in perimenopause are mainly due to

Total score of Green climacteric scale

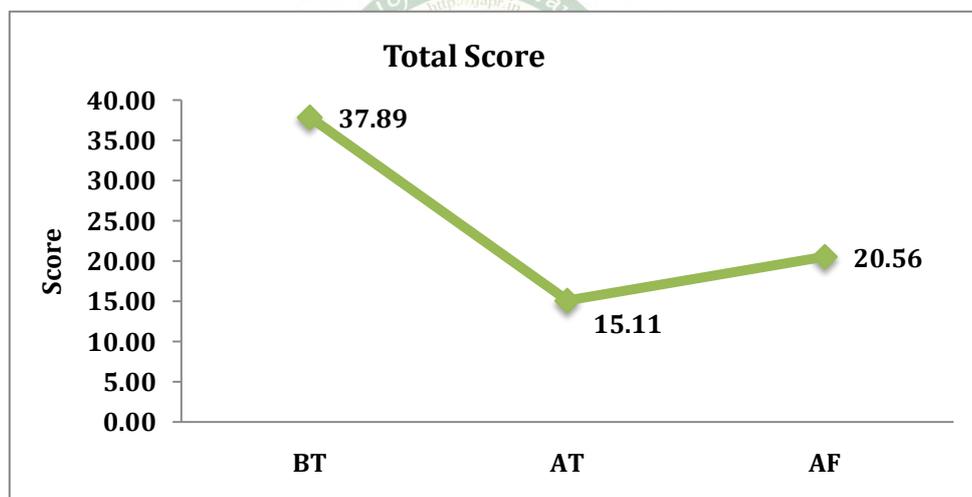
Vatavrudhi and *Pitta kopa*. *Guduchi* has *Deepanapachana*, *Vata pitta samaka* and *Snigdha*guna which helps to relieve the muscle and joint pain. *Pittaraktaprasadaka* property of *Guduchi* can relieve dizziness and fainting. *Snigdha*guna of *Guduchisatva* attribute to *Balya*, *Jeevaneeya* properties.

Total score of Greene climacteric scale: After one month of treatment, there is reduction in total score of Greene climacteric scale. As per Paired t test there is statistically highly significant result after treatment and after follow up with P value <0.001. This shows *Guduchi satva* along with *Ksheera* is highly effective in reducing the total score of Greene climacteric scale.

Table 1: Effectiveness of the Treatment in Reducing Total Score of the GCS.

	N	Total Score		Paired Comparison	Paired Difference		Paired t test	
		Mean	Std. Deviation		Mean	Std. Deviation	T	p value
BT	27	37.89	5.287	BT-AT	22.778	4.933	23.993	0.000
AT	27	15.11	4.300	AT-AF	-5.444	3.856	-7.336	0.000
AF	27	20.56	4.475	BT-AF	17.333	3.199	28.159	0.000

