

## CLINICAL EVALUATION OF VANGA BHASMA PREPARED BY TWO DIFFERENT METHODS IN THE MANAGEMENT OF MADHUMEHA (DIABETES MELLITUS)

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### ABSTRACT

The present study was planned to evaluate the efficacy of *Vanga Bhasma* prepared by *puta* and *Vastraputa* method and same was subjected to patients having classical sign and symptoms of *Madhumeha*. Diabetes mellitus is similar to *Madhumeha* which is a sub-type of *Vataja Prameha*. A Clinical trial was carried out on 50 patients having classical signs and symptoms of *Madhumeha*. Selected patients were divided into two groups i.e. group A and B treated with *Vanga Bhasma* prepared by *Putra* and *Vastraputa* method respectively. The obtained results were analyzed on the basis of improvement in classical features. *Vanga Bhasma* prepared by *Putra* method shows significant improvement on subjective as well as on objective parameters.

**Keywords:** *Vanga Bhasma*, *Madhumeha*, Diabetes mellitus, hypoglycemic effect, Anti-hyperglycemic effect.

**INTRODUCTION:** Diabetes mellitus is a common chronic metabolic disorder prevalent all over the world. It has turned out to be the biggest “silent killer” in today’s world. The mortality rate due to Diabetes mellitus is very high and is ranked fifth amongst the ten major causes of death in southern part of India<sup>1</sup>.

According to data released by the International Diabetes Federation, 41 million of the 659 million people in the age group of 20-79 years in India have diabetes. Currently the number of cases of Diabetes worldwide is estimated to be around 150 million. This number is predicted to double by 2025 with over 20% being from urban set-ups.<sup>2</sup> Although the prevalence of Type I and Type II D. M. is increasing worldwide, the prevalence of Type II D.M. is expected to rise more rapidly

in future because of increasing obesity and reduced physical activity.

The word ‘*Madhu*’ is derived from the root “*Manyante Viseshena Jananti Jana Yasmin.*”(Shabdakalpadrum). The ‘*Meha*’ word is mainly related with the excretions through urine<sup>3</sup>. Thus the definition is the clinical entity in which patient voids the urine having concordance with *Madhu* i.e. of *Kashaya* and *Madhura* taste, *Ruksha* (dry) texture and honey like colour and body acquires sweetness called *Madhumeha*.<sup>4</sup>In Ayurveda *Madhumeha* has been described as one among the 20 types of *Prameha* & is a sub-type of *Vatik Prameha* in which patient passes excessive amounts of urine that tastes & looks like honey<sup>5</sup> and *Avaranjanya Madhumeha* can be correlated with diabetes mellitus type 2 for their similar.<sup>6</sup>

Diabetes mellitus is a metabolic disease characterized by deregulation of

carbohydrate, protein and lipid metabolism.<sup>7</sup> The primary feature of this disease is elevation in blood glucose levels (hyperglycemia), resulting from either a defect in insulin secretion from the pancreas, a change in insulin action, or both. The hyperglycemia has been shown to affect almost all tissue in the body and is associated with significant complications of multiple organ systems, including the eyes, nerves, kidney and blood vessels.<sup>8</sup> In spite of tremendous advancement of modern system of medicine till date, an ideal drug which can cure it is not yet available. The modern medicine is not satisfactory because of the hazardous side effects. One of the most common side effect of the modern medicine is occurrence of Hypoglycemia during medicament. Hypoglycemia or abnormally low blood glucose, is a complication of several diabetes treatments. It may develop if the glucose intake does not cover the treatment. The patient may become agitated, sweaty, and have many symptoms of sympathetic activation of the autonomic nervous system resulting in feelings similar to dread and immobilized panic. Consciousness can be altered, or even lost, in extreme cases, leading to coma and/or seizures, or even brain damage and death.<sup>9</sup> so, it is a need of a time to assess Anti hyperglycemic activity as well as hypoglycemic activity for *Ayurvedic Pramehghana* Drug too. All the classical texts are having same opinion for *Vanga Bhasma* for its *mehahara* effect. In the classics, *Madhumeha* is included in *Vatika Prameha*, so the very same disease has been selected for clinical trial.

*Vanga* is more popular for its wide spread uses than any other metals, as *Vanga* is

used abundantly in practice of Ayurveda in *Bhasma* form. It is clearly mentioned that as lions can kill elephants likewise *Vanga Bhasma* can eradicate the disease *Prameha*.<sup>10</sup>

*Vanga Bhasma* is a choice of Drug for the management of the Disease *Madhumeha*.

### AIMS AND OBJECTIVES

- To evaluate the efficacy of *Vanga Bhasma* and *Vastraputa Vanga Bhasma* for Hypoglycemic and Anti hyperglycemic effect.
- The data generated by all the above methods are used to find out overall effect of *Vanga Bhasma* and *Vastraputa Vanga Bhasma*.

