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Research Article

CONTROLLED CLINICAL EVALUATION OF "MAMAJJAK CHOORNA" IN STHULA MADHUMEHA VIZ-A-VIZ TYPE 2 DIABETES MELLITUS

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ABSTRACT

Sthula Madhumeha (viz-e-viz type 2Diabetes Mellitus) is the vital problem in present era. The change in lifestyle and food habit is the major concern of the problem. The available drug therapy concentrating on levels of blood sugar rather than symptoms of patients like excessive thirst, Nocturnal enuresis, burning sensation in hands, feet and many more. Ayurveda emphasized more on these symptoms. These symptoms affects the patient's routine life and work capacity. On behalf of these symptoms the role of Mamajjak Choorna which is described by Acharya Priyavrat Sharma in his book Dravya guna Vidnyan Vol. 2 page 705 found to be more effective in comparison to modern oral hypoglycemic and well practiced drug Metformin. Total 40 patients of newly diagnosed of Diabetes Mellitus were taken and divided in two groups as Trial group 20 patients on Mamajjak Choorna 5 gm B.I.D. given for 12 weeks. Control Group 20 patients on tab. Metformin 500 mg B.I.D. given for 12 weeks.

On consumption of *Mamajjak Choorna* for 12 weeks it was found that there is improvement in the symptoms *Pipasati Pravrutti* (74.27%), *Nakta mutrata* (83.33%), *Hasta-padatala daha* (82.5%) *Pippalika Sancharvaat prachti* (85.71%), *Prabhuta Avila mutrata* (77.5%), *Swedatipravritti* (82.5%) so far as consumption of Metformin is concern, it was found as follows *Pipasati Pravrutti* (64.71%), *Nakta mutrata* (72.94%), *Hasta-padatala daha* (51.28%), *Pippalika Sancharvaat prachti* (50%), *Prabhuta Avila mutrata* (71.88%), *Swedatipravritti* (51.16%). With P<0.05 (that highly significant results in *Mamajjak Choorna* group).

KEYWORDS: Mamajjak Choorna, Sthula Madhumeha, Diabetes Mellitus.

INTRODUCTION

Prameha is one of the diseases which have prime importance, because it has been included in *Mahagad*^[1] i.e. Diseases difficult to treat. Increase in frequency and quantity along with Turbidity of urine is the cardinal symptom of Madhuameha. Traditionally Madhumeha is rich man's diseases. Particularly because, the person who is able to enjoy the pleasure of life without any physical work and who takes over nutritious food is more prone to the disease^[2]. But in changing form and pattern of lifestyle the middle class and lower class also, suffers from this disease. Mainly due to stressful conditions, fast food eating, excessive hybrid form of diet. Charaka consider this as one of the varieties of Vataja Pramehas. As according to Sushruta, All types of Pramehas not properly treated and attended to at the onset, may ultimately lead to *Madhumeha* types which are incurable [3]. Whatever it may be the fact, Madhumeha does have the fundamental characters viz. Polyuria and turbidity of urine. (Prabhut Avila Mutrata). [4]

Diabetes has been recognized among a large number of people of various social conditions throughout the world especially in India. W.H.O. survey has identified India as a global capital of Diabetes in 2020. With abrupt change in the modern lifestyle, the prevalence of all type of Diabetes is increasing by 4 to 5% per year with an estimated 40-50% of individuals over the age 65 years

having either type 2 Diabetes or impaired glucose tolerance. However the developing countries will bear the brunt of escalating epidemic in future. Modernization accompanying economic development in developing countries has been followed by a substantial increase in Diabetes. This global pandemic principally involves type2 Diabetes Mellitus and it associated with several contributory factors including increased longevity, Obesity, unsatisfactory diet, sedentary lifestyle and increasing urbanization.

The Mamajjak choorna is Laghu, Ruksha Tikta ras, Katu vipak and Ushna virya [5], which exactly opposite to patho-physiological factors of Madhumeha. It was thought in mind to evaluate the role of Mammajak in the form of Choorna. As this form give more surface area for absorption and action starting in Amashaya which is moola Sthana of Kapha.

Taking above considerations in mind study entitled, "Controlled clinical evaluation of effects of 'Mamjjak Choorna' in Sthula Madhumeha viz-e-viz type 2 Diabetes mellitus". Was planned to evaluate efficacy of Mamajjak choorna in the management of Sthula Madhumeha viz-e-viz type2 Diabetes mellitus and to compare its result with standard modern drug, for that purpose Metformin in the dose of 500mg tablet twice a day was given.

Aims and Objective

Aim: To evaluate the efficacy of *Mamajjak choorna* in management of *Sthula Madhumeha* w.r.t. Type2 diabetes Mellitus.

