

“CLINICAL EVALUATION OF GUDUCHI GHANA VATI AND SHILAJATU VATI IN MADHUMEHA W.S.R. TO NIDDM”

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ABSTRACT

Background: In diabetes sometimes the disease become resistant to the treatment even by conventional system of medicine Hence there is an urgent need to develop effective and affordable Ayurvedic drug or treatment module in this disease. Hence an effort has been made to evaluate the effect of guduchighanavati and silajativati in cases of NIDDM. Guduchi is reported as a highly potent anti diabetic herb and Silajatu as a Naimittika Rasayana for Madhumeha. **Aim:** The aim of this study is to evaluate combined effect of Guduchi Ghana Vati & Shilajatu Vati in Madhumeha. **Materials and Methods:** A minimum of 40 patients suffering from Madhumeha were selected after thorough history taking, clinical assessment and laboratory investigation from IPD & OPD of MIAMS to evaluate the Guduchi Ghana Vati(500mg), Shilajatu Vati(250mg) and Guduchi Ghana Vati(500mg) alone in GroupA & group B Patients. **Statistical Analysis:** The results were statistically interpreted using Student's 't'-test for paired and unpaired data to assess the statistical significance and the significant level was set at $P < 0.05$. **Results:** GGV and SV showed mild reduction in FBS 32% , PPBS 40%, urine Sugar 61%, Lipid Profile(Total Cholesterol)31% and overall 95% improved in GroupA and GGV(Control Drug) FBS 20% , PPBS 28%, urine Sugar 60%, Lipid Profile(Total Cholesterol) 27% and overall 80% improved. **Conclusion:** After evaluating the observation of the present series of investigation it is concluded that Guduchi Ghana Vati and Shilajatu Vati has a beneficial role in reducing the severity of all the Subjective & Objective Parameter.The Trial group drug showed good tolerability with high acceptance without any adverse drug reaction. The use of Guduchi Ghana Vati and Shilajatu vati provides better alternative which are usually less toxic and affordable.

Key Words : Ayurveda, Madhumeha, Guduchi Ghana Vati ,Shilajatu Vati.

INTRODUCTION :

Man can live in happiness without many earthly possessions, but not without good health¹. The prevalence of diabetes mellitus is increasing globally with a rise from about 30 million cases in 1985 to 177 million cases in 2000 and worldwide estimates project that more than 360 million individuals will have diabetes by the year 2030². India has been projected by WHO as the country with the fastest growing population of Diabetic patients. It is estimated that between 1995 – 2025 diabetic patients in India will

increase by 195%³. Diabetes mellitus is included under the broad heading of Prameha. Diabetes Mellitus is a chronic disorder of Carbohydrate, fat, protein metabolism, with a relative or absolute deficiency in insulin secretory response resulting in hyperglycaemia. Insulin resistance is a major factor in the development of type2 diabetes, which is seen in obese patients⁴. Complication of diabetes includes Retinopathy, nephropathy, Neuropathy, Macro vascular, gastrointestinal, glaucoma, Cataracts⁵.

It is also classified as a maharoga because if not treated in time it can lead to severe complications⁶. It is include

under lifestyle disorder presently⁷. In madhumeha the line of treatment that has been prescribed by our Acharya, not only help in reducing the blood glucose levels but also correct the Dhatuavastha etc.

The Study focuses on assessing the effect of Guduchi&Silajatu in Madhumeha with special reference to Diabetes Mellitus.

Guduchi is reported as a highly potent anti diabetic herb. Its safety and non-toxic natures have been reported in experimental and clinical studies in various systems of the body. Numbers of pharmacological studies have been carried out on different parts of guduchi including exploring its anti-hyperglycaemic potential. Ethyl acetate and hexane extracts of stem⁸.

Shilajatu as a Naimittika Rasayana for Prameha and hence it is advisable to use shilajatu in prediabetics and /or in diabetic management as an adjuvant therapy for promotive and preventive measure⁹. Acharya Sushruta has described that it is very effective drug for the management of madhumeha in Madhumehacikitsaadhya¹⁰

In diabetes sometimes the disease become resistant to the treatment even by conventional system of medicine Hence there is an urgent need to developed and effective and affordable Ayurvedic drug or treatment module in this disease Hence an effort has been made to evaluate the effect of guduchighnavati and silajatu vati in cases of NIDDM.

