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A Clinical Study to Evaluate the Efficacy of *Vanga Shilajatu* in *Madhumeha* with Special Reference to Type 2 Diabetes Mellitus - A Study Protocol

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Abstract: Background: Madhumeha is made up of the words Madhu and Meha. Madhu means "sweet," and Meha signifies "excess urination" (atipravritti/ Bahula Avila Mutrata).Madhumeha is a clinical condition identified as one of the forms of Vataja Prameha in Ayurveda.[1] Avil Prabhuta Mutra is Prameha's main feature.[2] Madhumeha is induced by Dhatukshaya and manifests as a thin and asthenic individual as a result of Oja loss or imbalance. The vitiated Kapha and Meda in Margavaranjanya Madhumeha obstruct the path of Vata. The obstructed Vata becomes vitiated again and transports Ojas to Basti, manifesting Madhumeha.[3] Madhumeha is associated with a comparable condition. Diabetes mellitus is a syndrome characterised by abnormal metabolism and hyperglycemia caused by a lack of insulin secretion or a combination of insulin resistance and inadequate insulin production. [4] This study was chosen to evaluate the efficacy of Vanga Shilajatu in Madhumeha (Type 2 Diabetes Mellitus).
Aim and Objectives: To study the effect of drug on clinical parameter & biochemical finding associated with Madhumeha (Diabetes Mellitus) and also to advise preventive measures to check the occurrence of disease individuals and masses. Methodology:50 Patient of either sex will be selected from age-group of 25-60 and fulfilling all the criteria's and will be administered with Vanga-Shilajatu capsules twice a day for 28 days. Results: Result will be decided on the basis of changes in subjective and objective parameters after the treatment. Conclusion: Vanga-Shilajatu may have significant results in Madhumeha (Type 2 Diabetes Mellitus).
Keywords: Madhumeha, Vanga Shilajatu, Prameha, Diabetes Mellitus, Hyperglycemia

I. INTRODUCTION

Sedentary lifestyles, bad eating habits, and physical inactivity in the present period attract several metabolic illnesses such as hypertension, ischemic heart disease, diabetes, crystal arthropathy, arthritis, and hyperuricemia. In ancient literature, the Acharyas mentioned an illness called *Madhumeha*, which resembles Type 2 Diabetes Mellitus in modern studies. *Madhumeha* is an type of *Parmeha*. The cardinal feature of the *Prameha* has been described as *Avile Prabhuta Mutrata*.[5] *Dhatukshaya* causes *Madhumeha*, which manifests as a thin and emaciated individual due to an imbalance in *Oja* or loss of *Oja*. The vitiated *Kapha Dosha* and *Meda Dhatu* impede the *Vata* channels in *Margavaranjanya Madhumeha.* The obstructed *Vata Dosha* becomes vitiated again, sustaining *Ojas* to *Basti* and manifesting as *Madhumeha.* In classical writings, *Madhumeha* is referred to as *Mahatyaya,* which means *Mahavyapattikara* (creating great problems).

It demonstrates a complex disease process due to the involvement of all three *Doshas* as well as the majority of body components as *Dushyas,* including *Rasa, Rakta, Mamsa, Medas, Majja, Shukra, Ambu, Vasa, Lasika, Ojas,* and *Sweda.* Furthermore, *Asthi's* influence cannot be overlooked, as the development of *Kesha* and *Nakha* is chronicled in *Poorvarupa*. To try successful care, ancient Indian physicians classified the condition in several ways, including etiological, pathological, and prognostic perspectives.[6]

Diabetes cases increased from 108 million in 1980 to 422 million in 2014.

Diabetes-related premature mortality increased by 5% between 2000 and 2016. Diabetes was the ninth biggest cause of mortality in 2019, accounting for an estimated 1.5 million deaths. Diabetes mellitus is expected to affect up to 79.4 million people in India by 2030.[7]

Thus, it is demand of time to seek safe and effective ayurvedic treatment. No study has been done on *Vanga Shilajatu* together for 50 randomly selected *Madhumeha* patients.Thus this study is taken.

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II. REVIEW OF LITERATURE

All Ayurvedic classical literature, including *Brih-trayi, Laghu-trayi, and Nighantu*, as well as recent text books will be studied. Websites such as PubMed, Google Scholar, Scopes, Articles, Journals, and Research Papers, among others, will be scanned for information on the subject.

