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Research Article

A CLINICAL STUDY ON *GUDUCHI SATTAVA* (STARCH OBTAIN FROM STEM OF *TINOSPORA CORDIFOLIA*) IN *MADHUMEHA* W.S.R. TO DIABETES MELLITUS TYPE II

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ABSTRACT

Madhumeha (Type 2 Diabetes Mellitus) is a global burden. At present, it occupies significant position among non-communicable diseases. It is a major cause of mortality and morbidity in middle age group people. Alterations in metabolism have been main culprit in the pathology of Type 2 Diabetes Mellitus. There are several challenges in diabetes management, including a rising prevalence in urban and rural areas, lack of disease awareness among the public, limited health care facilities, high cost of treatment, suboptimal glycemic control and rising prevalence of diabetic complications. India has to take drastic and urgent steps to develop an integrated national system for early detection and prevention and better management of Diabetes Mellitus. The present clinical study conducted to evaluate the effectiveness of *Guduchi sattava* in reliving the symptoms of hyperglycemia. Fifty newly diagnosed *Madhumeha* patients of either sex in the age group of 30-70 years are included in this study. *Guduchi sattava* (1g daily) are given orally for 90 days with plan water with and without diet restriction and exercise. Type 1Diabetes Mellitus, Diabetes Mellitus with pregnancy, Gestational diabetes etc are excluded here. All patients are evaluated based on clinical features, and laboratory parameters like-blood glucose level, lipid profile and HbA_1C. The present study concluded that *Guduchi sattava* has definite hypoglycemic effect and more effective on fasting glucose level then postprandial glucose along with diet and exercise.

KEYWORDS: *Madhumeha*, Diabetes Mellitus, *Guduchi sattava*, *Tinospora Cordifolia.*

INTRODUCTION

Madhumeha (T2DM) is now one of the greatest threats to humanity. The changing life style of human being by means of dietetic and behavioral pattern plays a major role in the manifestation of several diseases. This-changing patterns may also leads to the development of *Madhumeha* (T2DM). *Madhumeha* (T2DM) and its complication now become a potential public health problem. Though modern anti-diabetic drug are effective but there are some limitation also. Therefore, a vigorous searching of solution from natural remedies is going in all over the world to get an effective control of this disease as well as its complication. Ethno botanical studies of traditional remedies used for diabetes around the world have identified more than 1,200 species of plants with hypoglycemic activity although only a few of them have scientifically studied. *Guduchi* is a well-known classical drug, successfully used in *Ayurvada* for the management of *Madhumeha*. *Guduchi sattava* is also effective in the management of *Madhumeha* (T2DM)[1]. Here study have been carried out to get a critical analysis between *Madhumeha* & T2DM, and to get a scientific data about its varying degree of hypoglycemic and anti hyperglycemic activity of *Guduchi sattava*.

MATERIALS AND METHODS

Study area: 50 patients of *Madhumeha* (Diabetes Mellitus Type II) have selected from the OPD & IPD of IPGAE&R at SVSP Hospital based on details history taking, clinical examinations & pathological investigations.

Study population: Mainly around North Kolkata area.
Study period: 90 days

Sample size: 50 patient;

Sample design

Grouping of patients: The total patient has been divided into two equal groups (25 in each group). Group A- Treated with *Guduchi sattava* along with diet and exercise. Group B- Treated with diet and exercise only.

Exclusion criteria

1. Type - I diabetes mellitus
2. Diabetes mellitus with pregnancy
3. Gestational diabetes
4. PPBS > 210mg/dl
5. Creatinine > 1.5mg/dl
6. Diabetes mellitus with ketoacidosis or H/O it or any others complications.

Inclusion criteria

1. Newly diagnosed cases of diabetes mellitus type II
2. PPBS ≤ 210mg/dl

Study design

Step I: Patients has been selected from the OPD & IPD of IPGAE&R at SVSP Hospital as per selection criteria. Inform consent has been taken from all the subjects for the purpose of the studies.

Step II: Confirmation of diagnosis.