Objectives

- Hetus [6] that are described in these texts should be study and observed for its presence in *Pramehi* patients, also to use this knowledge for control this disease.
- Study of efficacy of "Mamajjak Choorna" in Prameha.

Materials And Methods

Name of Institute: Shree Saptashrungi Ayurved Mahavidyalaya, Nashik.

Plan of work: The proposed study was done in two levels 40 patients of *Madhumeha* divided into 2 groups randomly. Group one called as Trial group comprised 20 patients, in which "*Mamajjak Choorna*" was given for 12 weeks duration, while another group called as control group also comprises 20 patients of *Madhumeha* were given tablet of Metformin 500mg.BD was given for 12 weeks duration.

Type of Study – Open randomized controlled study. **Selection of cases**

Patients of *Madhumeha* were selected after clinical and objective examination. Follow up assessment was done by specially prepared case record forms of every patient to meet all baseline requirements. Follow up signs and symptoms were recorded.

Criteria of Inclusion

- Random selection of patients
- Confirmed case of Diabetes mellitus (Non-insulin dependent)
- Not having any Macro or Micro-vascular complications.
- · Both sexes.
- Age between 25 Yr. to 65 Yr. Old.
- The post prandial blood venous glucose level < 400 mg/dl.
- Fasting plasma venous glucose > 140mg/dl.
- Body mass index of patient above 25.

Criteria of exclusion

- Blood glucose level (post prandial) > 450 mg/dl.
- Age below 25 Yrs. & above 65 Yrs. will be excluded.
- Pregnancy & lactating mothers.
- All patient having acute complications likehyperglycemic coma, ketoacidosis, infection like gangrene.

 $\textbf{Gradation of Symptoms:} \ ^{[7]}$

1. Daurbalya

Grade 0: No weakness in any sort of work
Grade 1: Weakness in routine work but able to cope up
Grade 2: Weakness enough to hamper routine work
Grade 3: Weakness in slight work or at rest requiring bed rest.

2. Kshudhavrudhhi

Grade 0:	Two meals a day
Grade 1:	Three meals a day
Grade 2:	Four meals a day
Grade 3:	Four meals a day but still feels hungry.

- All patients having chronic complications of diabetes like- nephropathy, neuropathy, retinopathy etc.
- Body Mass Index (B.M.I.) less than 25.

Drug: The drug "Mamajiak Choorna"

Dose: 5gm. BID

Time of administration: Before meal morning and

evening.

Anupan: Luke warm water

Duration: 12 weeks.

Aahar: No change in regular diet. Only direct sugar or recipes, which contain sugar, will not be permitted.

Follow-up: fortnightly. Laboratory investigation will be carried out after 4 week.

Number of Pt: - 40 patients, each of 20 patients, in Trial and Control group.

Clinical examination: A person with classical symptoms of *Madhumeha* mentioned in *Ayurvedic* text

Criteria of Assessment

A) Subjective Assessment

Symptoms 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 four-grade scale (0 to 3) 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.

B) Objective Assessment

All patients were randomly selected for the study irrespective of Sex, Marital status, Educational status and Economical status. They were randomly classified as Trial group and Control group. All the patients selected for the therapy have been assessed on clinical, physical and hematological parameters.

- 1. Blood sugar fasting and post prandial sugar will be estimated every 4 weeks.
- 2. Glycosylated hemoglobin (HbA₁C) will be estimated at the entry point and at the end of the study to assess the level of average glycaemic control during the trial.
- 3. Lipid profile will be estimated at the starting and end point of study to assess the status of dys-lipidemia commonly found in Diabetes.
- 4. Effect of therapy has been assessed to observe any change in clinical symptoms by every week.
- 5. Total effect of therapy has been assessed on patients in terms cured, Improved, Markedly improved and Unchanged. These terms have been explained here in, later on.

3.Pipasatipravrutti

Grade 0:	Need normal amount of water to satisfy quench
Grade 1:	Need water twice than normal for himself for quench
Grade 2:	Need water thrice than normal for himself for quench
Grade 3:	Not satisfying after drinking abundant of water

4. Prabhuta Avila Mutrata

Grade 0:	Urine output between 1500 – 2000 ml per 24 hour with no turbidity of urine
Grade 1:	Urine output between 2000 – 2500 ml per 24 hour with less turbidity of urine
Grade 2:	Urine output between 2500 – 3000 ml per 24 hour with moderate turbidity of
	urine 10 – 12 glasses of water a day
Grade 3:	Urine output more than 3000 ml per 24 hour with severe turbidity of urine