III. REVIEW OF MODERN LITERATURE

Diabetes mellitus is a chronic condition caused by an inherent or acquired lack of insulin production by the pancreas, or by inefficient insulin synthesis. Such a deficiency causes an increase in the concentration of glucose in the blood, which damages numerous physiological systems, including the blood vessels and nerves. Diabetes is caused by a combination of pathogenic mechanisms. These range from autoimmune death of pancreatic -cells, resulting in insulin insufficiency, to anomalies that result in insulin resistance. Diabetes is characterised by anomalies in glucose, lipid, and protein metabolism caused by insulin's ineffective action on target tissues. [8]

Drug Review[9]

वंग शिलाजतुयुतं तु मतं प्रमेहे धातुक्षये दुर्बलनष्टशुक्रयोः ।

(योग रत्नाकर, प्रमेह चिकित्सा)

S.no	Drug	Scientific name	*Rasa*	*Guna*	*Virya*	*Vipaka*
1.	*Vang Bhasma*	Tin (Stannum)	*Tikta, Kashaya,* slight *Lavana*	*Ruksha, Laghu*	*Ushna*	*Katu Vipaka*
2.	*Shuddha Shilajita*	Asphaltum Punjabianum	*Kashaya and* slight *Amla Rasa*	*Ruksha*	slight *Sheeta,* slight *Ushna*	*Katu Vipaka*

IV. METHOD OF PREPARATION

The *Vang Shilajatu* will be prepared in the form of a capsule containing *Vang Bhasm* 125 mg and *Shuddha Shilajatu* 250mg in pure form and it will be administered with water.

1) Need Of Study - The modern medical system's line of therapy focuses mostly on stringent glycemic control, and long-term use of these treatments creates adverse effects such as low blood sugar levels, allergic skin rashes, and bone marrow depression. A better choice is to seek safe and effective ayurvedic treatment. A lot of research has been done on *Vanga Bhasma* and *Shuddha Shilajatu* individually for *Madhumeha*, but no study has been done on *Vanga Shilajatu* for 50 randomly selected *Madhumeha* patients. There is a research gap in proving the efficiency of *Vanga Shilajatu in Madhumeha* (Diabetes) and also there is need to find out the most effective, safe and cheap available management of *Madhumeha.*
2) Source Of Data - Total 50 patients of either sex and age group 25-60 will be selected randomly for this study from the OPD & IPD of *Kayachikitsa* department of Shri Krishna govt. Ayurvedic College and Hospital, Kurukshetra (Haryana), those fulfilling the inclusion criteria and ready to give informed consent.

V. AIM AND OBJECTIVES

1) To study the effect of drug on clinical parameter & biochemical finding associated with *Madhumeha* (Diabetes Mellitus)
2) To advise preventive measures to check the occurrence of disease individuals and masses.
3) To standardize an ayurvedic line of treatment both drug and dose which may have an effective role in management of patients of *Madhumeha.*
4) To explain the *Madhumeha* on the basis of critical review in classic text of Ayurveda and with the help of modern literature.
5) To provide cheap, safe and effective treatment from Ayurveda to *Madhumeha* patients.

VI. CASE DEFINITION

A unique proforma will be produced that includes all of the points of detailed history and physical examination specified in Ayurveda as well as modern parameters Each patient will be assessed using this proforma, which includes a detailed history, signs and symptoms, *Nidana panchaka,* and other information.

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All vital signs such as blood pressure, pulse rate, respiratory rate, and temperature will be closely checked in each patient. All patients chosen for the experiment will be informed about the nature of the study, and their agreement will be obtained prior to the start of the trial.

Type Of Study: Single centered, simple Random sampling, open label clinical study

Research Question: Efficacy of *Vanga Shilajatu* in *Madhumeha* (Type 2 Diabetes Mellitus)?

Hypothesis

Alternate Hypothesis (H1): *Vanga Shilajatu* is significantly effective in the management of *Madhumeha* (Type 2 Diabetes Mellitus).

Null Hypothesis (H0): There is no significant efficacy of *Vanga Shilajatu* in management of *Madhumeha* (Type 2 Diabetes Mellitus).

Type of Study: Single centered, simple Random sampling, open label clinical study

Site of Study - Shri Krishna Govt. Ayurvedic College and Hospital,Kurukshetra Haryana.

Posology - 1 capsule of *Vanga Shilajatu* BD (Each capsule contains 125 mg of *Vanga Bhasma* and 250 mg *Shuddha Shilajatu* twice a day 15 minutes before meal with water

A. *Inclusion Criteria:*

1) Patients willing for clinical trials and ready to give written consent.
2) Patients with age between 25-60yrs of either sex.
3) Patients possessing signs and symptoms of *Prameha* (Diabetes Mellitus).
4) Diagnosed & confirmed cases of *Madhumeha* on the basis of Diagnostic criteria for diabetes.