Step III: Patients has been divided into two groups. Group A has treated with *Guduchi sattava* and diet, exercise. Group B has been treated with diet and exercise only.

Step IV: Regular follow up for three months through clinical examinations and laboratory investigations.

Step V: Assessment of results & statistical analysis.

Parameter has been studied

Clinical symptoms: *Pravuta Mutrata* (Polyurea), *Ati Pipasa* (Polydipsia), *Ati Lolota* (Polyphagia), *Krishatwa* (Weight loss), *Sithilangata* (General Weakness).

Laboratory investigations-FBS, PPBS, HbA $_1$C, Lipid Profile

Study Technique: Group A has been treated with *Guduchi sattava* along with diet and exercise

1) Dose of *Guduchi sattava* - 1g twice daily, orally.
2) Vehicle - plain water.
3) Diet- The calories value of diet was 30 kcal/kg body weight.
4) Exercise- Morning exercise for 30 min.

Group B has been treated with diet and exercise only.

Plan for data analysis: Assessment of result has been done and data has been analyzed by standard statistical method as mean +_SE, followed by Student t test.

OBSERVATION AND RESULT: Demographic profile

Age Distribution

Table 1: Age distribution in 50 cases of *Madhumeha* (T2DM)

S. No.	Age distribution in years	No. of Patients	Percentage
1.	31 - 40 years	2	4%
2.	41 - 50 years	32	64%
3.	51 - 60 years	14	28%
4.	61 - 70 years	1	2%
5.	71 and above	1	2%
	Total	**50**	**100**

The age distribution of 50 cases of *Madhumeha* (T2DM) revels that maximum number of patients between age group of 41 - 50 years i.e. 64%. This is followed by next higher incidence i.e. 28% patients in the age group of 51 - 60 years.

Incidence of sex: In this series of 50cases *Madhumeha* (T2DM) it observes that females (60%) were more than the male (40%). So it can be inferred that *Madhumeha* can effect in both sexes, but more in female. Standard textbook of medicine also clearly mentioned that T2DM is higher in female than the male.

Incidence of Occupation

Table 2: Occupational incidence in 50 cases of *Madhumeha* (T2DM)

S.No.	Occupation	No. of Patient	Percentage
1.	Professional	5	10%
2.	Semi Professional	2	4%
3.	Clark/ Shop Owner/Farm Owner	30	60%
4.	Skilled Worker	6	12%
5.	Unskilled Worker	3	6%
6.	Unemployed	4	8%
	Total	50	100. 00

Occupational incidence was noticed in all the cases of *Madhumeha* (T2DM) and it was found that highest incidence is 60% was of Clark/ Shop-Owner/ Farm-Owner which was followed by the next higher incidence of unemployed i.e. 8%. So it can be interpreted that sedentary lifestyle is closely related with this disease. Both *Ayurvedic* & Western Literature has mentioned that there is a relation between sedentary lifestyle and the development of this disease.

Incidence of Habitat: Distribution of Habitat in all 50 cases of *Madhumeha* (T2DM) was assessed. It was found that 38 patients i.e. 76% came from urban area and 12 patients i.e. 24% come from rural area. In rural area the prevalence of T2DM is 2.4% and 11.6% among urban population. It is due to High familial aggregation, raised stress lebel and lifestyle. As in our study it is also seen.

Incidence of Education: The education incidence of 50 patients reveals that the maximum numbers of patients were belonging to the Graduate education group i.e. 52%, followed by 20% patients were belongs to Literate group.

Incidence of Marital Status: In the present series of 50 cases of *Madhumeha* (T2DM) showed that maximum numbers of patients were married that is 76%, followed by 6 patients were widow (12%) and 3 patients were Unmarried (09%). Married people are exposing to maximum stress and strain because of greater complexities of married life.

Socio economic Status: Incidence of income status was observed in all the 50 cases of *Madhumeha* (T2DM). In this series 9% patients were under lower income group and their monthly income were below 10000/- month. Higher incidence of monthly income was 60% i.e.> Rs. 20000/- Month. Form the table it can be conclude that *Madhumeha* can affect in higher - economic group.