Graph 1: Effectiveness of the Treatment in Reducing Total Score of the GCS

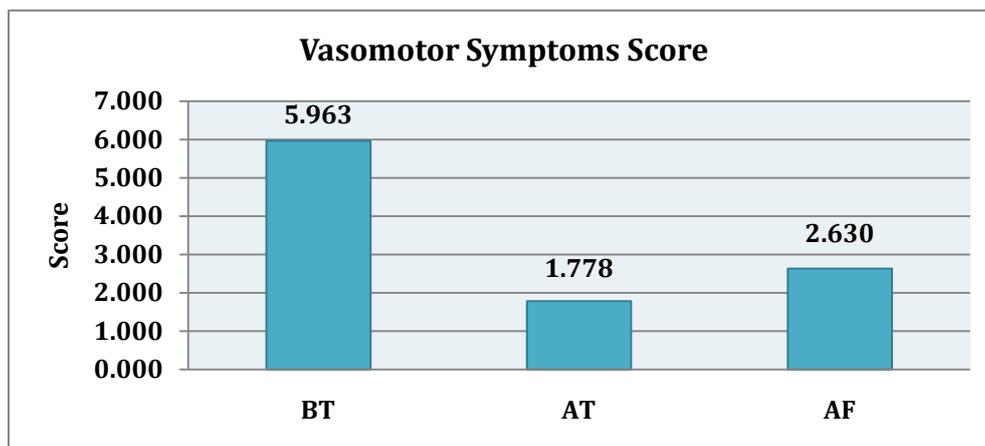


Vasomotor symptoms score

Table 2: Effectiveness of Treatment in Reducing Vasomotor Symptoms Score

	N	Vasomotor Symptoms		Paired Comparison	Paired Difference		Paired t test	
		Mean	Std. Deviation		Mean	Std. Deviation	T	p value
BT	27	5.963	0.192	BT-AT	4.185	1.360	15.993	0.000
AT	27	1.778	1.368	AT-AF	-0.852	1.610	-2.749	0.011
AF	27	2.630	1.149	BT-AF	3.333	1.144	15.146	0.000

Graph 2: Effectiveness of Treatment in Reducing Vasomotor Symptoms Score

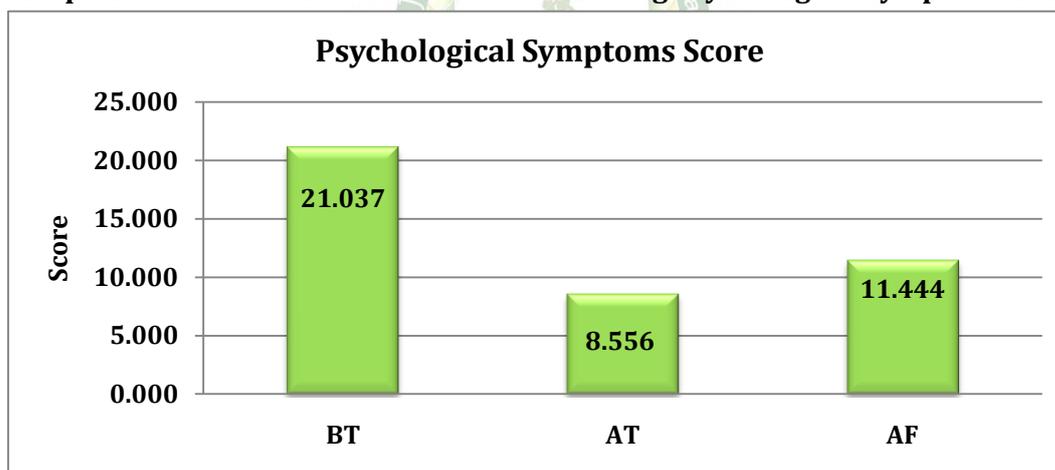


Psychological Symptoms Score

Table 3: Effectiveness of Treatment in Reducing Psychological Symptoms Score.

	N	Psychological Symptoms		Paired Comparison	Paired Difference		Paired t test	
		Mean	Std. Deviation		Mean	Std. Deviation	T	p value
BT	27	21.037	3.888	BT-AT	12.481	2.979	21.771	0.000
AT	27	8.556	2.940	AT-AF	-2.889	2.501	-6.001	0.000
AF	27	11.444	3.226	BT-AF	9.593	2.438	20.446	0.000

