

## ROLE OF MADHUTAILIKA VASTI IN MENOPAUSAL SYNDROME- A CLINICAL TRIAL

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### ABSTRACT

Every woman faces varies physiological and psychological changes during this "change of life" as a part of hormonal derangement. Sometimes such disturbances attain the stage of disease or syndrome called as "Menopausal Syndrome" which is accompanied by various symptoms like profuse sweating, burning sensation in vagina etc. and other systemic features like oosteoporosis etc. Though menopause is a natural event as a part of the normal process of ageing, it is turning into a major health problem in recent years in developed as well as developing countries like India. Therefore, there is a wide scope of research to find out safe, potent, cost effective remedy from *Ayurveda* for the management of afore said lacuna. Therefore, considering it as challengeable melody, this project has been undertaken in order to find out a safe and effective medicament in *Ayurveda* without creating any adverse effect and for the management of Menopausal Syndrome. A clinical study was done on 38 patients of Menopausal syndrome administrating *Madhutailikavasti* for 10 days. The clinical study gives statistically significant results in reducing the symptoms and further improving quality of life of individual.

**Keywords:** Menopausal Syndrome, Ayurveda, *MadhutailikaVasti*

### INTRODUCTION

Menopause is defined as the time at which menstruation ceases, whereas climacteric is the phase of waning ovarian activity and may start two or three years before the menopause and continue for two or five years after it. The climacteric is thus a phase of adjustment between active and inactive ovarian function and may occupy several years of a woman's life.<sup>[1]</sup> The age of menopause ranges between 45-55 years, average being 50 years,<sup>[2]</sup>. The Menopausal Syndrome means cessation of menstruation. A woman is usually consid-

ered to be menopausal if she has not had a menstrual period for six month and there is no other underlying cause<sup>[3]</sup>. The main clinical features of Menopausal Syndrome are hot flushes [head, chest and arms becomes red and feet hot, lasting from a couple of minutes to as long as an hour] followed by profuse sweating, burning sensation in vagina etc. and other systemic features like oosteoporosis etc. Though *Rajonivritti* as a diseased condition is not described separately in the classics, *Rajonivrittikala* is mentioned by almost all

Acharyas without any controversy, few direct references are available in Sutra<sup>[4]</sup> and Sharira Sthana<sup>[5]</sup>. Moreover, in *Ayurveda*, the "Vayah" is described on the basis of *Kala* only. As this "Vayowastha" itself is manifested by the virtue of *Kala*, *Acharya Charaka* also beautifully explains that the characteristics of particular age or the changes taking place in different stages of age have to be attributed to the same factor i.e. *Kala*<sup>[6]</sup>.

*Kapha* is the principal humor responsible for growth and development while *Pitta* is responsible for vigour and vitality of youth. *Vayu* according to its fundamental properties precipitates atrophy and involution i.e., *Kshaya* and *Shosa* of *Dhatu*s which is responsible for most of the manifestations of ageing. As a function of ageing, with advancing age *Kapha* gets gradually depleted and *Vata* increases spontaneously<sup>[7]</sup>. *Ayurvedic* science has divided all diseases into 4 major types; *Agantu*, *Sharira*, *Manas* and *Swabhavika*<sup>[8]</sup>. Among them 'Swabhavika' type is described that includes all those conditions, which are naturally occurring. *Acharya Sushruta* has mentioned a group of naturally occurring diseases under the heading of *SwabhavabalaPravritta* includes *Kshudha* (Hunger); *Pipasa* (Thirst), *Nidra* (Sleep), *Jara* (Ageing) and *Mrityu* (Death)<sup>[9]</sup>. Menopause or *Jaravastha* is the part of the sequel of the process of ageing, has been considered as the *Vata* predominant stage. As ageing is a 'Vata' predominant stage of life but why the feature of *Pitta* ( Hot flushes, Night Sweat etc.) are found? *Ashayapakarsha* is a very specific concept of *Ayurvedic* Science. Not going in detail, in this condition, *Pitta Dosh*a is not vitiated, but aggravated *Vata Dosh*a displaces the *Prakrita Pitta Dosh*a from its *Ashayas* and manifests the symptoms, which are broadly like of *Pittavridhi* or