Religious Distributions: Patients of all regions were included for this study. In this series maximum 35(70%) patients were having Hindu community, followed by 12(24%) patients having Muslim community.

CLINICAL PROFILE: Pattern of duration of illness in 50 cases of *Madhumeha* (T2DM)-

Duration of illness observed in 50 patients of the present study. Maximum no. Of patient i.e. 30 (60%) were in the duration of illness in the range of 0 - 1 year. There were 14 patients (28%) in the range of 1 - 3 years and remaining 6

(12%) give the history of 3 years and above duration of illness.

Incidence of family history: Family History of the disease was enquired in all 50 cases of *Madhumeha* (T2DM). It was Present only in 16 Patients i.e. (32%). It was absent in remaining 34 patients i.e. (68%).

Incidence of Nature of work

The nature of work was studied in all the 50 cases of *Madhumeha* (T2DM), it was observed that maximum number of patients i.e. 34 (68%) gave the history of Sedentary type of work. 12 patients i.e. (24%) were enjoying Moderate type of work habit. Both *Ayurveda* and Conventional Medicine clearly noted the direct relation between sedentary habits and the disease.

Incidence of Chief Complaints

Table 3: Incidence of Chief Complaints in 50 cases 0f *Madhumeha* (T2DM)

S. No.	Complaints	No. of Patients	Percentage
1.	Polyuria/ *Prabhutamutrata*	10	20%
2.	Polydipsia/ *Ati Pipasa*	4	8%
3.	Polyphagia/ *Ati Lolota*	7	14%
4.	Wight loss/ *Krishatwa*	5	10%
5.	General weakness (*Sithilangata*)	25	50%
6.	Burning sensation in hands and feet/ *Hasta Pada Daha*	2	4%

Incidence of clinical presentation was observed in all the 50 patients of *Madhumeha* (T2DM). 20% patients were complaining of polyuria (*Prabhutamutrata*) and 50% of general weakness (*Sithilangata*), weight loss was 10%, Poly phagia (*Ati lolota*) was 14%, Polydipsia (*Ati pipasa*) 8%, Burning sensation in hands and feet (*Hasta Pada Daha*) was 4%. All the clinical presentation are showing in table no. 12 and

Incidence of Body Weight: Incidence of body weight was studied in all 50 cases of *Madhumeha* (T2DM). It was observed that maximum number of patients i.e. 30 (60%) having the body weight between 71 - 85 kg. 15 patients i.e. 30% were between 56 - 70 kg while 5 patients (10%) were between 40 - 55 kg.

Incidence of Addiction: Addiction incidence was noticed in all the cases of *Madhumeha* (T2DM) and it was found that highest incidence i.e. 80% patients were addicted by Tea/Coffee which was followed by the next higher incidence was of Smoking i.e. 24%.

Incidence of Diet Habit: In this series of *Madhumeha* (T2DM), it observes that maximum number of patients were non-vegetarian i.e. 94% followed by 3 patients were vegetarian i.e. 6%.

Incidence of Prefer *Rasas*: Incidence of preference of *Rasas* was observed in this study of *Madhumeha* (T2DM) in all 50 cases. It was found that maximum number of patients i.e. 28 (56%) prefers the *Madhura Rasa*; followed by 20% patients were in preference of *Amla Rasa* i.e. 20%.

Incidence of *Dehaprakriti* : Incidence of *Dehaprakriti* was noticed in all the cases of *Madhumeha* (T2DM). It reveals that maximum number of patients i.e. 30 (60%) were *Vata - Kaphaja* while the rest higher *Dehaprakriti* was *Pitta-Kaphaja* i.e. 20%.

Incidence of *Manas Prakriti*: In the present study of *Madhumeha* (T2DM), *Manas Prakriti* was observed in all 50 cases. It was found that maximum number of patients i.e. 30 (60%) were in Tama *Prakriti* followed by 20 patient i.e. 40% were in Raja *Prakriti*.