Table 01: Diagnostic criteria for diabetes

Parameter	Normoglycemia (mg/dl)		Prediabetes (mg/dl)		Diabetes (mg/dl)
	WHO	ADA	WHO	ADA	
FPG	< 110	< 100	110-125 (IFG)	100-125 (IFG)	≥ 126
2-h PG	< 140		140-199 (IGT)		≥ 200
HbA1c	<5.7%		5.7-6.4%		≥ 6.5%
Random plasma glucose*					≥ 200 (with symptoms of diabetes)

- * Individuals with random plasma glucose between 140-199mg/dl are recommended to undergo OGTT
- WHO - World Health Organisation; ADA-American Diabetes Association; IFG - Impaired Fasting Glucose; IGT - Impaired Glucose tolerance; FPG - Fasting Plasma Glucose; 2-h PG-2 hour post load Glucose test (oral glucose tolerance test) plasma glucose; HbA1c – Glycosylated Haemoglobin

5) FBS-126-200mg/dl PPBS-200-300mg/dl
6) HbA1c 6.5 % - 7%

B. *Exclusion Criteria:*

1) Patients not willing for the clinical trial.
2) Patient not fulfilling the inclusion criteria.
3) Patients below the age of 25 years and above the age of 60 years
4) Fasting Blood Sugar Level <126 mg/dl and >200 mg/dl
5) Post Prandial Blood Sugar Level <200 mg/dl and >300 mg/dl
6) HbA1c <6.5% and >7%.
7) Patients of Insulin dependent Diabetes Mellitus (IDDM)
8) Patients with diabetic complications such as impaired renal functions.

9) Patients suffering from Secondary Diabetes.
10) Gestational diabetes.
11) Pregnant ladies and lactating mothers.

C. Withdrawal Criteria:
1) Patients developing any serious adverse effects
2) Deteriorations of the condition of the patients after taking treatment
3) Patients not willing to continue in study.
a) Follow Up – Patients will be followed up on every 7 days during the course of therapies to assess variation in symptomatology and to know any complication.
b) Discussion - *Madhumeha* is induced by *Dhatukshaya* and manifests as a thin and asthenic individual as a result of *Oja* loss or imbalance. The vitiated *Kapha* and *Meda* in *Margavaranjanya Madhumeha* hinder the transit of Vata. The impeded *Vata* becomes vitiated again and transports *Ojas* to *Basti*, manifesting *Madhumeha*. *Vanga Shilajatu's* contents include *Vanga Bhasma* and *Shuddha Shilajatu*. *Tikta, Katu Rasa, Laghu, Ruksha Guna, Ushna Virya*, and *Katu Vipaka* would act on the *Kapha Dushti* in *Vanga Bhasma*. *Mehahara, Gulmahara, Medohara, Agnimandyahara, Kshayaghna, Panduhara, Shosahara, Vranahara,* and *Shukrakshayahara* are some of the names. *Shuddha Shilajatu* contains *Tikta Rasa, Ushna Virya,* and *Katu Vipaka*, all of which will influence the *Kapha Dushti*. Its *Ushna Virya* breaks *Vata Avarana* and has *rasayana* and *vrishya* qualities.[10]

D. Subjective Criteria:
All the Symptoms will be assessmed by using Symptom Rating Scale and thes symtoms are-
1) Avila Mutrata (Turbidity)
2) Mutramadhurya (Glycosuria)
3) Pipasa-Adhikya (Increased Thirst)
4) Kshudha-Adhikya (Increased Appetite)
5) Swedadhikya (Perspiration)
6) Angagandha (Bad Odour)
7) Nidradhikya (Increased Sleep)
8) Hasta-Pada-Tala Dahakara
9) Pada Suptata
10) Prabhuta Mutrata (Polyuria)

E. Objective Criteria
Following investigations will be done for safety of the drugs and to exclude the cases as per the exclusion criteria mentioned earlier
11) FBS AND PPBS
12) HBA1C
13) CBC
14) Lipid Profile
15) Blood Urea
16) Serum creatinine
17) SGOT
18) SGPT
19) URINE (Routine and microscopic)
Criteria For The Assessment Of Overall Effect Of The Therapies:
The results will be evaluated on the basis of clinical parameters obtained before and after the completion and the assessment will be carried out on further finding in below mentioned tabulated form.

S. No.	Positive Result Findings	Assessment
1.	han 25%	Non-satisfactory

2.	to 50%	Good
3.	o 75%	Satisfactory
4.	o 100%	Excellent

VII. STATISTICAL ANALYSIS

The information gathered on the basis of above observations was subjected to statistical analysis in terms of mean (x), standard deviation (S.D.) and standard Error (S.E.). Necessary and applicable statistical test will be applied.

