

A CLINICAL STUDY TO EVALUATE THE ROLE OF SOMAVALKAJA VASTI IN PRAMEHA W.S.R.TO MADHUMEHA

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ABSTRACT

Madhumeha is one of the 20 *Pramehas*, which comes under *Vataja* subtype and is characterized by the sweet urine resembling Honey. Diabetes is a metabolic syndrome characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Being an important tool for the control of *Vata*, *Vasti* can play a key role in the management of '*Madhumeha*', which is one of the 4 types of *Vataja Prameha*. The drug *Somavalka* is indicated for *Prameha* in the form of *Vasti*, in *Caraka samhita, Siddhi sthana* – 10th chapters. In the present clinical study with single group, 27 patients out of 30 enrolled patients completed the study. All the patients were subjected to *KALA VASTI* i.e., *Niruha Vasti* with *Somavalkaja Ka ayam & Anuvasana vasti* with *Somavalkaja Tailam* for 16 days. The efficacy of treatment is assessed by Objective Parameters and by adopting scoring methods for the Subjective Parameters and the results are analyzed statistically by paired “t” test. The results of the study indicate that the ‘p’ value is highly significant to extremely significant in all parameters and Glycemic values of blood are significantly reduced after treatment.

Key words: *Madhumeha, Prameha, Somavalka, Kala Vasti*

INTRODUCTION

Madhumeha is one of the 20 *pramehas*, which comes under *Vataja* subtype and is characterized by the sweet urine resembling Honey¹. Diabetes is a metabolic syndrome characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. As of 2015, an estimated 415 million people have diabetes worldwide, with type 2 DM making up about 90% of the cases². According to the Indian Heart Association, India is the diabetes capital of the world with a projected 109 million individuals with diabetes by 2035³. It is the high time for *Ayurvedic* community to look into the every possible *Ayurveda* classics and treatises for gathering as much

as possible information regarding management of *Madhumeha* and at the same time bring those evidences into the light of modern world perspective, by re-establishing their efficacy and safety through present day scientific methods. The present study ‘A Clinical study to evaluate the Role of *Somavalkaja Vasti* in *Prameha* w.s.r.to *Madhumeha*’ has been selected from an untouched portion of *Caraka Samhita – Siddhi Sthana* 10th chapter, named ‘*Vasti Siddhim*’, where the drug ‘*Somavalka*’ is indicated for *Prameha* in the form of *Vasti*⁴. According to *Cakrapani*, commentator of *Caraka Samhita*, this drug *Somavalka* is considered as ‘*Vitkhadira*’⁵ which is the synonym

of 'Arimeda'. The botanical identity of the plant is – 'Acacia farnesiana' which belongs to Mimosaceae family.

AIMS & OBJECTIVES

1. To evaluate the efficacy of *Somavalkaja Vasti* in the management of *Madhumeha*.
2. To evaluate the efficacy of *Vasti Karma* (*Kala Vasti* schedule) in the management of *Madhumeha*.

MATERIAL AND METHODS

It is an open clinical study on 30 subjects with 16 days treatment procedure. Total 30 patients who have attended the OPD and IPD of the *Pañcakarma* Dept. of S.V. Ayurvedic Hospital, Tirupati between 30 to 70 years of age, suffering from *Madhumeha* were selected for the study. Among them 27 patients completed the study and 3 patients were discontinued due to personal reasons.

The material used for the present study is *Somavalkaja Kashayam*, *Somavalkaja Tailam*, *Makshikam*, *Saindhava Lavanam*, *Satapushpa Kalkam*, *Vasti Yantra*, Disposable gloves, Mortar and pestle. The oil for the present clinical study is prepared in TTD's Sri Srinivasa Ayurveda Pharmacy, Tirupati, as per the classical references and the ingredients are Stem bark of *Arimeda* (*Acacia farnesiana*) and *Tila taila*. For *Niruha Vasti*, *Kashayam* prepared from the coarse powder of *Arimeda* stem bark is used. This *Kashayam* is prepared on the day of *Niruha Vasti*.

Clinical Plan

Phase 1: Selection of 30 cases from OPD/IPD of dept of *Panchakarma* of S.V. Ayurvedic Hospital irrespective of sex, caste and religion, according to Inclusion and Exclusion criteria.

