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A clinical study to evaluate the efficacy of *Dahaprashamana Gana* in the management of Vasomotor Symptoms in Perimenopause and Menopause

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ABSTRACT

Background: Menopause is a transitional phase marking the finale of the reproductive life of a woman. It's associated with complex physical and psychological changes. The vasomotor symptoms are the hallmark of menopause, affecting 75% of women and among this 25% are severely affected and are the most common and long-lasting symptoms according to many studies. In Ayurvedic literature "*Rajonivrutti*" has very little references available. The age of *Rajonivruthi* is said to be around 50 years as per the classics and it is considered as a premonitory sign of *Jara* in women. The vasomotor symptoms like hot flushes, night sweats, irritability clearly indicate the involvement of dominant *Pitta Dosh*a associated with *Vata*. Hence a drug that pacifies *Pitta* along with *Vata*, without disturbing *Kapha* will be ideal for treatment. *Dahaprashamana Gana* explained in Charaka Samhitha Sutrasthana, denotes a group of medicinal plants, which has been indicated as useful in removing *Daha* which is a direct manifestation of *Pitta*. **Aim:** To analyse the effect of *Dahaprashamana Churna* in the management of vasomotor symptoms in perimenopause and menopause. **Method:** A simple randomized open label controlled clinical study thirty subjects fulfilling the diagnostic criteria of Vasomotor symptoms were selected and randomly categorized to Group A and Group B by using lottery method. **Result:** *Dahaprashamana Churna* found to be effective in all subjective and objective parameters. **Conclusion:** *Dahaprashamana Churna* is more effective than Vitamin E in the management of Vasomotor symptoms in Perimenopause and Menopause

Key words: Vasomotor Symptoms, Rajonivrutti, Pittahara, Dahaprashamana, Vitamin E capsule

INTRODUCTION

Menopause is a transitional phase marking the finale of the reproductive life of a woman. It is associated with complex changes in both physical and psychological aspects. The changes are chiefly classified as vasomotor, psychological, genital and

urinary symptoms. Among these, vasomotor symptoms are hallmark of menopause affecting 75% of women and in this 25% are severely affected. Vasomotor symptoms of menopause are characterized by episodes of profuse hot flushes accompanied by sweating, experienced predominantly around the head, neck, chest and upper back. These symptoms are experienced by majority of women during menopausal transition and they are the most common and long-lasting symptoms according to many cohort and cross sectional studies. Following menopause hot flashes are still pervasive and are experienced by 50% to 85% of menopausal women. Study done in group of women living in Asia, the intensity of vasomotor symptoms was 58% of women surveyed in 2013. Among menopausal symptoms, vasomotor symptoms among women range from 30% to 80% and they are affecting quality of life too.^[1] Contemporary science offers hormone therapy to ease menopausal symptoms. Hormone therapy

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carries increased risk of endometrial & breast cancer, thromboembolic disorders, biliary diseases, dementia, emotional changes. There is an increased rate of discontinuity of HRT among women. It is therefore necessary to introduce safe and effective medications for the management of the same.^[1]

The term for menopause in Ayurveda is “*Rajo Nivruthi*.” Ayurvedic literature has very little reference available about *Rajo Nivruthi* or menopause. The age of *Rajonivruthi* is said to be around 50 years as per the classics and it is considered as a premonitory sign of *Jara* in women. The vasomotor symptoms clearly indicate the involvement of dominant *Pitta Dasha* associated with *Vata*. Hence a drug that pacifies *Pitta* along with *Vata* is considered for this study. *Dahaprashamana Gana* which has been explained in *Charaka Samhitha Sutrasthana*, denotes a group of medicinal plants, which has been indicated as useful in removing *Daha* or burning sensation which is a direct manifestation of *Pitta*. The name is derived from the word *Daha*, meaning burning sensation or internal heat and *Prashamana* which can be translated as “pacifying”. The *Gana* contains a total ten drugs grouped together viz; *Laaja, Chandana, Kashmarya, Madhuka, Sharkara, Nilotpala, Usheera, Shariba, Guduchi* and *Hreebera*.^[2]

OBJECTIVES OF THE STUDY

1. To evaluate the effect of *Dahaprashamana Gana* in the management of vasomotor symptoms in menopause.
2. To re-evaluate the effect of Vitamin E capsule in the management of vasomotor symptoms in menopause.
3. To compare the efficacy of *Dahaprashamana Gana* and Vitamin. E capsule in the management of vasomotor symptoms in menopause and analyze the results statistically.
4. To assess correlation of FSH and Estradiol levels in the occurrence and severity of vasomotor symptoms and management outcome of vasomotor symptoms in perimenopause and menopause.