### PLAN OF STUDY

#### Criteria for Selection of Patients:

- The patient having classical symptom of *Madhumeha* were selected from O.P.D. and I.P.D. of I.P.G.T. & R.A., Hospital, and Jamnagar.
- Blood glucose concentration  $\geq 11.1$  mmol/L (200 mg/dl) or Fasting plasma glucose  $\geq 7.0$  mmol/L ( $\geq 126$  mg/dl) or Two hour plasma glucose  $\geq 11.0$  mmol/L ( $\geq 200$  mg/dl)
- Age group of patients in between 30 – 70 years.
- A special detailed proforma was prepared for comparing all the signs and symptoms based on both the *Ayurvedic* and Modern description and a detailed history of each patient was taken

#### EXCLUSION CRITERIA:

- 1) Patients of IDDM.
- 2) Patients complicated with any cardiac problem.
- 3) Diabetes due to endocrinopathies e.g. Pheochromocytoma, Acromegaly, Cushing's syndrome, hyperthyroidism etc.

- 4) Drug or chemical induced Diabetes mellitus e.g. glucocorticoids, thyroid hormone, thiazides, phenytoin etc.
- 5) Patients suffering from any severe systemic disease.

**INVESTIGATIONS:** Routine Hematological Examinations like Hb%, TLC, DLC, ESR were done to rule out any other pathological condition.

#### **Biochemical Examinations**

- a) Blood Sugar: Fasting and post prandial.
- b) Lipid profile: - S. cholesterols. Triglyceride, S. HDL
- c) Blood urea and S. Creatinine: To assess the functional status of kidney.

**Urine:** Routine and Microscopic Examination

These investigations were done in all the patients before treatment and after completion of treatment.

#### **MATERIALS AND METHODS:**

**Groups:** Selected patients were randomly divided into two groups –

**Group A:** The patients were treated with Vanga Bhasma prepared by *Putra* method.

**Group B:** The patients were treated with Vanga Bhasma prepared by *Vastraputa* method.

#### **Posology :**

**Dose** : Same For both the group i.e. Cap.250 mg BD before meal.

**Duration** : 28 days

**Route** : Oral

**Anupan** : warm water

**Diet:** All the patients were allowed to take their routine diet but advised not to take extra carbohydrate and fatty diets.

#### **CRITERIA FOR ASSESSMENT**

After the completion of the treatment, the results were assessed by adopting the following criteria:

- Improvement in signs and symptoms of disease on the basis of the symptoms score.
- F.B.S. and P.P.B.S. levels.
- Serum Cholesterol.
- Blood urea and Serum Creatinine
- Urine sugar.

#### **STATISTICAL ANALYSIS:**

The obtained data were analyzed statistically. The values were expressed as mean  $\pm$  SEM. The data were analyzed by paired 't' test and comparison of both test drugs was analyzed by unpaired 't' test, a level of  $P < 0.05$  and  $P < 0.01$  were considered as statistical significant and highly significant respectively. For the assessment of the effect of the therapy following chief complaints and biochemical parameters were selected

*Prabhuta Mutrata* (Polyuria) *Trisha Adhika* (Polydipsia), *Aavil Mutrata* (Turbidity) *Kshudha Adhika* (Polyphagia), *Hasta-Pada-Tala Daha*, *Kara-Pada Suptata*, (Buring and numbness of hand & feet) *Pindikodvestana* (Leg Cramps) Fasting blood sugar, Postprandial blood sugar. *Prakriti*, *Sara* and *Samhanta* of the patients were also examined.

**RESULTS & DISCUSSION:** Total 50 patients were registered for the present study in which 47 were completed and 3 patients left treatment against medical advice. Out of these 28 were registered in Group A, 3 left against medical advice and 25 completed the treatment. 22 patients were registered in Group B and all the patients completed the treatment. (Table 1). 34.00 % were reported in the age group of 41 -50 years followed by 30.00 % in the age group of 51 -60 years, 20.00 % in the age group of 61-70 years, 16.00 % were in the age group of 31-40 years. This reveals

that maximum prevalence of the disease at Middle age. These findings were concordant to the recent statistical data which shows that the onset of Type II Diabetes mellitus after the forties is most common<sup>11</sup>.

Majority of the patients i.e. 36.00 % reported to have a chronicity more than 1 years followed by 26.00 % having > 5 years, 14.00 % having >10 year and 24.00% were having a chronicity of less than 1 year. Maximum number of the patients i.e. 50.00% were having *Kapha-Vata Prakriti* followed by 30.00% having *Vata-Pittaja* and 20.00% having *Kapha-Pittaja Prakriti*. *Madhumeha* was present in 82.00 % of the patients & in the rest 18.00 % patients no family history of *Madhumeha* was found. 82.00% of the patients confirmed the family history of *Madhumeha* which shows that Genetic predisposition is more important in *Madhumeha*. All the patients were having *Dwandvaja Prakriti* with maximum number of patients i.e. 50.00% were *Vataj-Kaphaja Prakriti*. Majority of the patients i.e. 90.00% were having *Madhyama Sara*, *Madhyama Samhanana* 92.00% and *Madhyama Satva* 62.00 %.