Inclusion Criteria:

- Patients with symptoms of *Madhumeha* as per *Ayurvedic* classics and Type II D.M as per modern medicine.
- Age group 30 - 70 years

- FBS levels within 150mg/dL and PPBS levels within 250mg/dL

Exclusion Criteria:

- Age less than 30 and more than 70
- Type 1 D.M
- Gestational diabetes
- D.M due to other illness like acromegaly, ca pancreas etc.
- Patients with other systemic complications like Cardiovascular, nephropathic, neuropathic etc.

Phase 2: Recording of Subjective & Objective Parameter values.

Phase 3: Administration of *Kala Vasti* for 16 days. *Anuvasana Vasti* with *Somavalkaja Tailam* (1,3,5,7,9,11,13,14,15,16th days). *Niruha Vasti* with *Somavalkaja Kashayam* (2,4,6,8,10,12th days)

Phase 4: Recording of Subjective & Objective Parameter values and Statistical analysis of results. The efficacy of treatment was assessed by Objective Parameters and by adopting scoring methods for the Subjective Parameters and the results were analyzed statistically by paired "t" test.

Subjective Parameters:

1. *Prabhuta Mutrata* [Increased Quantity & Frequency of Urine]
2. *Avila Mutrata* [Turbid Urine]
3. *Kshudadhikyata* [Increased Appetite]
4. *Trishnadhikyata* [Increased Thirst]
5. *Pindikodvestanam* [Cramps in Calf muscles]
6. *Kara-Pada Tala Daha* [Burning sensation in Hands and Soles of Feet]
7. *Kara-Pada Suptata* [Numbness in Hands and Feet]
8. *Daurbalya* [Weakness]

Objective Parameters:

1. FBS
2. PPBS
3. Urine Sugar
4. HbA1c

OBSERVATIONS

In the present study majority of patients belong to age group 50-59 years (37%) followed by the age group 40-49 years (33%). Majority of patients are Males (60%) and 87% patients are Hindus. 40% of patients are poor and 30% are doing agriculture. Majority of patients have mixed diet habit (53%) and 63% have no addictions. Majority of patients have disease chronicity of 4-12 months (53%) followed by >1year (30%). Majority of patients

belong to *Vata Kaphaja Prakriti* (40%) followed by *Pitta Kaphaja* (27%) and *Vata Pittaja Prakriti* (20%). Among 27 patients who completed the study *Prabhuta Mutrata* is seen in 24 patients, *Avila Mutrata* is seen in 18 patients, *Kshudadhikyata* is seen in 23 patients, *Trshnadhikyata* is seen in 21 patients, *Pindikodveshtanam* is seen in 18 patients, *Kara-Pada Tala Daha* is seen in 18 patients, *Kara-Pada Suptata* is seen in 18 patients and *Dourbalya* is present in 18 patients.

RESULTS

Table 1: Showing Statistical Analysis of Results of improvement in Subjective Parameters

Assessment Criteria	Mean ± Sd		Mean Difference	DF	t stat Value	p Value	Inference
	BT	AT					
<i>Prabhuta Mutrata</i>	1.916 ± 0.862	0.916 ± 0.759	1.0	23	6.782	p<0.0001	Ex. Significant
<i>Avila Mutrata</i>	1.444 ± 0.598	0.611 ± 0.590	0.833	17	5.000	p<0.001	Hi.Significant
<i>Kshudadhikyata</i>	1.478 ± 0.650	0.391 ± 0.488	1.086	22	7.800	p<0.0001	Ex. Significant
<i>Trishnadhikyata</i>	1.619 ± 0.785	0.666 ± 0.642	0.953	20	5.898	p<0.0001	Ex. Significant
<i>Pindikodvestanam</i>	1.555 ± 0.684	0.833 ± 0.687	0.72	17	4.579	p<0.001	Hi.Significant
<i>Kara-Pada Tala Daha</i>	1.666 ± 0.745	0.777 ± 0.628	0.89	17	4.531	p<0.001	Hi.Significant
<i>Kara-Pada Suptata</i>	1.333 ± 0.577	0.555 ± 0.598	0.78	17	5.102	p<0.0001	Ex. Significant
<i>Dourbalya</i>	1.611 ± 0.755	0.722 ± 0.650	0.889	17	4.531	p<0.001	Hi.Significant

BT: Before treatment; AT: After treatment; DF: degrees of freedom; Ex.: Extremely; Hi. : Highly