MATERIALS AND METHODS

Since the present study was a controlled study two drugs i.e., a standard and the test drug was selected, they are:

- *Dahaprashamana Churna*
- Vitamin E Capsule

Dahaprashamana Churna ingredients are *Laja, Chandana, Kashmarya, Madhuka, Guduchi, Usheera, Sariva, Nilothpala, Hreebera*

The raw drugs of *Dahaprashamana Gana* - 200gram each were cleaned and dried properly. Each drugs was separately finely powdered and sieved. Then accurately weighed and then all were mixed together with 3600 grams of *Sharkara*, after allowing to cool, the prepared *Churna* was collected and stored in air tight container. 360gram of *Dahaprashamana Churna* was measured and packed in zip lock cover and provided to individual subjects.

Sampling Method and Research Design

Source of data

A series of 30 subjects with Vasomotor symptoms were randomly selected, from the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. The selected 30 patients were divided into 2 equal groups of 15 patients. A detailed Proforma were prepared considering all points pertaining to the study were prepared. The parameters considered for the study was scored on the basis of Standard methods and were analyzed statistically.

Research design

It is an open labelled controlled clinical study with pre and post-test design, where 30 subjects with Vasomotor symptoms were selected for the study.

Diagnostic Criteria

Diagnosis will be made on the basis of the following criteria of perimenopause / menopause. The stages of reproductive aging workshop^[3] (STRAW Criteria)

Inclusion Criteria

- Subjects aged between 40 to 60 years.
- Subjects having vasomotor symptoms in perimenopause / menopause

Exclusion Criteria

- Subject aged less than 40 years and above 60 years.
- Hemoglobin less than 8 gram percentage.
- Subject known case of, or having history of coagulopathy.
- Subjects with other systemic illnesses like Diabetes Mellitus, Hypertension, Thyroid irregularities, Cardiac diseases.
- Subject recognized as carcinoma or Previous history of carcinoma.
- Any pre-existing psychological disorder.

General Investigations

- Hemoglobin
- RBS
- FSH
- Estradiol
- Thyroid profile

Group A

The subjects in this group will be administered with the following drug orally

- Dahaprashamana Gana Churna* 6g BD with Hot water.
- Time of administration - Before food
- Duration of treatment for above drug would be one month.
- Follow up - 30th day and 60th day.

Group B

The subjects in this group will be administered with following drug orally

- Vitamin E capsule (200 IU) - 1 BD
- Time of administration- Before food

- Duration of treatment- 30 days
- Follow up -30th day and 60th day

Criteria for Assessment

The improvement in the symptoms was assessed mainly on the basis of relief in the signs and symptoms of the disease.

Subjective Parameters

Each of the symptoms are assessed by present or absent, no. of times per day, severity, which ever interferes with daily activities.

- Hot flushes
- Night sweat
- Palpitation
- Anxiety

Objective Parameters

- Daily Hot Flash Dairy (Sloan *et al.* 2001) (Hot Flush Index)
- Hot Flash Related Daily Interference Scale (HFRDIS)
- The Pittsburgh Sleep Quality Index (PSQI)
- Hamilton Anxiety Rating Scale (HAM-A)

OBSERVATIONS

All the 30 patients who approached the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. All the patients were the fresh case and were not initiated on other allopathic and Ayurvedic drugs. In this clinical study maximum number of subjects 36.6% (11) belonged to the age group of 41-45 years, followed by 33.3% (10) belonged to 46-50 age group, 23.3% (7) age group of 51-55yrs and 6.6% (2) belong to 56 - 60yrs of age group. Maximum number of subjects were under middle class with 46.6% (14) and in upper middle class 40% (12) followed by lower middle class 13% (4).: Among 30 subjects 60% (18) were Employees and 40% (12) were Housewives.