MATERIALS AND METHODS

All Ayurveda, Modern literatures and contemporary texts including the journals, Previous research works, websites etc. were reviewed pertaining to the drug and diseases in the intended study. The present study was conducted on 40 patients from OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal and from referral sources and special camps. The data collected from the clinical trial were sorted out and processed further by subjection to varied statistical methods to find the significance.

Pharmaceutical Procedure:

The formulations selected for research work Guduchi Ghana Vati and Shilajatu Vati was prepared in the SDM pharmacy as per the Standard Operative procedure.

Preparation of Medicine:-

- All the ingredients are collected after authentication of identify and quality. The useful parts and ratio of the individual ingredients are per classical reference and proportion. Guduchi mixed with water till we get decoction is filter and boiled till it becomes ghana. Then 500mg pills are prepared by using expient.
- Shilajatu is purified with following Shodhna procedures, by adding suitable expedients 250mg tab are prepared.

Methods of collection of data

Sample size

A minimum of 40 patients fulfilling the diagnostic and inclusion criteria irrespective of their gender, caste, religion, education status and socio-economic status were taken for the study.

Study design

Single blind randomized control clinical study.

Statistical Analysis

All the BT score of all symptoms of a patient were added. All the AT score of every symptom of that patient were added. The information gathered based on observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation, Standard error. For all symptoms in both group name of test applied is Wilcoxon-Matched-Pairs-Signed-Ranks Test & Mann-Whitney test .. The obtained results were interpreted as: NS - not significant: $p > 0.05$; *significant: $p < 0.01$; **more significant: $p < 0.001$; ***highly significant: $p < 0.0001$.

Treatment period and Observation period:

Treatment period: Patients will be assessed clinically before treatment on 7th, 14th, 21th day during treatment and 31st day (next day after stopping the treatment) the response of patient's disease condition to the drug will be observed and recorded before, during and after the treatment in the specially designed case proforma which includes detailed history, physical examination, laboratory investigations and assessment based on objective and Subjective parameters for which appropriate scoring pattern is adopted.

Diagnostic criteria:

The patients will be diagnosed based on the following clinical factors.

- **FBS** : 110-220 mg/dl
- **PPBS** : 181-280mg/dl
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Inclusion criteria:

1. Patients of either sex
2. Freshly diagnosed case and old cases without any modern medication.
3. Patients with age above 30 years and below 60 years.
4. Madhumeha patients with or without lakshanas of madhumeha will be selected for study.
5. Mild and Moderate Non-Insulin Dependent Diabetes mellitus cases will be selected for the study.

Exclusion criteria:

1. Patient with Insulin dependent Diabetes mellitus or severe grade blood glucose levels that is more than 280 mg/dl.
2. Patient with complications like diabetic ketoacidosis.
3. Gestational diabetes will be excluded from the study.
4. Multisystem involved diabetic patients.
5. Diabetes with other endocrinal disorders like Cushing's syndrome will be excluded from the study.

Method

At baseline, informed consent was obtained after checking the inclusion and exclusion criteria and relevant medical history. All prior medications were stopped 1 weeks before the start of the study. The patients were asked to take Guduchi Ghana vati. No

concomitant drugs were allowed during the study. Global assessment scoring systems are administered throughout the study. Patients are enquired about adverse events and compliance with the study medication on all follow ups. Statistical methods were employed to study the significance level from baseline to follow up .

Assessment criteria

The following subjective and objective parameters were assessed using different grading and scoring methods before and after treatment. Subjective & Objective Parameters of Madhumeha mentioned in the texts, and practically observed have been assessed at each follow up. Presence or absence of these symptoms has been registered. Different symptoms have been graded into five-grade scale (0 to 4) on the basis of severity to assess the changes in clinical symptoms of Madhumeha. Study of changes in the gradation of each symptom has been done in each follow up.

Consequent Drug, Diet and Regimen:

Anti diabetic food habits, moderate exercise, 15 minutes walk.

Drop-out Criteria:

During the course of treatment if any serious condition or serious adverse effects occur, or subject him/her want to withdraw from the study, such subjects will be withdrawn from the study.

Scoring pattern

The improvement provided by the therapy was assessed based on relief in signs and symptoms of the disease and Dushti Lakshana of Dosha, Dushya etc. FBS, PPBS urine sugar, Total cholesterol were repeated. All the signs and symptoms were assigned score depending upon their severity to assess the effect of the drugs objectively in **Table No 1** .