*Pitta* vitiation, so, *Ashayapakarsha* of *Pitta* by *Vata*s mainly responsible for the *Lakshanas* of *Rajonivritti*<sup>[10]</sup>. Thus, the symptoms of menopause experienced by some women are similar to the symptoms seen when the *Vata Dosh*a rises and upsets the normal balance of the body. *Vasti* is mainly indicated in *Vata*-predominant diseases<sup>[11]</sup>. Among all the *Vastis*, *Madhutailika Vasti* is selected because, it is suitable to royal dignitaries, women, delicate persons, children and the old people in order to eliminate the *dosh*as and promote strength and complexion<sup>[12]</sup>.

### Material and methods:-

#### Plan of study-

It is an open label efficacy trial on 38 patients for 10 days duration procedure naming *Madhutailika Vasti* used in the patients of Menopausal Syndrome. Total 38 patients were selected from the Post Graduate O.P.D. of S.V. *Ayurvedic* College and Hospital, Tirupati based on the criteria. Study was approved by Institutional Ethics Committee with approval no. IEC SYAYC/131908002.

#### Aims and Objective-

1. To study the *Menopausal Syndrome* both in *Ayurvedic* & Modern view.
2. To study the effect of *Madhutailika Vasti* in Menopausal syndrome.

#### Inclusion Criteria-

1. Patients with clinical features of *Menopausal Syndrome* are included in the study.
2. Patients of early menopause with clinical features also are included in the study.
3. Patient who are not included in exclusion criteria.

#### Exclusion Criteria-

1. Patients with carcinoma or suffering from any acute disease are not included in the study.

2. The Patient in whom *Vasti* is contraindicated are also not included in the study.

#### Laboratory Evaluation-

- Following laboratory investigations were carried out in each patient only before treatment to rule out any other systemic diseases.
- Blood- Haemoglobin, TLC, DLC, ESR, RBS.
- Urine- Routine & Microscopic.

#### Assessment criteria-

Assessment was totally based on the changes in the clinical features of *Menopausal Syndrome* and improvement in Scoring index of hot flushes, sweating, sleep disturbance, anxiety, joint & muscular discomfort. For all these symptoms, the following symptom scores were given depending upon the changes seen before and after the treatment.

#### Cardinal Symptoms of Menopausal Syndrome-

1. Hot flushes
2. Night sweat
3. Dryness in vagina
4. Burning in vagina
5. Dyspareunia
6. Burning in micturition
7. Incontinence of urine
8. Anxiety
9. Flatulence

#### General symptoms of Menopausal Syndrome-

- 1) Constipation
- 2) Insomnia
- 3) Pain in joints
- 4) Palpitation
- 5) Depression
- 6) Loss of memory
- 7) Facial hair
- 8) Weakness

#### Doshika Symptoms of Menopausal Syndrome-

*Vatika* symptoms include *kostatoda*, *samcharana*, *gardavarchstva*, *incontinence of urine*, *krodha*, *bhaya*, *paripluta*, *smritinasha*.

*Patika* symptoms includes *daha*, *sweda*, *yonidaha*, *mutradaha*, *indriyadaurbalya*, *alpanidra*, *murcha*, *krodha*, *bhrama*.

*Kaphaja* symptoms include *sandhishaitilya*, *rukshata*, *dourabalya*, *prajagarana*, *antardaha*, *trishna*, *hridayadrava*, *glani*, *shabda-asahisnuta*.

#### Design of Clinical Study-

##### Treatment protocol-

Before starting the treatment, *Deepana*– *Pachana* drugs (*Hingvastaka* and *Bhaskaralavana* at 3 gm dose twice daily) were given for 5 days (medicine is of hospital supply).