Observations on Education, Maximum subjects were Graduates i.e., 53% (16) followed Higher Secondary with 23% (7) then by Post Graduates with 10% (3) and High School Primary 6% (2). In this clinical study, 60% (18) were following mixed diet and 40% (12) were vegetarian. On observation on Dominant Rasa 73.3% (22) subjects were having *Ahara* with *Katu Rasa* dominant followed by 16% (5) with *Amla Rasa* dominant and then 10% (3) *Madhura Rasa* dominant. Habits: While observing *Kautumbhika Vruttantha*, 40% (12) whose mothers having same symptoms, 33.3% (10) were not having family history, 26.6% (8) whose sister having same symptoms.

Observation on *Diwaswapna* 63.3% (19) were doing *Diwaswapna* and 36.6% (11) were not doing. Incidence based on parity Maximum of 86.6% (26) subjects were of multiparous, 10% (3) were primi and 3.3% (1) were nulliparous. While observing on Method of Contraception, 73.3% (22) were Tubectomised, 16.6% (5) were using Condom and 10% (3) were not using any method of contraception. While we are seeing *Prakriti* 66.6% (20) were *Vata Pitta Prakriti* followed by 23.3% (7) were *Pitta Kapha Prakriti* and 10% (3) were *Vata Pitta Prakriti*. 70% (21) were under Normal Index, 20% (6) were under Over weight, 6% (2) were Under weight and 3% (1) under Obesity.

History of Medical Treatment for Vasomotor symptoms: Among 30 subjects 83.3% (25) were not underwent treatment for vasomotor symptoms previously and 16% (5) were took treatment previously. While analyzing Hb percentage 19 patients (63%) had Hb% less than 11.5gm% and 11 patients (37%) had it ranging between 11.5-16 gm%.

Observation on FSH, out of 30 subject 26.6% having FSH value between 101 to 300mueU/ml, 23.3% having FSH value between 40-100mueU/ml and 20% having FSH value between 300 to 400mueU/ml and 3.3% value less than 40mueU/ml. While observing Estradiol Values 46.6% (14) having Estradiol value between 21 to 40pg/ml, 33.3% (10) having Estradiol value less than 20pg/ml, 10% (3) having Estradiol value between 41 to 60pg/ml and 6.6% (2) vales between 61 to 80 pg/ml and 3.3% (1) having value between 81 to 100pg/ml.

Friedman's test - Statistical Analysis of Hot Flash within Group A

Result of comparison of Hot Flash

Parameter	Group	0 th Day	30 th Day	60 th Day	P value	Inference
Hot Flash	A	2.79 ± 0.49	0.29 ± 0.469	0.07 ± 0.26	p<0.000 p<0.000	HS
	B	2.67 ± 0.488	2.06 ± 0.834	2.40 ± 0.828	p-0.233 p-0.233	NS
Night Sweat	A	2.40 ± 0.737	0.27 ± 0.458	0.07 ± 0.258	p<0.000 p<0.000	HS
	B	3.00 ± 0.00	2.38 ± 0.352	3.00 ± 0.00	p-0.135 p-0.725	NS

Friedman's Test within Group A and B for Palpitation and Anxiety

Parameter	Group	0 th Day	30 th Day	60 th Day	P Value	Inference
Palpitation	A	0.67 ± 0.488	0.27 ± 0.458	0.07 ± 0.258	p-0.001 p-0.001	S
	B	0.93 ± 0.258	0.83 ± 0.352	0.93 ± 0.258	p-0.360 p-0.360	NS
Anxiety	A	1.93 ± 0.704	0.40 ± 0.507	0.20 ± 0.414	p-0.000 p-0.000	HS
	B	2.87 ± 0.352	2.41 ± 0.507	2.73 ± 0.594	p-0.150 p-0.150	NS

Repeated Period Anova within the Groups for Daily Hot Flash Dairy

DHF D	0 th Day	P Value	30 th Day	P Value	60 th Day	P Value
Group A	5.27 ± 0.884	0.000 HS	0.27 ± 0.458	0.000 HS	0.07 ± 0.258	0.000 HS

Group B	5.53±0.743	0.08 S	4.93±0.884	0.08 S	5.40±0.737	0.493 NS
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Showing Effect size of Daily Hot Flash Dairy