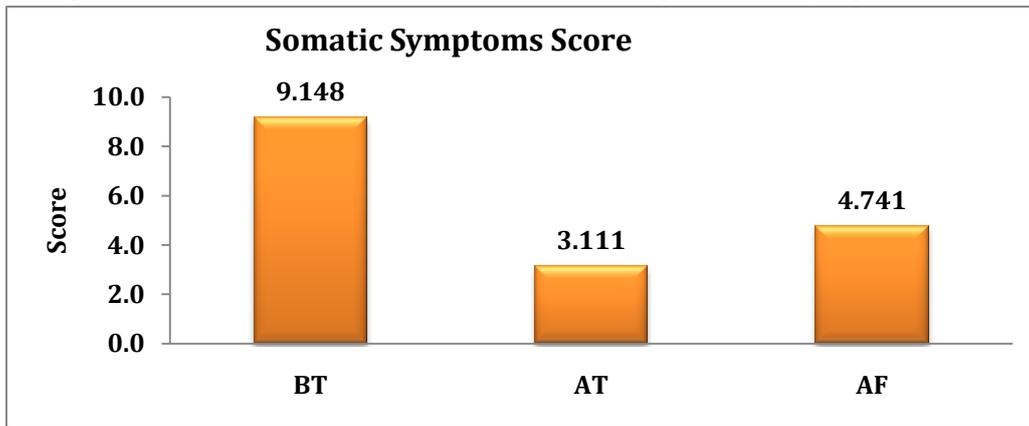
Graph 3: Effectiveness of Treatment in Reducing Psychological Symptoms Score



Somatic Symptoms Score

Table 4: Effectiveness of Treatment in Reducing Somatic Symptoms Score

	N	Somatic Symptoms		Paired Comparison	Paired Difference		Paired t test	
		Mean	Std. Deviation		Mean	Std. Deviation	T	p value
BT	27	9.148	3.860	BT-AT	6.037	2.638	11.890	0.000
AT	27	3.111	2.154	AT-AF	-1.630	1.523	-5.560	0.000
AF	27	4.741	2.654	BT-AF	4.407	2.117	10.818	0.000

Graph 4: Effectiveness of Treatment in Reducing Somatic Symptoms Score**Probable Mode of Drug Action**

Guduchi satva is having *Madhura rasa*, *Madhura vipaka*, *Laghu Snigdha Guna* and *Vatapitta samana* properties. It is also act as *Raktaprasadaka*, *Pachana deepana*, *Jeevaniya*, *Dahaprasamaka*. The vasomotor symptoms due to *Prakupitha pitta* are sudden and acute increase in body heat followed by profuse sweating. The drug *Guduchi* being *Rasa Rakthaprasadaka* and *Santhapa Samaka*, it is more preferred to relief vasomotor symptoms in perimenopause. *Ksheera* is having *Madhura rasa*, *Guru Snigdha guna*, *Seethaveerya*, *Madhura vipaka*, owing to its properties, it acts as *Vatapittahara*, *Preenana*, *Brimhana*, *Jeevaniya*, *Balya*, *Manaskara*. The combined effect of *Guduchisatva* and *Ksheera* can be acting effectively in perimenopausal symptoms.

CONCLUSION

- The drug *Guduchisatva* along with *Ksheera* is significant with P value <0.05 in the vasomotor symptoms as per Greene Climacteric Score scale. This can be due to the *Vata pitta samaka* and *Rasa raktaprasadana* property of *Guduchisatva* and its *Anupana Ksheera*. In Ayurvedic practice, the drug *Guduchi* widely uses as a *Santhapasamaka* drug.
- The drug *Guduchisatva* along with *Ksheera* is significant with P value <0.05 in the psychological symptoms of the patients. This can be due to the *Vatapittasamaka* and *Medhyaproperty* of the *Guduchisatva* and its *Anupana ksheera*.

- The drug *Guduchisatva* along with *Anupana* of *Ksheera* is significant with P value <0.05 in the somatic symptoms of patients. This can be due to the *Vata Pittaprasamaka*, *Agnideepana* and *Amapachana* property of the *Guduchisatva* attributed by its *Madhura rasa* and *Madhuravipaka*.
- Hence there was a highly significant reduction with P value <0.001 in the total score of Greene Climacteric Scale which include vasomotor, psychological and somatic symptoms.
- A common *Pathyahaaravihara* protocol to all patients also helped in attaining the above result.

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