➤ Method of *Vasti Karma*:

*Madhutailika* (*Yapana*) *Vasti* was administered at inpatient and outpatient level after *Deepana*, *Pachana* therapy.

**Dose**- approximately 500 ml.

**Route**- rectal route.

**Duration**- total 10 days.

**Kala**- In Morning between 8.00am to 9.30am (empty stomach)

##### Procedure of *Vasti*:

Poorvakarma :

➤ Drugs and instruments required for *Snehana* and *Svedana*, & *Vasti* were kept ready.

➤ Patients were asked to lie down on the table comfortably for *Snehana*.

➤ Local *Abhyanga* (*Kati-Prushtha-Pada-Parsva-Adhodara*) with luke warm *Balataila* for 20 minutes was done.

➤ *Svedana*: By *NadiSweda* (*Kati - Prushtha - Pada- Parsva- Adhodara*) for 20 minutes was given.

*Pradhana Karma*:

- After completion of *Poorvakarma*, patient was asked to lie in left lateral Position on the table.
- Freshly prepared *Vastimaterial* was administered through rectal route.
- At the time of insertion of *Vasti*, patient was asked to inhale and exhale deeply and keep herself, as relaxed as possible.

**Pashchat Karma:**

- Patient was asked to lie down supine for at least 2 hrs and during this period, patient is advised to pass stools whenever she feels the urge.
- All the dietetic regimens were explained for *PoorvaandPashchata karma*.
- Time of *VastiPratyagamanawas* noted in every patient.

**Pathya /Apathya:**

As Madhutailika *Vasti* is *Yapana-Vasti*, no specific restrictions are mentioned in classics however patients were advised to avoid *Diwasvapa* and food which could cause indigestion like spices etc.

The patients who were admitted in the I.P.D. for (the treatment), were advised to takenormal hospital diet. For the O.P.D.

patients also light diet was advised. The patients were recommended not to get exposed to *Vata, Atapaetc*.

**Follow up Study:-**

The patients admitted for the treatment in the I.P.D. were followed daily andthe changes in general condition were noted followed by *Vasti* part on 10 days(B), 30 days(C), and again after 60days(D)*Vasti* were noted.

Followed by *Vasti*, the O.P.D. patients were checked again once in 10 days, 30 days and 60 days and changes wereobserved in signs and symptoms.

**Statistical Analysis:-**

The effect of therapy has been presented here, with the help of repeated ANOVAtest&paired t test.Graph Pad in Stat Software used for statistical analysis.

**Observations and Results:-**

In the present study total 41 patients were enrolled of which 3 patients discontinued before completion of the course, against medical advice. So their data is not included, 5 patient had not comfort for the follow up for 60 days. The remaining 38 patients were studied.

**Effect of therapy on Cardinal Signs and Symptoms of Menopausal Syndrom**

Symptoms	Comparison	A vs B	A vs C	A vs D
Hot flushes (F value- 5.221 P value-<0.001)	M.D.	2.00	2.667	3.00
	q value	16.25	19.71	28.14
Night Sweat (F-4.401&P-<0.001)	M.D.	1.939	2.758	3.091
	q value	15.82	19.08	28.15
Vaginal dryness (F- 4.859 & P-< 0.001)	M.D.	2.121	2.818	2.848
	q value	36.77	34.84	26.46
Burning in vagina (F-4.446& P-<0.001)	M.D.	2.152	2.939	3.091
	q value	27.98	34.03	28.15
Dyspareunia (F-3.839&P-<0.001)	M.D.	1.970	2.545	2.727
	q value	17.77	17.56	25.02
Burning in Micturition(F-3.702&P-<0.001)	M.D.	1.939	2.485	2.758
	q value	22.45	17.95	22.50