The 70.00% patients of this series were having *Prabhuta Mutrata* both in terms of quantity as well as frequency. The *Trishnadhikya* 72% and *Kshudhadhikya* 56.00% were found in patients and *Avila Mutrata* was found in 30.00% patients. From these observations, it can be predicted that the *Prabhuta Mutrata*, *Trishnadhikya* and *Kshudhadhikya* were the most common symptoms in the patients of *Madhumeha*.

Effect of *Vanga Bhasma* (group A), improvement on the chief symptoms of *Madhumeha* was found to be statistically

highly significant. At the level of  $P < 0.001$  were obtained in *Prabhutmutrata*, *Kshudhadhikya*, *Trishadhikya*, *Pindikoudvesthana* and in *Aavil Mutrata* at the level of  $p < 0.01$ , while in *Karpadadaha*, *Karapadasuptata* at the level of  $p > 0.1$  improvement was observed. Effect of *Vastraputa Vanga Bhasma* (group B), in improvement on the chief symptoms of *Madhumeha* was also found to be statistically highly significant. At the level of  $P < 0.001$  were obtained in *Prabhutmutrata*, *Kshudhadhikya*, *Trishadhikya*, *Pindikoudvesthana* while  $P < 0.01$  was obtained in *Aavil Mutrata* and *Karapadasuptata* at the level of  $p < 0.05$ . While in *Karpadadaha* statistically non-significant decrease were found in both the group.(Table 2).

Analysis of the HB percentage shows that *Vanga Bhasma* increases the Hb% of patients; however this increase is statistically non-significant. Which reveals that use for one month duration of *Vanga Bhasma* preparation not show any degenerative changes in the body. Statistically significant decrease in FUS was observed in Group B however this Group shows statistically non-significant decrease in FBS & PPBS level. (Table 3)

Group A shows statistically significant decrease on FBS(8.12%) and PPBS (11.56%) level.(Table 4) Lowering of blood sugar level may be due to several mechanisms like increase in the secretion of insulin from the islet cells, decrease in the secretion of glucogenic hormones like glucagons and gluco-corticoids, increased uptake in the peripheral tissues<sup>11</sup>. Which of these mechanisms is operating can be elucidated only through further studies. Both the Group don't show any changes in S.creatinine and Blood Urea level indicate

that both Kind of *Bhasma* not producing any hazardous effect to the Kidney function.

Data in Table no.5 shows that in Group-A moderate improvement was seen in 23.40% of patients, mild improvement in 17.02% patients and no change was seen in 8.51% patients. In Group-B 31.82% patients shows moderate improvement, 36.36% mild improvement and 22.72% patients shows no relief. In total 8.51% patients shows marked improvement, 19.15% patients show no change in the condition, 34.09% patients shows mild improvement and 38.29% patients shows moderate improvement.

**Pharmacological action:** There was no serious toxicity found in Charles foster albino rats in both the treated groups with even  $5 \times$  TED (Therapeutic Equivalent Dose) for continuous 90 days.

**Probable mode of action:**

In *Vanga Bhasma Tikta-Katu- Rasa, Laghu- Ruksha- Guna, Ushna Virya* and *Katu Vipaka* might have corrected the *Kapha Dushti*. Along with this, it contains the *Tikta Rasa*, which might have corrected the vitiation of *Pitta* in this way; *Vanga Bhasma* acted on *Kapha-Pitta* and also *Kaphavargiya Dushyas*, hence providing significant relief in the disease *Madhumeha*. So, this drug may have been effective on *Kapha* and *Pitta* mainly and due to its *Ushna Virya* may break the *Aavarana* of *Vata*. This *Tridoshashamaka* property of this drug helped to correct the *Dhatudushti* and *Srotodushti* leading to their normal functioning.

**CONCLUSION:**

In this study, clinical trial for both the *Vanga Bhasma* has been performed on patients of *Madhumeha* (Diabetes mellitus) for evaluating its Hypoglycemic and anti-

hyperglycemic effect. Total 50 patients were registered for the study, among them 25 were completed in Group A and 22 were in Group B. 3 patients left the treatment against medical advice. Highly Significant improvement in symptoms like *Prabhutmutrata*, *Aavilmutrata*, *Kshudhadhikya*, *Trishadhikya* and *Pindikoudvesthana* were observed in both the treated groups. While in *Karapada suptata* significant decrease was observed only with Group B. In objective parameters like FBS & PPBS significant decrease were found in Group A in comparison to Group B. Both the drugs don't show any Hypoglycemic effect on any patients. *Vanga Bhasma* prepared by *Putra* method exhibited better improvement on the objective parameters, although both the *Vanga Bhasma* don't show any hypoglycaemic effect to the patients.

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