EVALUATION OF CLINICAL EFFICACY OF RAJATA YOGA IN 
PRAMEHA W.S.R. TO DIABETES MELLITUS

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ABSTRACT

Rasa Shastra has been serving humanity from centuries with its unique metallic and herbo-mineral formulations. Prameha is one among the 8 Mahagadas as numerated by our Acharyas. The syndrome Diabetes mellitus has been largely covered under the broad heading of Prameha. Diabetes mellitus is a metabolic disorder of carbohydrate, fat & protein characterized by hyperglycemia with or without glycosuria. According to the International Diabetic Federation (IDF), the disease affects 285 million people of the world’s population in the 20 – 79 years age group and this number is expected to grow to 380 million by 2025. Rajata Yoga is mentioned in Rasa Tarangini and indicated in all types of Prameha. Rajata bhasma and Trijataka churna are the main ingredients of Rajata Yoga. Its clinical efficacy was evaluated in 30 patients of Prameha based on the signs and symptoms mentioned in classics. Rajata Yoga showed statistically extremely significant relief (p<0.0001) in Prabhuta mutrata, Avila mutrata, Karapada daha & suptata, Dourbalya, Kruchravyavayata, Pindikodveshtana, FBS, PPBS. It showed very significant relief (p<0.001) in Sweda atipravruttii and significant relief in (p<0.05) in Pipasaadhikyata, Kshudaadhikyata.

KEYWORDS: Prameha, Rajata Yoga, Diabets Mellitus.
INTRODUCTION
The incidence of Diabetes mellitus is increasing rapidly because of changes in dietetic habits and lifestyle. Diabetes is part of a larger global epidemic of non-communicable diseases. The IDF published findings revealing that in 2007, the country with the largest numbers of people with diabetes is India (40.9 million), followed by China (39.8 million), the United States (19.2 million).[1] With the largest number of diabetic patients, India leads the world with earning the dubious distinction of being termed the “Diabetes Capital of the World”.[2] Prameha as a disease itself is having a peculiar type of samprapti. The ahara vihara those causing Kapha Medo Mutra Vrudhi are the causative factors of Prameha. Due to indulgence of nidana like Svad, Amla, Guru, Snigdha aharas and Asya Sukham, Swapna Sukham etc, Kapha dosa along with Medo Dhatu undergoes Prakopa and gets Sthanasamsrayi in Vasti. Later, during the progress of the disease Pitta (along with Rakta dhatu) and Vata becomes associated with it.[3] A great deal of work has also been done by Ayurvedic research scholars on various herbal and mineral drugs to find an effective treatment for Prameha. So to fulfill the expectations from the Ayurvedic Rasa Shastra field and to find out more effective and safe therapy for Prameha, the formulation ‘Rajata Yoga’ was selected for present research work.[4] A special case proforma was prepared taking the signs and symptoms both from Ayurveda and contemporary science. 30 patients were evaluated for these parameters and given scoring. Follow up was carried out at on 15th and 30th day. Based on the scoring obtained paired ‘t’ test was applied by using Graph pad prism software between the scoring of first day and 30th day to evaluate the efficacy of Rajata Yoga.

MATERIAL AND METHODS
It’s an open, non-group, non-randomized clinical trial. Total 30 patients were selected from OPD of Department of Rasa Shastra & Bhaisajya Kalpana and Department of Kaya Chikista, S.V. Ayurvedic Hospital, Tirupati. Study was approved by Institutional Ethics Committee with approval no. IEC/SVAYC/15/RS/47 dated 26-03-2015. All the patients were given an information sheet stating all the details of the study protocol, benefits of the trial and do’s & don’ts to be followed by patient.

Inclusion Criteria
1. Age group between 30-70 years were selected irrespective of Sex, Religion and Occupation.
2. Fulfilment of Diagnostic Criteria of Diabetes Mellitus - Fasting blood glucose ≥126 mg/dl or Post Prandial blood glucose ≥200 mg/dl.