Incontinence of urine (F-4.949&P-<0.001)	M.D.	1.939	2.848	2.970
	q value	20.05	32.24	24.94
Anxiety (F-4.195&P-<0.001)	M.D.	1.758	2.788	3.061
	q value	20.12	19.53	28.86
Flatulance F-4.108&P-<0.001)	M.D.	2.08	2.78	3.00
	q value	16.61	29.37	26.05

**Effect of therapy on General Signs and Symptoms of Menopausal Syndrome**

Symptoms	Comparison	A vs B	A vs C	A vs D
Constipation (F-3.987&P-<0.001)	M.D.	1.485	2.636	3.152
	q value	15.08	19.33	29.27
Insomnia (F-4.702&P-<0.001)	M.D.	1.939	2.333	2.848
	q value	14.14	15.06	26.46
Pain in Joints (F-2.192&P-<0.001)	M.D.	2.091	2.485	1.818
	q value	16.61	13.41	6.65
Palpitation (F-2.53&P-<0.001)	M.D.	1.970	2.061	1.879
	q value	17.77	10.35	8.676
Depression (F-3.662&P-<0.001)	M.D.	2.00	2.818	2.97
	q value	17.37	23.72	22.16
Loss of memory (F-2.097&P-<0.001)	M.D.	1.939	2.152	1.121
	q value	15.82	10.51	3.768
Facial hairs (F-1.45&P-<0.001)	M.D.	2.061	3.00	2.545
	q value	21.30	48.74	10.66
Weakness F-1.976&P-<0.001)	M.D.	1.970	2.879	2.424
	q value	19.33	34.13	9.84

**SHOWING OVERALL EFFECT (PERCENTAGE) OF CARDINAL SYMPTOMS**

S.No.	Symptoms	10 days % of relief	30 days % of relief	60 days % of Relief
1.	Hot flushes	55.52	80.60	89.17
2.	Night sweat	55.71	79.02	88.79
3.	Dryness in vagina	63.09	83.86	84.42
4.	Burning in vagina	60.79	83.02	87.31
5.	Dyspareunia	60.24	77.67	83.39
6.	Burning in micturition	57.95	74.62	82.58
7.	Incontinence of urine	56	82.31	86.08
8.	Anxiety	50.22	78.09	85.95
9.	Flatulance	62.65	83.73	90.36

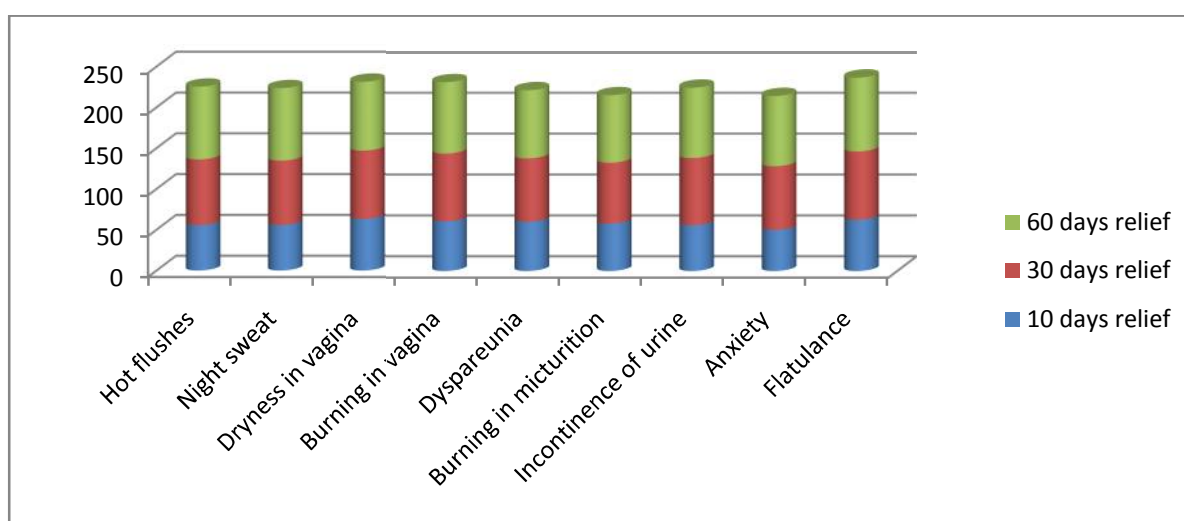
**Overall effect of therapy on Doshika(Menopausal)Symptoms on 38 patients**