Table No 1

SL NO	Criteria	Details	Score
SUBJECTIVE			
1	Prabhoota Mootrata Quantity of urine (in liter)	1.50 to 2.00	0
		2.00 to 2.50	1
		2.50 to 3.00	2
		3.00 onwards	3
2	Prabhoota Mootrata Frequency of urine	3-6 times per day, rarely at night	0
		6-9 times per day, 0-2 times per night	1
		9-12 times per day, 2-4 times per night	2
		More than 12 times per day, more than 4 times per night	3
3	Pipasadhikya (Polydypsia)	Feeling of thirst 7-9 times/24 hours, either/ or Intake of water 5-7 times/24 hours with quantity 1.5-2.0 liter/24 hours	0
		Feeling of thirst 9-11 times/24 hours, either/ or Intake of water 7-9 times/24 hours with quantity 2.0-2.50 liter/24 hours	1
		Feeling of thirst 11-13 times/24 hours, either/ or Intake of water 9-11 times/24 hours with quantity 2.50-3.00 liter/24 hours	2
		Feeling of thirst > 13 times/24 hours, either/ or Intake of water > 11 times/24 hours with quantity > 3.00 liter/24 hours	3
4	Kshudhadhikya (Appetite)	As Usual	0
		Slightly increased (1-2 meals)	1
		Moderately increased (3-4 meals)	2
		Markedly increased (5-6 meals)	3
5	Kara-Pada-Tala-Daha/Supti (Neuropathy)	No Daha	0
		Kara-Pada-Tala-Daha/Supti in continuous	1
		Kara-Pada-Tala-Daha/Supti continuous but not severe	2
		Kara-Pada-Tala-Daha/Supti continuous but severe	3
6	Avila Mootrata (Turbidity)	Crystal clear fluid	0
		Faintly cloudy or smoky (turbidity barely visible)	1
		Turbidity clearly present but newsprint easily read through test tube	2
		Newsprint not easily read through test tube	3
		Newsprint cannot be seen through test tube	4
		Sweating after heavy work and fast movement or in hot weather	0

7	Swedadhikya (Perspiration)	Profuse sweating after moderate work and movement	1
		Sweating after little work and movement (Stepping ladder etc)	2
		Profuse sweating after little work and movement	3
		Sweating even at rest or in cold weather	4
8	Dourbalya(Weakness)	Can do routine exercise/work	0
		Can do moderate exercise with hesitancy	1
		Can do mild exercise only, with difficulty	2
		Cannot do mild exercise too	3
9	Visra Sariragandha	No odour	0
		Bad odour but not so offensive	1
		Strong body odour but can be lessened by deodorants	2
		Very strong odour even after using fragrances	3
OBJECTIVE			
10	FBS (mg/dl)	75-110	0
		111-125	1
		126-180	2
		>180	3
11	PPBS(mg/dl)	Upto 140	0
		141-160	1
		160-300	2
		>300	3
12	Urine Sugar (%)	Absence of Glucose in urine	0
		<0.5% glucose in urine	1
		0.5-1.0% of glucose in urine	2
		>2.0 glucose in urine	3
13	Lipid Profile (Total Cholesterol)	<200 mg/dl	1
		200-239mg/dl	2
		>240mg/dl	3

RESULTS

Analysis

The fortnightly follow-up of patients has been done as regards the symptomatic improvement and blood sugar level has been monitored 1st and 31st day interval. Statistical analysis has been done.

Result**Table 2: Showing Effect On Symptoms Score Of 40 Patients Of Diabetes Mellitus (BT=Before Treatment ; AT=After Treatment ; Diff= Difference)**

Sl NO	SYMPTOMS	Trial Group				Control Group			
		BT	AT	Diff.	% Of Relief	BT	AT	Diff	% Of relief
1	PrabhootaMootrata(Quantity)	33	10	23	70%	34	20	14	41%
2	PrabhootaMootrata(Frequency)	44	12	22	73%	34	21	13	38%
3	Pipasadhikya	42	15	27	64%	33	19	14	42%
4	Kshudhadhikya	44	16	28	64%	45	34	11	24%
5	Kara Pada Daha	36	7	29	81%	34	21	13	38%
6	Avila Mootrata	29	9	20	69%	31	21	10	32%
7	Swedadhikya	38	17	21	55%	37	22	15	41%
8	Dourbalya	41	12	29	71%	42	30	12	29%
9	Sariragandha	44	12	32	73%	42	24	18	43%
10	FBS	59	40	19	32%	55	44	11	20%
11	PPBS	40	24	16	40%	40	29	11	28%
12	Urine Sugar	33	13	20	61%	30	12	18	60%
13	Lipid profile	48	33	15	31%	45	33	12	27%