The obtained results will be interpreted as:

Insignificant - $P < 0.10$

Significant - $P < 0.05$, < 0.01

Highly Significant - $P < 0.001$

VIII. SUMMARY AND CONCLUSION

The work will be summarized and the result will be concluded after the above mentioned study with the help of statistical data.

A. Ethics and Publication

The ethical committee has approved the research topic following thorough review and presentation.

B. Assent or Consent

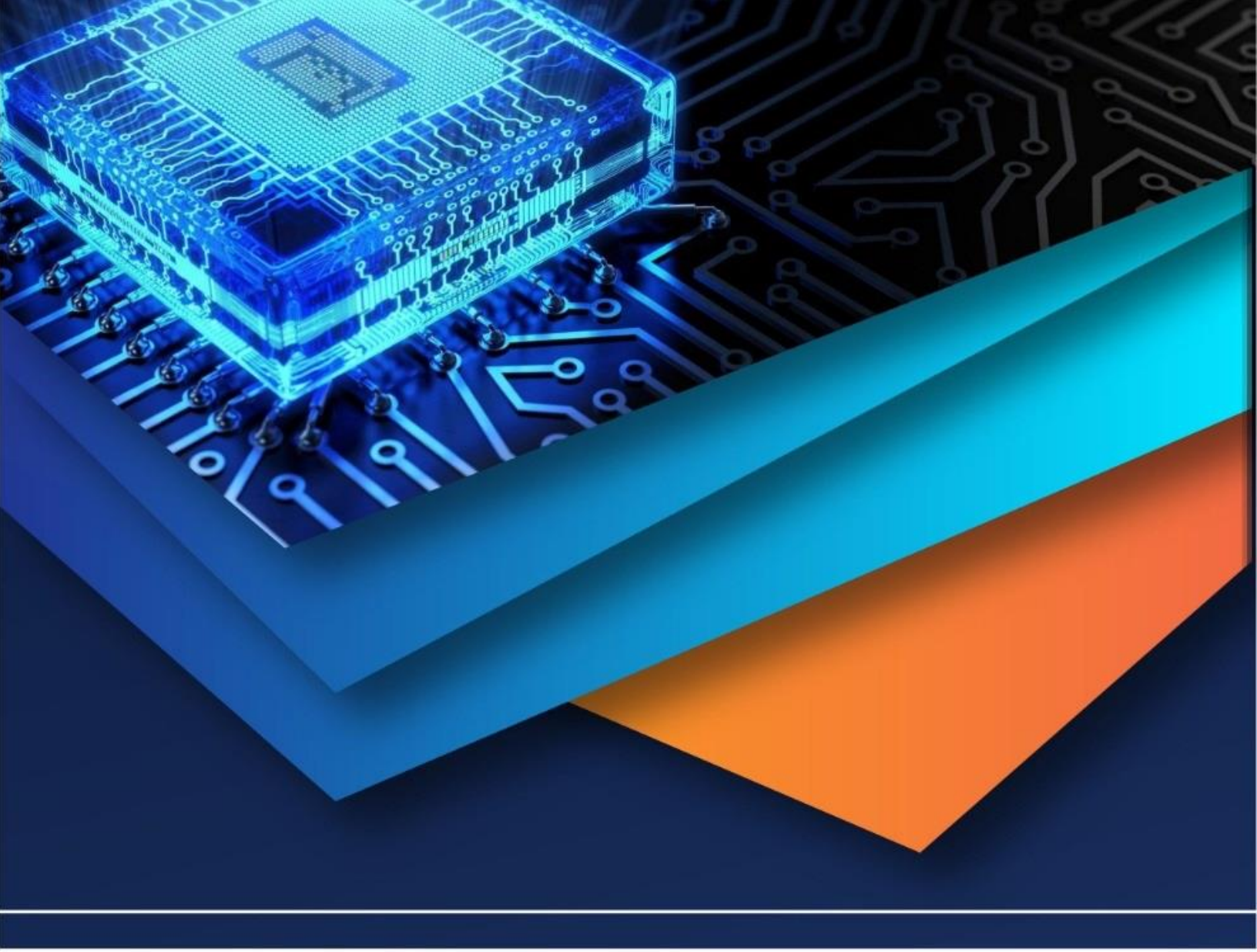
Subjects will be given detailed treatment information in their native language. Before beginning the trial, patients will be asked to provide written consent.

IX. RESULTS

The treatment's results will be tabulated and statistically evaluated using relevant tests, and the level of significance and then it will be published.

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