INTRODUCTION

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. As of 2015, an estimated 415 million people have diabetes worldwide, with type 2 DM making up about 90% of the cases. According to the Indian Heart Association, India is the diabetes capital of the world with a projected 109 million individuals with diabetes by 2035. 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. According to Cakrapani, commentator of Caraka Samhita, this drug Somavalka is considered as ‘Vitkhadir’ which is the synonym of Caraka Samhita – Siddhi Sthana 10th chapter, named ‘Vasti Siddhim’, where the drug ‘Somavalka’ is indicated for Prameha in the form of Vasti.
of ‘Armeda’. 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 Taitlam, Makshikam, Saindhava Lavanam, Saptapushpa 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 Arimedea (Acacia farnesiana) and Tila taila. For Niruha Vasti, Kashayam prepared from the coarse powder of Arimedea 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

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 Taitlam (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, Trishnadhikyata 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

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

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

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Mean ± Sd</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBS</td>
<td>127.2 ± 24.58 mg/dL</td>
<td>113.3 ± 20.72 mg/dL</td>
</tr>
<tr>
<td>PPBS</td>
<td>203.2 ± 35.83 mg/dL</td>
<td>170.3 ± 33.94 mg/dL</td>
</tr>
</tbody>
</table>

BT: Before treatment; AT: After treatment
Table 3: Showing Statistical Analysis of Results of improvement in Objective Parameters

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Mean ± Sd</th>
<th>Mean Difference</th>
<th>DF</th>
<th>t stat Value</th>
<th>p Value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBS</td>
<td>2.407±1.497</td>
<td>1.259±1.293</td>
<td>1.148</td>
<td>26</td>
<td>5.112</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>PPBS</td>
<td>3.666±1.586</td>
<td>1.925±1.463</td>
<td>1.740</td>
<td>26</td>
<td>9.190</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>HbA1c</td>
<td>7.39±0.865</td>
<td>6.81±0.568</td>
<td>0.58</td>
<td>26</td>
<td>5.164</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Urine sugar</td>
<td>1.761±0.810</td>
<td>0.761±0.609</td>
<td>1.0</td>
<td>20</td>
<td>5.790</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

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
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
Role of the drug ‘Somavalka’ in Avarana Janya Madhumeha

The drug Somavalka/Arimeda possesses the properties of Kashaya and Tikta Rasas, Ushna Gunas & Virya and Katu Vipakas. 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.

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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Source of Support: Nil
Conflict of Interest: None Declared