Table no- 3 Showing Effect On Symptoms Of 20 Patients Of Diabetes Mellitus Of Trial Group By Wilcoxon-Matched-Pairs-Signed-Ranks Test GROUP-A

No	Symptom		Mean	SD	SEd	W	Number of patients (n)	Z	P
1	PrabhootaMootrata (Quantity)	BT	1.650	0.489	0.109	171	20	3.91	<0.001
		AT	0.500	0.607	0.136				
		Diff	1.150	0.587	0.131				
2	Prabhoota Mootrata (Frequency)	BT	2.200	0.616	0.138	210	20	4.021	<0.001
		AT	0.600	0.503	0.112				
		Diff	1.600	0.598	0.134				

3	Pipasadhikya	BT	2.100	0.641	0.143	171	20	3.834	<0.001
		AT	0.750	0.639	0.143				
		Diff	1.350	0.671	0.150				
4	Kshudhadhikya	BT	2.200	0.616	0.138	210	20	4.053	<0.001
		AT	0.800	0.523	0.117				
		Diff	1.400	0.503	0.112				
5	Kara Pada Daha	BT	1.800	0.410	0.091	210	20	4.041	<0.001
		AT	0.350	0.489	0.109				
		Diff	1.450	0.510	0.114				
6	Avila Mootrata	BT	1.450	0.510	0.114	136	20	3.704	<0.001
		AT	0.450	0.605	0.135				
		Diff	1.000	0.649	0.145				
7	Swedadhikya	BT	1.900	1.071	0.240	120	20	3.535	<0.001
		AT	0.850	0.671	0.150				
		Diff	1.050	0.826	0.185				
8	Dourbalya	BT	2.050	0.826	0.185	190	20	3.923	<0.001
		AT	0.600	0.754	0.169				
		Diff	1.450	0.686	0.153				
9	Sariragandha	BT	2.200	0.894	0.200	171	20	3.866	<0.001
		AT	0.600	0.681	0.152				
		Diff	1.600	0.754	0.169				
10	FBS	BT	2.950	0.224	0.050	190	20	4.359	<0.001
		AT	2.000	0.000	0.000				
		Diff	0.950	0.224	0.050				
11	PPBS	BT	2.000	0.000	0.000	136	20	4.000	<0.001
		AT	1.200	0.410	0.092				
		Diff	0.800	0.410	0.092				

12	Urine Sugar	BT	1.650	0.489	0.109	210	20	4.472	<0.001
		AT	0.650	0.489	0.109				
		Diff	1.000	0.000	0.000				
13	Lipid Profile	BT	2.400	0.503	0.112	66	20	3.035	<0.001
		AT	1.650	0.489	0.109				
		Diff	0.750	0.786	0.176				

Table -4 Showing Effect On Symptoms Of 20 Patients Of Diabetes Mellitus Of Control Group By Wilcoxon-Matched-Pairs-Signed-Ranks Test GROUP-B

No	Symptom		Mean	SD	SEd	W	(n)	Z	P
1	Prabhoota Mootrata(Quantity)	BT	1.700	0.801	0.179	91	20	3.500	<0.001
		AT	1.000	0.795	0.178				
		Diff	0.700	0.571	0.128				
2	Prabhoota Mootrata(Frequency)	BT	1.700	0.571	0.128	66	20	3.127	<0.001
		AT	1.050	0.605	0.135				
		Diff	0.650	0.671	0.150				
3	Pipasadhikya	BT	1.650	0.671	0.150	66	20	3.071	<0.001
		AT	0.950	0.510	0.114				
		Diff	0.700	0.733	0.164				
4	Kshudhadhikya	BT	2.250	0.639	0.143	55	20	3.051	<0.005
		AT	1.700	0.733	0.164				
		Diff	0.550	0.605	0.135				
5	Kara Pada Daha	BT	1.700	0.571	0.128	78	20	3.357	<0.001
		AT	1.050	0.605	0.135				
		Diff	0.650	0.587	0.131				