Assessment of Daily Hot Flash Dairy		
	30 th Day	60 th Day
Group A	0.27±0.458	0.07±0.258
Group B	4.93±0.884	5.40±0.737
	MD = 4.66 SD Pooled = 2.70	MD = 5.33 SD Pooled = 2.11
ESD	1.72 - Large	2.52 - Large

Showing Effect size of PSQI

Assessment of PSQI		
	30 th Day	60 th Day
Group A	2.00±0.655	2.00±1.195
Group B	14.33±2.320	14.80±1.971
	MD = 12.33 SD Pooled = 6.59	MD = 17.52 SD Pooled = 5.84
ESD	1.86- Large	2.19 - Large

Showing Effect size of HAM- A

Assessment of HAM - A		
	30 th Day	60 th Day
Group A	4.80±3.460	3.07±2.01
Group B	22.33±2.440	21.67±2.320
	MD = 4.66 SD Pooled = 2.70	MD = 5.33 SD Pooled = 2.11
ESD	1.72 - Large	2.52 - Large

Showing Effect size of HFRDIC

Assessment of HFRDIS		
	30 th Day	60 th Day
Group A	6.73±3.615	6.53±4.406
Group B	59.13±12.374	59.13±10.608
	MD = 52.40 SD Pooled = 35.28	MD = 52.6 SD Pooled = 31.43
ESD	1.48- Large	1.67 - Large

Overall Percentage of Improvement in each parameter in Group A & B

Parameters	Group A %	Group B %	Significance	Clinical Effect Size
Hot Flash	98.7%	20.6%	HS	A >B
Night Sweat	88%	19.7%	HS	A >B
Palpitation	88%	13.2%	HS	A >B
Anxiety	83.2%	16.5%	HS	A >B
Sleep Disturbance	86%	18%	HS	A >B
Total	88.78%	18%		

Showing overall assessment of the study of Group A and B

Percentage of Improvement	Group A (No. of patients)	Group B (No. of patients)
No Change (0 - 24%)	0	9
Mild Improvement (25-49%)	0	6
Moderate Improvement (50-74%)	2	0
Marked Improvement (75 - 99%)	11	0
Complete Relief (100%)	2	0

DISCUSSION

Menopause (*Rajonivruthi*) is a *Swabhavika Kshaya Avastha* and symptoms associated with this condition are a reflection of disturbed *Pitta* and *Kapha Kshaya* and by dominating *Vata*. Hence, through Ayurvedic treatment protocol, we can manage vasomotor symptoms very effectively by doing *Samprapti Vighatana* and through *Vata Pittahara Chikitsa* based on the *Dosha Doosha Avastha* of the patients presenting with the symptoms.

Kala, Swabhava, Vaya, Jara which leads to *Vatavriddhi Avastha, Jaravastha*, generalised *Raukshya, Shosha* and *Kshaya*. This will leads to *Vata Vriddhi, Pitta Vriddhi, Kapha Kshaya* and also *Kha Vaigunya of Rasa, Rakta* and *Medas* which will lead to *Vata Pitta Vriddhi* and which further leads to *Ushnanubhuthi, Swedadhikya, Ratri Sweda* and *Daha*.^[4]

Vasomotor symptoms represent the most bothersome symptoms of menopause and the most common reason women seek medical care at the time of the menopausal transition. Often described by women as hot flushes or night sweats, vasomotor symptoms are associated with a sudden sensation of heat in the face, neck, and chest and persist for several minutes or less. Vasomotor symptoms may also include flushing, chills, anxiety, sleep disruption, and palpitations. During a hot flush, skin temperature rises due to peripheral vasodilation, particularly in the fingers and toes along with sweating. It may take 30 minutes or longer for the skin temperature to return to baseline.^[5]

Mode of action of Dahaprashamana Churna

Acharya Agnivesha in *Charaka Samhita Sutrasthana*, has mentioned '*Daaha Prashamana Gana*' in "*Shat Virechana Shathasritheeya Adhyaya*". The '*Gana*' contains a total of ten drugs grouped together viz; *Laaja, Chandana, Kashmarya Phala, Madhuka, Sharkara, Nilotpala, Usheera, Shariba, Guduchi* and *Hrebera*.