Table 2: Showing Original Values of FBS & PPBS Before & After treatment

Assessment Criteria	Mean ± Sd		Mean Difference
	BT	AT	
FBS	127.2 mg/dL ± 24.58 mg/dL	113.3 mg/dL ± 20.72 mg/dL	13.87 mg/dL
PPBS	203.2 mg/dL ± 35.83 mg/dL	170.3 mg/dL ± 33.94 mg/dL	32.88 mg/dL

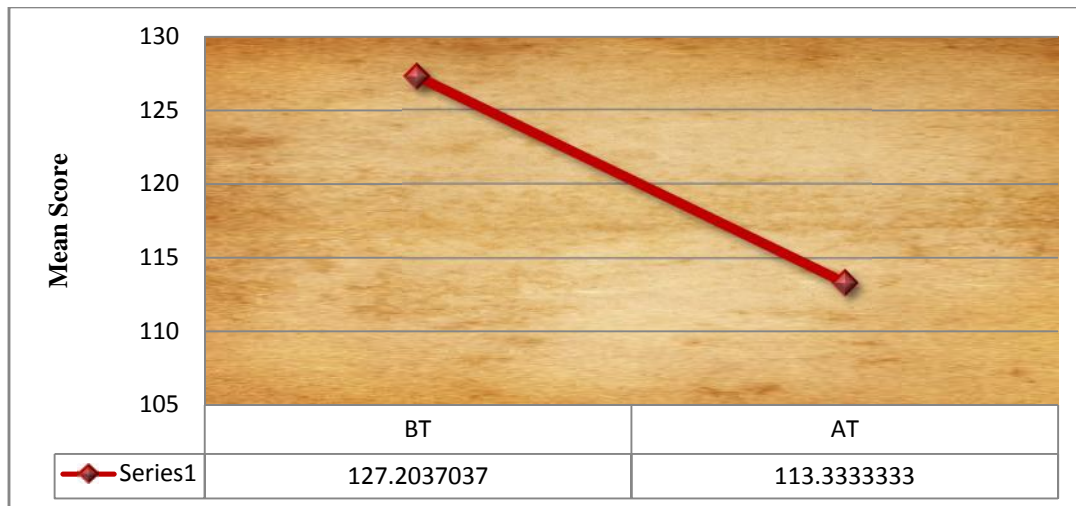
BT: Before treatment; AT: After treatment

Table 3: Showing Statistical Analysis of Results of improvement in Objective Parameters

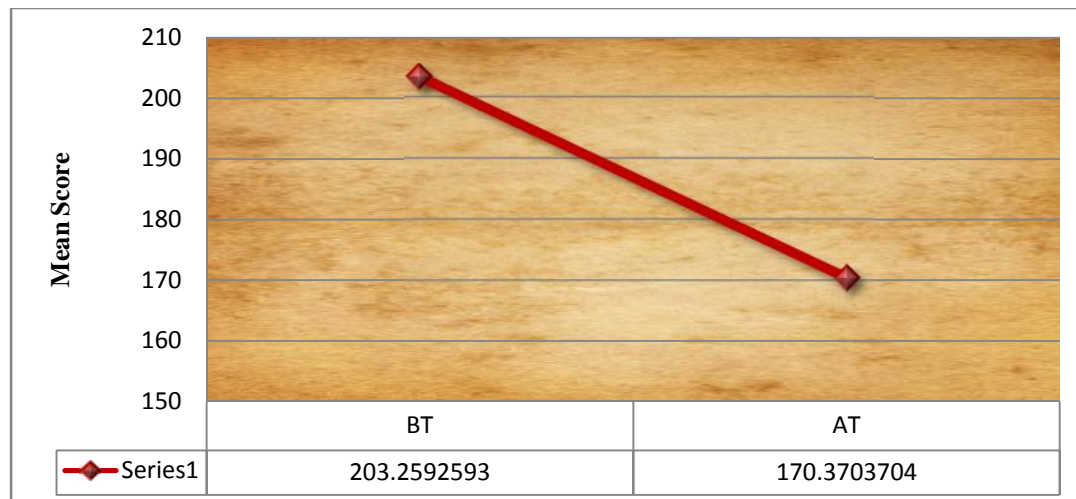
Assessment Criteria	Mean \pm Sd		Mean Difference	DF	t stat Value	p Value	Inference
	BT	AT					
FBS	2.407 \pm 1.497	1.259 \pm 1.293	1.148	26	5.112	p<0.0001	Ex. Significant
PPBS	3.666 \pm 1.586	1.925 \pm 1.463	1.740	26	9.190	p<0.0001	Ex. Significant
HbA1c	7.39 \pm 0.865	6.81 \pm 0.568	0.58	26	5.164	p<0.0001	Ex. Significant
Urine sugar	1.761 \pm 0.810	0.761 \pm 0.609	1.0	20	5.790	p<0.0001	Ex. Significant