Therapeutic Trial: The therapeutic trial was conducted in 50 cases of *Madhumeha* vis-a-vis Type two Diabetes Mellitus, who come for follow up studies. They were sub divided into treatment Group A and treatment Group B (25 patients in each group). As mentioned earlier Group A patient treated with *Guduchi sattava* 1gm twice daily morning & evening along with Luke warm water, orally for a period of 90 days an. Group B patients advised for diet and exercise only. The effect of treatment on symptom profile 'and statistical value of different parameters were evaluated.

Relief of Symptoms before and after treatment by *Guduchi sattava* along with diet and exercise

Table 4: Effect on Symptoms before and after treatment by *Guduchi sattava* along with diet and exercise

S.No	Symptoms	Before Treatment	After Treatment of 90 days
1.	Polyuria (*Prabhutamutrata*)	4	1
2.	Polydipsia (*Atipipasa*)	1	1
3.	Polyphagia (*Atilolota*)	3	1
4.	Weight loss*(Krisha*)	4	1
5.	General Weakness (*Sithilangata*)	18	13
6.	Burning sensation in hands and feet (*Hasta Pada Daha*)	2	2

Table 5: Relief of Symptoms before and after treatment by diet and exercise only

S. No.	Symptoms	Before treatment	After treatment 90 days
1.	Polyuria (*Prabhutamudrata*)	6	1
2.	Polydipsia (*Atipipasa*)	3	0
3.	Polyphagia (*Atilolota*)	4	1
4.	Weight loss*(Krisha*)	4	0
5.	General Weakness (*Sithilangata*)	7	0
6.	Burning sensation in hands and feet *(Hasta pada daha)*	0	0

Effect of treatment Fasting blood sugar in Group A and Group B patients of *Madhumeha* (T2DM)

Table 6: Effect of treatment on Fasting blood sugar in Group A and Group B patients of *Madhumeha* (T2DM)

Group	Mean Score		% of relief	SD(±)	SE(±)	T	P value
	BT	AT					
A	139.0	123	10.93	3.81	0.76	13.05	<.0.001
B	137	134.5	2.82	4.28	0.856	2.57	<0.01

BT=Before treatment; AT= After treatment; SD= Standard deviation; SE= Standard error; 't'= Paired test; P= the significant level of percentage.

Effect of treatment on Post prandial blood sugar in Group A and Group B patients of *Madhumeha* (T2DM)

Table 7: Effect of treatment on Post prandial blood sugar in Group A and Group B patients of *Madhumeha* (T2DM)

Group	Mean Score		% of relief	SD(±)	SE(±)	T	P value
	BT	AT					
A	206.6	198.6	3.87	3.475	0.695	11.51	<0.001
B	200.2	197.8	1.19	1.29	0.29	3.25	<0.05

BT=Before treatment; AT=After treatment; SD=Standard deviation; SE=Standard error; 't'=Paired test; P=the significant level of percentage.

Effect of treatment on Cholesterol in Group A and Group B patients of *Madhumeha* (T2DM)'

Table 8: Effect of treatment on Cholesterol in Group A and Group B patients of *Madhumeha* (T2DM)

Group	Mean Score		% of relief	SD(±)	SE(±)	t	P value
	BT	AT					
A	150	130.2	13.2	5.6	1.12	8.9	<0.001
T	148	139.6	5.8	1.092	0.218	3.21	<0.05

BT=Before treatment; AT=After treatment; SD=Standard deviation; SE=Standard error; 't'=Paired test; P=the significant level of percentage.

Effect of treatment on Triglyceride in Group A and Group B patients of *Madhumeha* vis-a-vis Type 2 Diabetes Mellitus

Table 9: Effect of treatment on Triglyceride in Group A and Group B patients of *Madhumeha* vis-a-vis Type 2 Diabetes Mellitus

Group	Mean Score		% of relief	SD(±)	SE(±)	t	P value
	BT	AT					
A	192.4	185.4	3.64	4.13	0.826	9.21	<0.001
B	189.6	186.4	1.68	3.12	0.624	2.45	<0.01

BT=Before treatment; AT=After treatment; SD=Standard deviation; SE=Standard error; 't'=Paired test; P=the significant level of percentage

Effect of treatment on HbA_1C in 10 patients of Group A

Table 10: Effect of treatment on HbA_1C in 10 patients of Group A

Group	Mean Score		% of relief	SD(±)	SE(±)	t	P value
	BT	AT					
A	7.6	7.5	1.315	0.01	0.0031	0.32	>0.01

BT= Before treatment; AT= After treatment; SD= Standard deviation; SE= Standard error; 't'= Paired test; P= the significant level of percentage.