**Exclusion Criteria**
1. Patients suffering from any severe Systemic disease.
2. Drug and Chemical induced Diabetes Mellitus. E.g. Glucocorticoids, Thyroid hormones, Thiazides, Phynitoin etc.
3. Patients who are on Insulin therapy (Type 1 DM).
4. Gestational Diabetes Mellitus.

**Investigations**
Blood examination: Fasting blood sugar, Post Prandial blood sugar.
Urine - Sugar and albumin.

**Assessment criteria:** The assessment criteria were taken on the basis of symptoms and signs quoted in Ayurvedic classics and were graded according to severity.
- Prabhuta Mutrata.
- Avila Mutrata.
- Pipasaadhikyata.
- Kshudhaadikyata.
- Kara pada daha & Suptata.
- Swedhaadhikyata.
- Dourbalyata.
- Kriccha Vyavayata.
- Pindikodveshtana.

The assessment was done on the first day of reporting and on the last day of treatment that is 30th day.

**Dose:** Rajata Yoga 500mg capsules.

**Frequency:** Twice a day after meals.

**Anupana:** Water.

**Duration of study:** 30 days.

**Follow up:** 15th day, 30th day.
Statistical analysis

Statistical test for comparison was done by paired ‘t’ test by using Graph pad prism software.

*Pathya* - Purana shali, Mudga, Yava, Tikta rasa pradhana ahara, leafy vegetables, Vyayama.

*Apathya* - The patients were advised to avoid sweets, curd and other Kapha vardhaka ahara, day sleep.

**OBSERVATIONS AND RESULTS**

The demographic data of 30 patients obtained by questionnaire showed that maximum i.e. 33.3% of patients were between 51-60 year age group, 60% of the patients were male, 73.3% of patients were Hindus, 90% were married, 56.67% belonged to the middle class, 46.6% belonged to business group, 40% of the patients were in 0-2 year chronicity, 40% were of Vata kapha prakruti, 56.6% were of Avara Sara; 60% were of Avara Satva, 63.3% were of Madhyama Samhana, 60% were of Krura Kostha, 66.67% patients were habituated to excess sleep, 73.33% were having family history of Diabetes mellitus, 86.6% were of consuming milk preparations and 70% were consuming Atimadhura and Medo vardaka ahara. In the present study, 66.7% patients had Mukha Talu Kantha Sosha and 50% patients had Karapada daha & Suptata as purvarupa. The highest percentages of Rupas found in patients were Prabhuta mutrata and Kshudhadhikyata i.e. 100% each, followed by 93.33% number of patients of Pipasaadhikyata.