BT : Before treatment; AT : After treatment; DF : degrees of freedom; Ex. : Extremely; Hi. : Highly

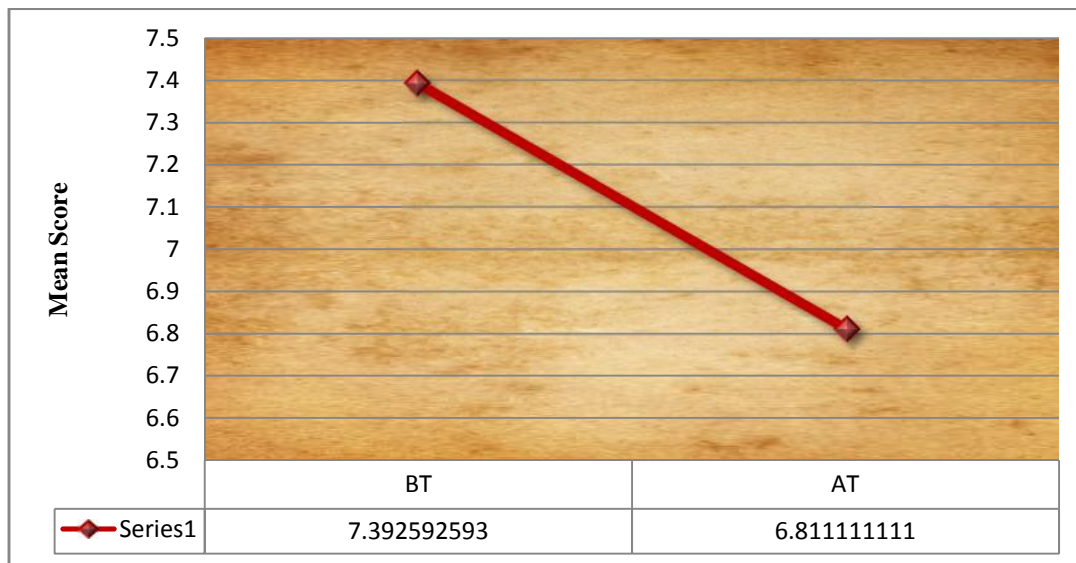
Graph No. 1: Showing Effect of Somavalkaja Vasti on FBS



Graph No. 2: Showing Effect of Somavalkaja Vasti on PPBS



Graph No. 3: Showing Effect of Somavalkaja Vasti on HbA1c



DISCUSSION

Effect on Fasting Blood Sugar (FBS): Among 27 patients, who completed the study, 14 patients have impaired glucose tolerance with FBS less than 126mg/dL and 13 patients have FBS more than 126mg/dL. Among those 27 patients, 1 patient with FBS 193mg/dL has shown marked response with 83 mg/dL reduction after completion of treatment. The mean score before treatment was 127.20mg/dL which was reduced to 113.33mg/dL after treatment with Mean difference 13.87mg/dL. For statistical calculation the entire data of FBS is converted into class intervals and then paired 't' test has been performed. The result was statistically extremely significant ($p < 0.001$) with t value 5.112.

Effect on Post Prandial Blood Sugar (PPBS) : Among 27 patients who completed the study, 12 patients have impaired glucose tolerance with PPBS less than 200mg/dL, but more than 140mg/dL and 15 patients have PPBS more than 200mg/dL. 4 patients have shown marked reduction in the PPBS levels after treatment with average reduction of more than 60mg/dL. The mean score before treatment was 203.25 mg/dL which was reduced to

170.37 mg/dL after treatment with Mean difference 32.88 mg/dL. For statistical calculation the entire data of PPBS is converted into class intervals and then paired 't' test has been performed. The result was statistically extremely significant ($p < 0.0001$) with t value 9.190.