Symptoms	BT	AT	Mean dif-	% of	S.D.	S.E.	t	P
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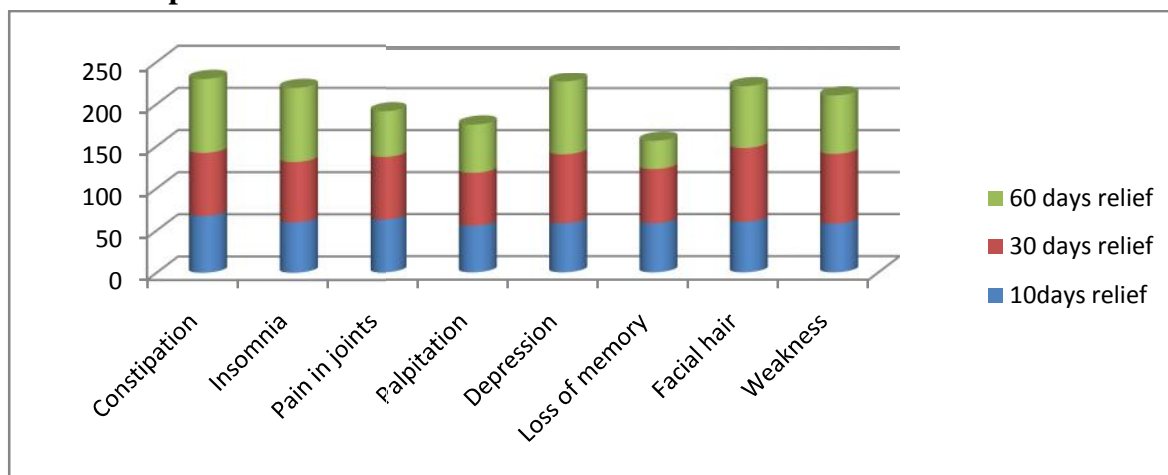
			ference	relief				
Vatikasymptoms	29.73	10	19.74	66.39	4.524	.7339	26.89	<0.001
PaittikaSymptoms	27.86	9.76	18.11	64.96	.3883	.06299	287	<0.001
Kaphaja Symp-toms	27.78	9.75	18.03	64.86	.5446	.0883	204	<0.001

**Effect of therapy on Menopausal Symptoms on 5 patients  
(Not continue for follow up)**

Symptoms	BT	AT	Mean difference	% of relief	S.D.	S.E.	T	P
Menopausal symptoms	53.8	15	38.80	72.11	1.78	0.800	48.5	<0.001



**Graph No.1: Showing percentage of relief in Cardinal Symptoms of Menopausal Syndrome in 33 patients**



**Graph No.2: Showing percentage of relief in General Symptoms of Menopausal Syndrome in 33 patients**

**DISCUSSION**

Discussion is the step which helps in interpretation and understanding the subject with reference to its merits and demerits and guides to the conclusive

judgments. That’s why *Acharya Charaka* has stated in *Siddhithana* is that:, a scientist should use his power of logic regarding the facts because without logical thinking if one succeeds, it is purely by chance.

Thus discussion is the first step to enrich any conclusion<sup>[13]</sup>. On the basis of this clinical study, the present study is an attempt to assess the *MadhutailikaVasti*, as *Vasti* is the best therapy for *Vridhdhavata* based on *Ayurvedic* guidelines in the management of Menopausal syndrome.