**Table No.1: Showing effect of Rajata Yoga on Subjective parameters**

<table>
<thead>
<tr>
<th>Chief Symptom</th>
<th>n</th>
<th>B.T. ± SD</th>
<th>A.T. ± SD</th>
<th>MD</th>
<th>Relief (%)</th>
<th>“t”</th>
<th>P-value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prabhuta mutrata</strong></td>
<td>30</td>
<td>2.5 ± 0.63</td>
<td>0.6 ± 0.62</td>
<td>1.9</td>
<td>79.16</td>
<td>9.2</td>
<td>&lt;0.0001</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Avila mutrata</strong></td>
<td>24</td>
<td>2.0 ± 1.17</td>
<td>1.0 ± 0.87</td>
<td>0.9</td>
<td>45.00</td>
<td>5.3</td>
<td>&lt;0.0001</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Pipasaadhikyata</strong></td>
<td>28</td>
<td>1.6 ± 0.8</td>
<td>1.4 ± 0.8</td>
<td>0.2</td>
<td>12.50</td>
<td>2.5</td>
<td>&lt;0.05</td>
<td>Significant</td>
</tr>
<tr>
<td><strong>Kshudhadhikyata</strong></td>
<td>30</td>
<td>1.5 ± 0.7</td>
<td>1.5 ± 0.8</td>
<td>0.3</td>
<td>13.00</td>
<td>2.3</td>
<td>&lt;0.05</td>
<td>Significant</td>
</tr>
<tr>
<td><strong>Karapadada &amp; Suptata</strong></td>
<td>24</td>
<td>1.6 ± 1.0</td>
<td>0.8 ± 0.7</td>
<td>0.8</td>
<td>50.00</td>
<td>7.5</td>
<td>&lt;0.0001</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Daurbalya</strong></td>
<td>25</td>
<td>2.0 ± 1.0</td>
<td>1.0 ± 1.0</td>
<td>1.0</td>
<td>50.00</td>
<td>1.8</td>
<td>&lt;0.0001</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Krishchhvyavayata</strong></td>
<td>15</td>
<td>0.9 ± 0.5</td>
<td>0.4 ± 0.5</td>
<td>0.53</td>
<td>66.66</td>
<td>4.0</td>
<td>&lt;0.0004</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Pindikodveshtana</strong></td>
<td>23</td>
<td>1.6 ± 1.1</td>
<td>0.9 ± 1.0</td>
<td>0.7</td>
<td>43.75</td>
<td>6.1</td>
<td>&lt;0.0001</td>
<td>Ext Significant*</td>
</tr>
<tr>
<td><strong>Sweda Atipravrutti</strong></td>
<td>25</td>
<td>1.5 ± 0.9</td>
<td>1.2 ± 0.8</td>
<td>0.2</td>
<td>13.33</td>
<td>3.2</td>
<td>&lt;0.005</td>
<td>Very Significant</td>
</tr>
</tbody>
</table>

**Table No.2: Effect of Rajata Yoga on Objective Parameters.**

<table>
<thead>
<tr>
<th>Investigation</th>
<th>n</th>
<th>Mean ± S.D</th>
<th>MD</th>
<th>Relief (%)</th>
<th>“t”</th>
<th>P-value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.T.</td>
<td>A.T.</td>
<td>B.T.</td>
<td></td>
<td>A.T.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FBS</strong></td>
<td>30</td>
<td>225.33 ± 44.64</td>
<td>174.37 ± 32.09</td>
<td>50.96</td>
<td>22.61</td>
<td>11.62</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>PPBS</strong></td>
<td>30</td>
<td>325.13 ± 52.24</td>
<td>263.70 ± 54.72</td>
<td>61.43</td>
<td>18.89</td>
<td>9.53</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Graph No. 1: Showing effect of Rajata Yoga on Subjective Parameters in 30 patients.

Graph No. 2: Showing effect of Rajata Yoga on Objective Parameters in 30 patients.

Note

* Ext Significant: Extremely Significant; -n-: Number of patients suffering with symptom; B.T: Before Treatment; A.T: After Treatment; S.D: Standard Deviation; M.D: Mean difference ; P-Value: Indicates significance of treatment on specific symptom; S.D, ‘t’ and p-value are calculated substituting ‘n’ value as actual number of patients suffering from that specific symptom; but not the total number of patients.

- Inference of Statistical reports
Above data clearly shows that Rajata Yoga is effective on all the cardinal symptoms of Diabetes Mellitus.
- **Statistically Extremely Significant Relief** (P<0.0001) was seen in *Prabhuta mutrata, Avilamutrata, Karapada Daha & Suptata, Daurbalya, KruchraVyavayata, Pindikodveshtana, FBS, PPBS.*

- **Statistically Very Significant Relief** (P<0.001) was found in *Sweda Atipravruthi.*

- **Statistically Significant Relief** (P<0.05) was found in *Pipasaadhikya, Kshudhadhikya*

Table No. 3: Showing Overall assessment Percentage of clinical trial.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Result obtained</th>
<th>Number of Patients</th>
<th>Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Moderate improvement</td>
<td>17</td>
<td>56.66 %</td>
</tr>
<tr>
<td>2.</td>
<td>Mild improvement</td>
<td>13</td>
<td>43.33 %</td>
</tr>
</tbody>
</table>

The therapy had shown moderate improvement in 56.66% of patients and mild improvement was seen in 43.33% of patients.