6	Avila Mootrata	BT	1.550	0.686	0.153	55	20	3.162	<0.005
		AT	1.050	0.510	0.114				
		Diff	0.500	0.513	0.115				
7	Swedadhikya	BT	1.850	0.671	0.150	105	20	3.638	<0.001
		AT	1.100	0.447	0.100				
		Diff	0.750	0.550	0.123				
8	Dourbalya	BT	2.100	0.718	0.161	66	20	3.207	<0.001
		AT	1.500	0.688	0.154				
		Diff	0.600	0.598	0.134				
9	Sariragandha	BT	2.100	0.641	0.143	120	20	3.626	<0.001
		AT	1.200	0.768	0.172				
		Diff	0.900	0.641	0.143				
10	FBS	BT	2.750	0.444	0.099	66	20	3.317	<0.001
		AT	2.200	0.410	0.091				
		Diff	0.550	0.510	0.114				
11	PPBS	BT	2.000	0.000	0.000	66	20	3.317	<0.001
		AT	1.450	0.510	0.114				
		Diff	0.550	0.510	0.114				
12	Urine Sugar	BT	1.500	0.513	0.115	171	20	4.243	<0.001
		AT	0.600	0.503	0.112				
		Diff	0.900	0.308	0.069				
13	Lipid Profile	BT	2.250	0.550	0.123	78	20	3.464	<0.001
		AT	1.650	0.489	0.109				
		Diff	0.600	0.503	0.112				

Intergroup comparison between Group A and Group B on subjective parameters in the patients of Madhumeha (Mann-Whitney test) Table No 5

No	Symptom	Group	N	Mean (μ)	(SD) (\pm)	Mean (\pm) 1.96 SD	Mean X	(SE) (\pm)	Mann-Whi tney U- statistic	Z	P
1	PrabhootaMootrata (Quantity)	Group A	20	200	34.3	267.91	0.500	0.224	270	2.04	0.042
		Group B	20			132.08	1.000				
2	Prabhoota Mootrata (Frequency)	Group A	20	200	31.7	262.13	0.600	0.176	274	2.33	0.020
		Group B	20			137.87	1.050				
3	Pipasadhikya	Group A	20	200	31.2	261.15	0.750	0.183	164	1.16	0.337
		Group B	20								
4	Kshudhadhikya	Group A	20	200	34	266.64	0.800	0.201	329	3.80	<0.001
		Group B	20			133.36	1.700				
5	Kara Pada Daha	Group A	20	200	33.3	265.27	0.350	0.174	314	3.42	<0.001
		Group B	20			134.73	1.050				
6	Avila Mootrata	Group A	20	200	32.9	264.49	0.450	0.177	303	3.13	0.002
		Group B	20			135.52	1.050				
7	Swedadhikya	Group A	20	200	30.7	260.17	0.850	0.180	242.5	1.39	0.170
		Group B	20			139.83	1.100				
8	Dourbalya	Group A	20	200	35	268.6	0.600	0.228	318	3.38	<0.001
		Group B	20			131.4	1.500				
9	Sariragandha	Group A	20	200	34.2	267.03	0.600	0.230	284	2.46	0.015
		Group B	20			132.97	1.200				
10	FBS	Group A	20	200	19.2	237.63	2.000	0.92	240	2.08	0.040
		Group B	20			162.37	2.200				
11	PPBS	Group A	20	200	30.8	60.368	1.200	0.146	250	1.63	0.099
		Group B	20			139.63	1.450				
12	Urine Sugar	Group A	20	200	36	270.56	0.650	0.157	190	0.28	0.759

		Group B	20			129.44	0.600				
20	Lipid Profile	Group A	20	200	36.2	270.95	1.650	0.155	200	0	0.987
		Group B				129.05	1.650				

Table No.6 Overall effect of Group A on 20 patients of Madhumeha.

Total Effect	Percentage	No of Pts	%
Cured	100%	0	0
Markedly Improved	76-99%	0	0%
Moderately Improved	51-75%	1	5%
Improved	26-50%	16	80%
Unchanged	<25%	3	15%