**Cardinal symptoms** like hot flushes, night sweat etc. has shown that statistically more significant result in hot flushes by 59.52% (10day), 80.60% (30day), 89.17% (60day), in night sweat by 55.71% (10day), 79.02% (30day), 88.79% (60day), in dryness in vagina by 63.09% (10day), 83.86% (30day), 84.42% (60day), in burning in vagina 60.79% (10day), 83.02% (30day), 87.31%, in dyspareunia by 60.24% (10day), 77.67% (30day), 83.39% (60day), in burning in micturition by 57.95% (10day), 74.62% (30day), 82.58% (60day), in incontinence of urine by 56% (10day), 82.31% (30day), 86.08% (60day), in anxiety by 50.22% (10day), 78.09% (30day), 85.95% (60day), in flatulence by 62.65% (10day), 83.73% (30day), 90.36% (60day).

Among all the cardinal symptoms the effect is seen maximum in 0 and 60 days.

**General symptoms** like constipation, insomnia etc. has shown that statistically more significant result in constipation by 67.34% (10day), 74.99% (30day), 87.67% (60day), in insomnia by 59.56% (10day), 71.91% (30day), 87.84% (60day), in pain in joints by 62.79% (10day), 74.62% (30day), 54.35% (60day), in palpitation by 55.53% (10day), 63.02% (30day), 57.46% (60day), in depression by 58.47% (10day), 82.16% (30day), 86.84% (60day), in loss of memory by 58.48% (10day), 64.62% (30day), 33.66% (60day), in facial hair by 60.23% (10day), 88% (30day), 73.52% (60day), in weakness by 57.94% (10day), 83.18% (30day), 69.65% (60day).

Among all the general symptoms; in constipation, insomnia, depression the effect is seen maximum in 0 and 60 days. While in pain in joints, palpitation, loss of memory, facial hair and weakness the effect is seen maximum in 0 and 30 days.

The menopause stage generally occurs in the *Vridhdhavastha* (*Vata* predominant stage). There is none other than *vayu* which is the most important causative factor of diseases in *shakha*, *kostha*, *marma*, *urdhava*, *sarvaavayava* and *anga*<sup>[14]</sup>. Therefore, *Vasti* is considered by physicians to be half of the entire therapeutic measures. Some physicians even go to the extent of suggesting that *Vasti* represents (not half but) the whole of therapeutic measures<sup>[15]</sup>. Among all the *Vastis*, the *MadhutailikaVasti* is the *YapanaVasti*, as per shloka, the *Vasti* which prolongs the life and restores the health is called as *YapanaVasti*<sup>[16]</sup>. In the *MadhutailikaVasti*, there are no restrictions for riding, conjugation, food, and drinks (etc.); the benefits are plenty, with almost no complications/hazards. It can be adopted easily by those desiring the benefits of *Niruha-Vastienema* and which can be administered as and when required by the intelligent physician<sup>[17]</sup>. *MadhutailikaVasti* is one of the best *VataShamakaVastis*, which can be particularly used in delicate woman i.e. During *Jaravastha*. The ingredients as well as the procedure itself are having the best *Rasayana* and *VataShamaka* properties. Thus this procedure not only helps in suppression of *Vata* and maintenance of *Vata* by keeping all the *Doshas* in their positions (ie. bringing back *Pittato* its normal place), but also helps in prolonging the healthy life span of the woman by its *Rasayana* property. *MadhutailikaVasti* has the properties of both *Sneha* as well as *NiruhaVasti*. It does not require *Purvakarma* (*SnehaVasti*) on the previous day.

It can be utilized for young, old, sick and healthy people. It will not create problems like *Atiyoga* or *Ayoga*. It is panacea for all diseases and is suitable for administration in all seasons.

### CONCLUSION

The clinical Study has proven that in the *MadhutailikaVasti* has the quality to suppress the increased *Vata* in the body (which is increased in the Menopausal Syndrome) and the Menopausal Syndrome is the *AshayapakarshaSiddhanta* related disease.

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