Effect on HbA1c: Among 27 patients who completed the study, 2 patients have normal HbA1c levels i.e., less than 6%. 17 patients have that of Good control i.e., 6 – 8% and 8 patients have that of Fair control i.e., 8 – 10%. No one has poor control of HbA1c i.e., above 10%. (*Method: CLIA Waved-Borate affinity chromatography; Instrument: POC Bio-Rad in2it UK*) All the patients have shown reduction in the values of HbA1c after the completion of treatment. The mean score before treatment was 7.39 which was reduced to 6.81 after treatment with Mean difference 0.58. Statistical analysis shows the result was extremely significant ($p < 0.0001$) with t value 5.164.

In *Madhumeha* which is a type of *Vataja Prameha*, *Vayu* which is aggravated due to either *Dhatu Kshaya* or obstruction by vitiated *Kapha*, *Pitta*, *Mamsa* and *Medas*, loses its normal *Gati* and causes the disease by

drawing *Ojas* and into *Bastimukha*. In the present study only *Avarana Janya Madhumeha* patients are selected and hence to break the *Samprapti* of *Avarana Janya Madhumeha*, the following objectives should be fulfilled – Clearing the channels of *Vata* by removing obstruction, Controlling of *Vata* and bringing *Vatanulomana*, Normalcy of *Mutravaha* and *Medovaha srotas*, Restoration of normalcy to the vitiated *Kapha* and *Medas*, Removal of excessive *Kleda* formed in the body due to *Bahudrava Sleshma* and other vitiated *Drava Dhatus* and Restoration of *Agni* – Both *Jatharagni* and *Dhatvagni* (mainly *Medo Dhatvagni*)

Role of the drug ‘Somavalka’ in Avarana Janya Madhumeha

The drug *Somavalka/Arimeda* possesses the properties of *Kashaya* and *Tikta Rasas*, *Ushna Guna & Virya* and *Katu Vipaka*⁶. Thus it has predominance of *Vayu*, *Agni* and *Akasa Mahabhutas*. By virtue of these properties, it acts as *Kaphahara*, *Medo Soshana* and *Kledahara* drug and thus plays a key role in breaking the *Samprapti* of *Madhumeha*. More over it has direct reference in *Caraka Samhita* that the drug *Somavalka* is beneficial in *Prameha* in the form of *Vasti*. Recent researches show enough evidence of anti diabetic and anti hyperglycemic properties of *Acacia farnesiana*⁷.

Role of ‘Kala Vasti’ in Avarana Janya Madhumeha

When administered in to *Pakvasaya*, *Vasti* expels out the morbid *Vata Dosha* from its root which help to maintain the normalcy of *Vata* all over the body (Ca.Su.20:13). All micro and macro channels get cleansed by *Vasti* (Ca.Si.1:29/1). *Caraka* in *Siddhi Sthana* 1st chapter (*Kalpana Siddhi*), explained the benefits of *Niruha Vasti* that it promotes Digestive fire and expels *Kapha*, *Pitta*, *Vata*, *Mala & Mutra* and enriches the *Sukra & body’s strength*, by expelling the *Dosha San-*

chaya lodged in the entire body. *Caraka* opines that there is no other measure than using *Sneha* to counteract *Vata*. He also described the benefits of *Anuvasana Vasti* as – It gives pleasure to mind and enhances complexion and digestive fire. (Ca.si : 1/29-31). The *Virya* of *Vasti* administered into the *Pakvasaya* reaches the whole body through the channels (*srotas*), as the water when poured at the root of the tree reaches the whole plant (Su.Ci.35:24-25). Thus the active principles of the drug used in the *Vasti* will reach the entire body and show the desired effect.

CONCLUSION

There was direct reference in *Caraka Siddhi Sthana* 10th chapter i.e., *Vasti Siddhim Adhyaya* regarding the therapeutic utility *Somavalkaja Vasti* in *Prameha*. Till date no study has been done on *Somavalkaja Vasti* and hence this study is selected. Mostly newly detected cases are taken for the study with the patients falling under age group of 30 – 70 years. Among 30 patients selected for the study, 27 patients completed the treatment and 3 patients were discontinued due to personal reasons. The data shows statistically significant improvement in all the 27 patients who completed the treatment. Owing to the limitations of study only 30 patients that too with FBS 150mg/dL & PPBS 250mg/dL have been taken. As the study results are satisfactory, further studies on large scale and with chronic cases presumably will give more evidence and support to develop *Somavalkaja Vasti* as an important therapeutic modality for *Madhumeha* Patients.

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