Almost all drugs of *Dahaprashamana Churna* possess *Madhura, Tikta, Kashaya Rasas, Laghu, Snigdha Guna, Sheetha Veerya, Madhura Vipaka* and acts as a *Vata*

Pittahara Yoga overall. All drugs have *Dahaprashamna, Vata Pittahara* and *Raktapittahara* properties.

The medicines as a group acts more on pacifying the *Pitta* related issues where as individual actions also can be found such as *Medhya Guna, Sheetha Guna* etc. which will be helpful in reducing hot flushes and also the associated symptoms such as sweating, palpitations, irritability etc.^[6]

Based on Rasa

It is understood that *Kashaya, Tikta* and *Madhura Rasa* alleviate *Pitaa Dosha*.

Further, *Madhura Rasa* has action of *Dhatuwardhana, Prasadana* of all *Indriyas, Trishna Dahaprasamana, Preenana, Jeevana, Tarpana, Brimhana, Sandhanakara*. And has properties such as *Snigdha, Sheeta, Guru* etc.

Kashaya Rasa is having properties such as *Samshamana, Sangrahi, Kapha Shamana, Raktapitta Prashamana, Rooksha* and *Laghu Tiktha Rasa* is having actions such as reducing *Murcha, Daha, Kandu, Trishna* and also acts as *Deepana, Pachana*. *Tikta Rasa* also has properties such as reducing *Pitta, Kapha, Sweda* etc. as well.^[7]

It can be clearly understood that the above said *Rasa* based properties helps in reducing the *Vata Pitta Doshas* as well as help in improving the *Dhatus* in a person. It can be inferred that the drugs of *Dahaprashamana Gana* can thereby relieve *Lakshanas* of *Rajonivruthi*.

Based on Gunas

Sheeta Guna possess *Sthambana* and *Pittahara* properties. *Snigdha Guna* reduces *Vata*.

Based on Veerya

Most of the drugs in *Dahaprashamana Gana* possesses *Sheeta Veerya*. As we know that *Sheeta Veerya* reduces *Pitta Dosha* related symptoms, it can be inferred that, the *Gana* as such has the capacity to reduce *Pitta* related symptoms such as *Daha, Ushna, Sweda* etc.

Based on Vipaka

Madhura Vipaka in the drugs of *Dahaprashamana Gana* can reduce *Vata* and *Pitta Doshas*. But it is also

notable that more than the action at *Vipaka* level, it's more of *Rasa Guna* and *Veerya* that are seemingly working in case of alleviation of the symptoms related to *Rajonivruthi*.

Based on *Prabhava*

Even though *Guduchi* is having *Ushna Veerya*, it has *Dahaprashamana* action specially due to its *Prabhava*.^[8]

The qualities and properties of individual drugs constituting *Dahaprashamana Gana* has been enumerated in the previous sections and from those details and also looking at *Rasa Panchaka* of all the drugs in *Dahaprashamana Gana* it can be understood that the combination works well in pacifying *Vata*, *Pitta Doshas* as well as helps improve normal *Kapha*. This improves the *Satva Guna* in a patient and helps reduce the *Rajo-Tamo Gunas* on the psychological plane. This is being considered because symptoms of *Rajonivruthi* viz-a-viz vasomotor symptoms can be seen as impacting both the body and mind of a patient in the perimenopausal and menopausal phases. These hence, alleviates the symptoms of *Rajonivruthi* and improves the health of a patient both physically and psychologically.

Mode of action of *Dahaprashamna Churna* in Hot Flash

The data that has been obtained from the study and the details from the literatures available, clearly says that *Dahaprashamana Gana* as the name suggest and from what the acharyas have clearly mentioned, will reduce *Vata-Pitta* related symptoms. It can be seen that the symptoms of *Rajo Nivruthi* is predominantly *Vata-Pitta* related and also *Kapha Kshaya* can be seen. The drugs of *Dahaprashamana Gana* has been so carefully and precisely combined as we can see that the drugs have individual qualities of reducing aggravated *Vata* and *Pitta* symptoms and also some of the drugs helps improve *Kapha*.