DISCUSSION

Discussion on demographic data

Age: The data reveals that the individuals are more affected by type 2 DM after 4 decade,64% subject belongs to 41-50yrs of age, followed by 28% from 51-60 yrs of age. So it appear that T2DM is common in middle age group and older. The reason for this may be that the environmental factors like stress, food habit, life style etc. are common in this age group.

Gender: Total distribution of males was 40% & females were 60 %. Both male & females are having risk of getting Diabetes Mellitus but female are more prone to develop as per the study.

Occupational status: Occupation plays major role in the manifestation of *Madhumeha*. The recent dramatic increase indicates that lifestyle factors (sedentary lifestyle) may be particularly important in triggering the genetic elements that cause this type of diabetes.[2] In present study 60% subjects are Clark or shop owner or farm owner.

Habitat: There were 76% patients from urban area. This data reveals that urban lifestyle accounts for the increasing prevalence of *Madhumeha* (T2DM) as there is sedentary lifestyle in the urban.

Educational status: In present study 52% patients are belonging to graduate education.

Marital status: Data shows 76% patients were married. Stress and strain in married life may act as causative factor for the diseases.

Socio-economic status: Among 50 cases 60% belongs to higher income group, followed by 22% from middle income group. So it can be inferred that peoples belongs to higher socio economic are more prone to T2DM due to sedentary habits among them.[2]

Religion: In this study, 70% of patients were belongs to Hindu community.

Discussion on Data of Clinical Profile

Incidence of duration of illness: 60% of total patients having duration of illness of 0 to 1 yr.

Incidence of family history: Family history of Diabetes Mellitus, were absent in 68% of cases according to data.

Incidence of nature of work: Data showing that 68% of patients are related to sedentary habit followed by 24% 0f moderate work, while affected heavy worker are very low in number. It is clearly mentioned both in *Ayurvedic* [3] and Conventional classical text that sedentary life style is a major etiological factor for this disease.

Distribution of chief complain: Total 50 % patients among the cases were complaining of general weakness (*Sithilangata*) where as 20% patients were presented with *Prabhutamutrata* (polyurea). Respectively 14% with *Atilolota* (polyphagia), 10% with *Krishatwa* (weight loss), 8% with polydipsia and 4% with *Hasta pada daha* (burning sensation in hand and feet) were present.

Incidence of body weight: 60% of total patients were between 71-80 kg body weights, followed by 30% from 56-70 kg body weight, whereas only 10 of patients were within the range of 45-56 kg body weight. So from this data it is clear that obese persons are more prone to develop the disease *Madhumeha*.

Incidence of addiction: 80% among the patients were addicted to tea or coffee, where as 24% to smoking, 18% to tobacco, and 10% to alcohol respectively.

Incidence of diet habit: The non vegetarian persons were predominant in data covering 94% among all. From this data, it may b concluded that non-vegetarians are more susceptible to *Madhumeha*.

Incidence of prefer rasa: *Madhur rasa* was preferred by 56% of patients and *Amla rasa* by 20% where as *Lavana*, *Katu*, *Tikta*, *Kasaya* rasa was preferred by respectively 8%,8%,4%,4%.Ayurvedic classical text also mention that excessive intake of *Madhur rasa* may leads to *Madhumeha*.

Incidence of *Deha prakriti* and *Manas prakriti*

Maximum patients were found *Vata kaphaja* in nature who have T2DM.They are about 60%.*Pitta Kaphja prakriti* were found in 20%.So it can be inferred that *Prakriti* plays an important role in *Madhumeha*. Among the all patients, 60% were *Tamasa* in nature. Person having *Tamasa prakriti* perform a less physical activity [4] for which they are more prone to *Madhumeha*.