**DISCUSSION**

- Majority of the patient’s i.e. 33.3% were reported in the age group of 51-60 years. This may be due to increase in the incidence of the adult onset of Type 2 Diabetes Mellitus. The next predominance i.e. 30% was seen in between 30 – 40 years. Life style has a major role in Diabetes. Stressful working hours and irregular dietary habits of this age group may be the suggestive cause for the predominance of the disease in this age group.

- The sex wise distribution reveals that 60% of the patients were male and 40% were female. It indicates that the disease is more common in males than females in present
study. In fact the prevalence of Diabetes Mellitus is more or less common in both the sexes.

- Most of the registered patients are Hindus. This was due to high ratio of Hindus in sample from collected geographical region. These results cannot be measured for generalizing the religion wise distribution as the sample size is very small. Rather diabetes is common in all irrespective of religion.

- Among the registered patients 90% of them were married. Most of the patients were of age group between 30-50 years and were married.

- Maximum numbers of patients (56.67%) were belonging to middle class of economical status. Diabetes was once known to affect rich people. Now a day’s its incidence is changing to middle class of people. This may be due to rapidly changing life style and food habits in this class. The next predominance (23.3%) of distribution of Diabetes is seen in rich. This may be due to intake of high caloric diet, lack of exercise or minimal physical activity in them.

- It was observed that incidence is maximum in business group i.e.46.6%. The next predominance i.e. 23.33 % was seen in government service group. Occupational Stress is one of the main leading cause for many metabolic and life style disorders. Lack of physical exercise, improper food habits, negligence towards health due to lack of time and stress might be the reasons for prevalence in both these groups. Stress can alter the blood glucose levels in two ways. 1. People under stress may not take good care of them, may eat or drink (alcoholic) more and exercise less. 2. Stress hormones such as cortisol may also alter the blood glucose levels directly.\textsuperscript{[5]} In Ayurvedic classical texts also there is reference of Tyakta Chintana, Vishada, Avyayama as the causative factors in Prameha.\textsuperscript{[6]}

- The data shows that maximum number of patients i.e. 40% were having chronicity of 0-2 years, 33.3% patients had history of 2-4 years, 16.6% were above 6 years and 10% were 4-6 years. The observations of chronicity wise distribution vary from sample to sample. This also may indicate the awareness of the people to alternate system of medicine for restoration of quality life with minimal or no side effects.
Majority of the patients i.e. 40% had KaphaVata Prakruti followed by PittaKapha Prakruti (33.3%). It indicates that susceptibility of Prameha is seen more in Kapha dominant constitution. Prameha is one of the Santarpanajanya Vyadhis. The nidanas of Santarpana janya vyadhies is similar to nidana of Prameha i.e. intake of excess madhura, Snigdha, guru ahara, avayayama etc. It leads to vitiation of Kapha dosa and medo dhatu which are having similar qualities and participates in the manifestation of disease. So, Kapha Predominant Prakruti like Kapha Vata and PittaKapha were more prone to Prameha.

While assessing the Samhanana of patients, it was observed that majority of patients (63.3%) had Madhyama Samhanana. No specific reason can be attributed to it.

Majority of patients (60%) had krura kostha. Due to irregular food habits & modern life style, patients develop vishamagni which leads to Krura koshta. More over the incidence is higher in patients of age above 50 years. High blood sugar levels over a long period can lead to diabetic neuropathy. Damage to nerves controlling the digestive tract can lead to constipation, diarrhoea or incontinence.

Data reveals that maximum number of patient’s i.e. 66.67 % had Ati Nidra which is due to Kapha Vrudhi. In all classical references, Swapna Sukham, Diwaswapna are mentioned as the main causative factors for Prameha. A 2010 study in Diabetes Care found that people with sleep problems like difficulty in falling or staying asleep; sleeping fewer than five to six hours a night or more than eight to nine hours are more likely to develop type 2 Diabetes.