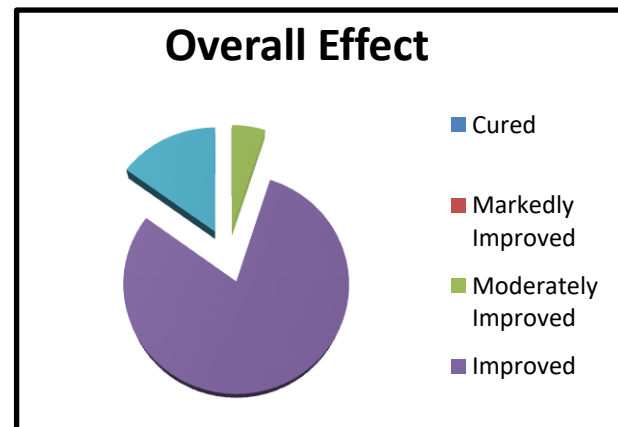
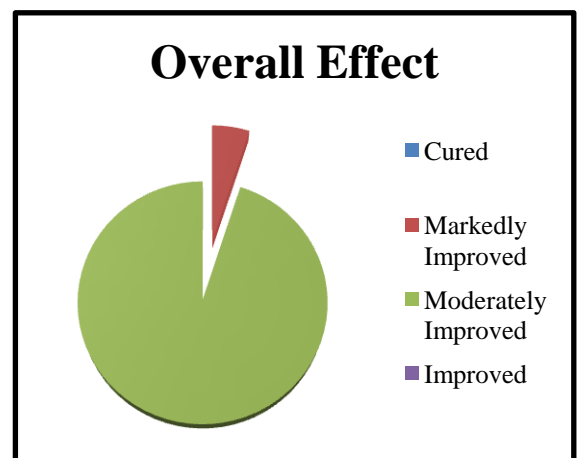


Table No. 7 Overall effect of Group B on 20 patients of Madhumeha.

Total Effect	Percentage	No of Pts	%
Cured	100%	0	0
Markedly Improved	76-99%	0	0%
Moderately Improved	51-75%	1	5%
Improved	26-50%	16	80%
Unchanged	<25%	3	15%



DISCUSSION

Among the 40 cases of Madhumeha the symptomatic distribution of Kara Pada Daha was 81%, i.e. highest, Muhur muhur mootratha & Sariragandha was 73%

,Dourbalya was 71%, PrabhootaMootratha was 70%, Pipasa & Kshudhadhikya was 64%. In statistical data follow up of 1 month duration has been shown in table, so there are total 2 follow BT (Before Treatment) and AT i.e. is after treatment due to enlargement of data in 4

follow up. In subjective assessment of Group A (Guduchi Ghana Vati & Shilajatu Vati) symptomatically the result was highly significant ($p > .001$) in Prabhoota mutrata (Quantity & Frequency), Pipasadhikya, Kshudhadhikya, Kara pada Daha, Avila mootrata, Swedadhikya, Dourbalya and Sariragandha. In objective assessment of Group I (Guduchi Ghana Vati & Shilajatu Vati) results based on laboratory investigations was highly significant ($p < .001$) in both FBS, PPBS, Urine Sugar, Lipid Profile (Total Cholesterol). In subjective assessment of Group B (Guduchi Ghana Vati) symptomatically the result was highly significant ($p > .001$) in Prabhoota mutrata (Quantity & Frequency), Pipasadhikya, Kara pada Daha, Swedadhikya, Dourbalya and Sariragandha. While it was significant in Kshudhadhikya and Avila mootrata ($p < .05$). In objective assessment of Group B (Guduchi Ghana Vati) results based on laboratory investigations was highly significant ($p < .001$) in FBS, PPBS, Urine Sugar, Lipid Profile (Total Cholesterol). Not any kind of side effect was detected after the end of the trial of 30 days.

CONCLUSION

- It is a type of Vataja Prameha has been considered as one among Ashtamahagadha. In the samprapthi of Madhumeha pradhana dosha is Kapha and dhusya meda & kleda, srothodushti are rasavaha and medovaha.
- After evaluating the observation of the present series of investigation, it is concluded that Guduchi Ghana Vati and Shilajatu Vati have a beneficial role in reducing the severity of all the symptoms that includes Prabhoothamutrata, Avilamutrata, Pipasadhikya, Swedadhikya, Dourbalya, Karapadadaha and controlling fasting blood sugar, postprandial blood sugar, Urine Sugar and lipid profile (Total Cholesterol). The Trial group drug showed good tolerability with high acceptance without any reported adverse drug reaction.
- Conventional management options available are expensive and often associated with negative side effects; therefore, the use of Guduchi Ghana Vati and Shilajatu vati provides better alternative which are usually less toxic and affordable.
- However, further research to elucidate its exact mechanism of action and studies over animal models to validate the claim are required

- Hence further continuation of the medication is justified or else this study will pave way for more clinical trials in this regard with more prolonged course.

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