Discussion on Clinical Trial

Mean value of Fasting blood glucose was present in Group A &Group B patients before treatment 139 & 137, after 90 days of treatment it was reduced to 123 & 134.5 respectively. So in respect of fasting blood glucose level, the drug *Guduchi sattava* shows the significant result i.e. $p<0.001$. In Group B patients treated with diet & exercise, the result was no significant i.e. $p<0.01$.

Mean value of Post prandial blood glucose was present in Group A & Group B patients before treatment 206 & 202.2, after 3months of treatment it was reduced to 198.6 & 197.8 respectively. So in respect of post prandial blood glucose level, the drug *Guduchi sattava* shows the significant result i.e. $p<0.001$, rather than the patients treated with diet & exercise, having also a significant result i.e. $p<0.01$.

The initial mean value of Serum cholesterol level of Group A patients was 150 & Group B patients was 148.It was reduced to 130.2 and 139.6 respectively after the end of the study period of 90 days. The effect of *Guduchi sattava* on serum cholesterol level was statistically significant ($t = 8.9, p<0.001$). Effect of diet & exercise was also significant on serum cholesterol level ($t = 3.21, p<0.05$).

In respect of Triglyceride level the drug *Guduchi sattava* has shown statistically significant result ($p<0.001$).No significant response was found in Group B patients treated with by diet & exercise ($p<0.01$).

Due to non availability of required laboratory facilities in concern institution only in case of 10 patients of Group A, HbA_1C was investigated. After getting the biochemical value, it was found statistically non-significant ($p<0.01$).

Probable Mode of Action of *Guduchi Sattava*

According to *Ayurveda*: The drug selected for the management of disease *Madhumeha* was *guduchi sattava* for this study. Most of classical herbs indicated in *Madhumeha* belong to *Tikta rasa*. *Tikta rasa* has "*kledo*

medo slesma sosana" property [5]. So it nicely effect on predominant *Dushya meda* and due to *Usna virya* it also precipitate *Vata*.

According to conventional system

The drug *Guduchi sattava* was given along with diet & exercise in 25 case of *Madhumeha* which show a better result in all parameters than the group treated with only diet & exercise. It has more effect on fasting glucose level then post prandial glucose. There are three major pathways to control blood glucose level Inhibition of gastro-intestinal glucose absorption, Regulation of glucose metabolism, Increase urinary clearance of glucose.[6] Regulation of glucose metabolism is performed mainly by, Insulin replacement, Increase insulin secretion, Increase insulin sensitivity or inhibition of hepatic glucose output.[7]

In fasting state hepatic glucose output contribute a important role to blood glucose level, whereas after food ingestion, insulin is secreted and hepatic glucose output is inhibited. Generally Insulin sensitizer or the drugs which regulate hepatic glucose output, have good effect on fasting hyperglycemia. Insulin secretion enhancer, control post prandial hyperglycemia by early phase insulin release.[8] According to previous experimental study on *Guduchi*, it has a role to control hepatic glucose output.[9] An experimental study on *Guduchi Sattava* in non diabetic animal model also shows its effect in fasting glucose level where as it is ineffective in post prandial glucose [10]. As fasting glucose level markedly depend on hepatic glucose output, *Guduchi sattava* may have some effect on hepatic glucose metabolism or insulin sensitivity as per clinical data obtained in this study also. Further detailed study is needed to explore its mechanism of action.

CONCLUSION

At the end of study the result reveals that the drug *Guduchi sattava* has been used from remote antiquity for the cure of the ailing and afflicts. Oral administration of *Guduchi sattava* is very effective for the treatment of *Madhumeha* along with diet & exercise. *Guduchi sattava* is cheap, innocent, and easily available. Hence, it will pave the path for better treatment of the patients suffering from *Madhumeha*. In order to reach a definite conclusion detailed and extensive clinical trial is needed in future.

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