22 patients (73.33%) were having previous family history of the disease which proves the fact that family inheritance is common in the Diabetics. Acharya Sushruta classified Prameha into two types, where Sahaja Prameha lakshanas show genetic predisposition. Beeja dosha is mentioned in all classical texts as one among the Nidanas of Prameha. People with a family history have more chance of getting Diabetes, as there is genetic pre-disposition in this disease. Scientists have linked several gene mutations to a higher diabetes risk. Not everyone who carries a mutation will get diabetes. But many people with diabetes do have one or more of these mutations. Some of the genes associated with type 2 diabetes risk include: TCF7L2, ABCC8, CAPN10 and
GCGR. These genes control production of glucose, production and regulation of insulin etc.\cite{13}

- In Nidana of the disease, it was found that over eating of milk and ati snigdha ahara (86.6% & 76.6%) followed by Ati madhura and medo vardhaka ahara (70%) were most common causative factors among the patients. It is mentioned that atiyoga of madhura rasa, medo vardhaka ahara, ati snigdha ahara leads to dhamani upalepa, sleshmaja vikara and mamsa vridhi.\cite{14} In modern science it’s said that increased circulating concentration of free fatty acids are associated with the development of Diabetes in which the lipids impinge on the intra cellular pathway of insulin signalling to reduce insulin sensitivity.\cite{15} While in Viharaja Nidana, Svapna Sukha (76.6%), Diva Svapna (70%) was found in maximum patients continuous or excess indulgence of sleep in a day leads to Kapha vrudhi and leads to manifestation of Prameha.

- The highest percentage of symptoms found in patients were Prabhuta Mutrata and Kshudha Adhikya (100% each) which were found in all the patients hence it can be said that these are the cardinal features of the disease. The next predominant lakshanas were Atinidra and Pipasaadhikyata (93.3%).

- Rajata bhasma is having Sara guna, Sheeta Virya, Madhura Vipaka and Pramehagna, Rasayana, Uttama lekhana, Medhya, Hridya, Sroto Shodhana properties. It is Vatapitta hara / Vatakapha hara / Tridoshahara.\cite{16} Many research works proved the Anti-diabetic activity of Silver nano partices on Intraperitonial administration in dextrose induced diabetic rats. It was proved by the effective inhibition against carbohydrate digestive enzymes such as α- amylase and α- glycosidase, the key enzyme for diabetes.\cite{17}

- Twak churna is having Katu, Tikta, Madhura Rasa, Laghu, Ruksha, guna, Ushna Virya, Katu Vipaka, Vatakapha hara, Grahi, Stambhaka, Krimighna properties.\cite{18} Recent research works have proven that cinnamon extract promoted a better glycemic control in Diabetes induced rats.\cite{19}

- Ela churna is having Katu rasa, Madhura Vipaka, Laghu Ruksha guna, Sita virya and VataKapha hara\cite{20} properties. Seeds of E. cardomomum posses anti oxidant activity and can increase levels of Gluthione, a natural antioxidant in body. Ethanolic cardomon
leaves extract was capable to reduce blood glucose levels as well as total cholesterol of Alloxan induced diabetic rats.\textsuperscript{[21]}

- *Patra churna* is having *Katu, Madhura rasa, Laghu, Tikshna gunas, Ushna Virya, Ruchya, Dipana, Uttejaka* and *Vatakapha hara* properties.\textsuperscript{[22]} Cinnamom tamala leaves extract showed the presence of saponins, Phytosterols, fatty acids, Geraniol etc, which are having anti diabetic activity.\textsuperscript{[23]}

**CONCLUSION**

All the ingredients of *Rajata Yoga* are having *VataKapha hara, Pramehaghna, Lekhana* properties; it acts both as *Hetu Vipareetaka* and *Vyadhi Vipareetaka*. By the synergistic action of the ingredients, *Rajata Yoga* gave statistically extremely significant effect on both subjective and objective parameters of *Prameha*. It was observed in the clinical study that there was moderate relief in 56.66% and mild improvement in 43.33% of patients.

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