We can see that the symptoms of *Rajo Nivruthi* are more related to aggravated *Vata* and *Pitta* owing to multiple factors including the age of the subjects pertaining to *Rajonivruthi*. These also reduces normal

Avastha of Kapha. We can see that the symptoms are both on physical and psychological plane and need to be managed on both aspects such that the patients get a proper and marked relief.

Hence, it can be understood that *Dahaprashamana Gana* is capable of reducing the symptoms of *Rajonivruthi*. The data obtained from the study also suggest the same and has been interpreted statistically as a highly significant result.

Almost all drug in *Dahaprashamana Churna* having chemical constituents like Isoflavanones Resveratol which are antioxidant and act like phytoestrogen. Which will exert estrogenic effect to hypothalamus and lead to thermoregulation and give relief from vasomotor symptoms

Mode of action of *Dahaprashamna Churna* in Night Sweat

Sweat or *Sweda* in usually related to the increased body heat and that is directly related to an increase in *Pitta Dasha* in the body. Patients who as in the stages of *Rajonivruthi* will have profuse sweat episodes owing to the aggravated *Pitta*. It has been clearly understood that *Pitta* related symptoms are relieved by the use of *Dahaprashamana Gana* as the drugs of the *Gana* has properties for reducing *Pitta Dasha*.

Mode of action of *Dahaprashaman Churna* in Anxiety

Symptoms such as anxiety are related to the mental plane can be attributed to aggravated *Vata* and *Pitta Dasha* as well as a *Kapha Kshaya* condition. This gets reduced as we can see that the drugs of *Dahaprashamana Gana* has the qualities to reduce *Vata* and *Pitta* as well as it supports the improvement of normal *Kapha Dasha*.

Mode of action of *Dahaprashamana Churna* in Palpitation

Madhura Vipaka Dravyas in *Dahaprashamana Gana* as well as the overall action of *Dahaprashamana Gana* helps reduce symptoms related to aggravated *Vata Dasha* and palpitation as can be seen, can be attributed to the *Chala Swabhava* of *Vata* and when the *Dasha* aggravates, the symptoms can increase. Since

Dahaprashamana Gana has the qualities to reduce aggravated *Vata* related symptoms associated to *Pitta* in *Rajonivruthi*, we can infer that it reduces the symptoms such as palpitation as well.

Chemical constituents like resveratrol having cardioprotective effect and also antioxidant properties which reduces palpitation.

Discussion on overall improvement of symptoms in both group

In Group A, 15 patients were treated with *Dahaprashamana Churna*. Symptoms were assessed by subjective and objective parameters. According to different scales, viz, daily hot flash dairy scale showed 98.7% improvement, The Pittsburgh sleep quality index showed 86.1% improvement, Hot flash related daily inference scale showed 88% of improvement and Hamilton anxiety rating score showed 83.2% improvement on assessing the whole group. All the parameters showed highly significant result with p value of less than 0.001 with *Dahaprashamana Churna* on statistical analysis

In Group B, 15 patients treated with Vitamin E capsule, in that only mild improvement and no improvement has been shown. According to each scales, Daily hot flash dairy showed only 9.6% improvement, whereas The Pittsburgh sleep quality index showed only 1.7% improvement, Hot flash related daily inference scale showed 6.2% improvement and Hamilton anxiety rating scale showed only 1.5% improvement in patients. All parameters in group B showed statistically insignificant with p value less than 0.05.

CONCLUSION

The present study was done to evaluate the efficacy of *Dahaprashamana Churna* (Trial group) and Vitamin E (Control group) in Vasomotor symptoms in Perimenopause and Menopause. It is also to be noted that *Dahaprashamana Churna* is cost effective than Vit E capsule considering the market value as well as duration of usage. When results were compared within the groups, Group A shown highly significant result with p value < 0.001 in reducing vasomotor symptoms.

When comparison was done between the group - Highly significant difference in the effect of treatment was noticed for 4 parameters in Group A with p value < 0.001. Effect Size for clinical efficacy shows that Group A is much better with respect to all the parameters of subjective and objective in providing clinical relief. Thus, Alternate hypothesis (H_1) is accepted. *Dahaprashamana Churna* is more effective than Vitamin E in the management of Vasomotor symptoms in Perimenopause and Menopause

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