5. Nakta mutrata

Grade 0:	No nocturnal micturation.
Grade 1:	1 – 2 times passing of urine at night
Grade 2:	2 – 4 times passing of urine at night.
Grade 3:	more than 4 times passing of urine at night

6. Pindikodweshtana

Grade 0:	No cramps
Grade 1:	Cramps after 1 hour of walk
Grade 2:	Cramps after 1/2 hour of walk
Grade 3:	Cramps after 10 minutes of walk

7. Swedatipravrutti

Grade 0:	No Swedatipravritti
Grade 1:	Swedatipravritti on more exertion
Grade 2:	Swedatipravritti on little exertion
Grade 3:	Swedatipravritti at rest

8. Hasta-paad tala Daha

Grade 0:	No burning sensations
Grade 1:	Burning sensation that is not continuous does not disturb routine activity
Grade 2:	Continuous burning sensation does not disturb routine activity
Grade 3:	Severe continuous burning sensation disturbs routine activity

9. Pipilika Sancharvaat Prachiti

Grade 0:	No tingling sensations
Grade 1:	Tingling sensation that is not continuous does not disturb routine activity
Grade 2:	Continuous tingling sensation does not disturb routine activity
Grade 3:	Severe continuous tingling sensation disturbs routine activity

Analysis

The fortnightly follow-up of patients has been done as regards the symptomatic improvement and blood sugar level has been monitored every 4 weeks interval. Statistical analysis has been done.

Observation and Results

Table 1: Showing Effect On Symptoms Score Of 40 Patients Of Diabetes Mellitus (BT=Before Treatment; AT= After Treatment; Diff= Difference)

		Trial	Trial Group				Control Group			
Sr. No	Symptom	ВТ	AT	Diff.	Percent-age of relief	ВТ	AT	Diff.	Percentag e of relief	
1	Daurbalya	40	11	29	72.5%	36	8	26	77.78%	
2	Pipasati Pravrutti	35	9	26	74.27%	34	12	22	64.71%	
3	Nakta mutrata	36	6	30	83.33%	37	10	27	72.94%	
4	Hasta-padatala daha	40	7	33	82.5%	39	19	20	51.28%	
5	Pippalika Sancharvaat prachti	40	9	31	77.5%	34	17	17	50%	
6	Prabhuta Avila mutrata	40	7	33	82.5%	32	9	23	71.88%	
7	Pindikodweshtan	35	6	29	82.86%	32	14	18	56.25%	
8	Swedatipravritti	42	6	36	85.71%	43	21	22	51.16%	
9	Kshudha vruddhi	33	4	29	87.88%	34	14	20	58.82%	
	Average Score	37.6	72.22	3.66	81.51%	35.66	13.77	21.66	60.74%	

Table 2: Showing Effect On Symptoms Of 40 Patients Of Diabetes Mellitus Of Trial Group By Wilcoxson-Matched-Pairs-Signed-Ranks Test

No.	Symptom	Mean	SD	SEd	Sum of all Signed Ranks	No. Of Pairs	Z	P
1	Daurbalya							
	BT	2	0.7255	0.1622	210	20	2.0201	.0.001
	AT	0.55	0.5104	0.1141	210	20	3.9201	<0.001
	Diff.	1.45	0.6048	0.1325				
2	Pipasati Pravrutti							
	BT	1.75	0.6387	0.1428	163	16	4.2104	<0.001
	AT	0.45	0.5104	0.1141	103	10	4.2104	<0.001
	Diff.	1.3	0.6048	0.1933				
3	Nakta mutrata							
	BT	1.8	0.6958	0.1556	190	19	3.8229	<0.001
	AT	0.3	0.4702	0.1051	150	19	3.0229	<0.001
	Diff.	1.5	0.6882	0.1539				
4	Hasta-padatala daha							
	BT	2	0.7255	0.1622	210	20	3.9201	<0.001
	AT	0.35	0.4893	0.1094	210	20	3.9201	<0.001
	Diff.	1.65	0.4893	0.1094				
5	Pippalik Sanchar prachiti							
	BT	2	0.7255	0.1622	210			
	AT	0.45	0.51042	0.1141	210	20	3.9201	< 0.001
	Diff.	1.55	0.6048	0.1352				
6	Prabhuta Avila mutrata							
	BT	2	0.7947	0.1771	210	20	3.9201	<0.001
	AT	0.35	0.4893	0.1094	210	20	3.7201	<0.001
	Diff.	1.65	0.5871	0.1313				
7	Pindikodweshtan	120		14.0				
	BT	1.75	0.7163	0.1601	171	18	3.7238	<0.001
	AT	0.3	0.4701	0.1053	1/1	10	3.7230	10.001
	Diff.	1.45	0.7591	0.1697				
8	Swedatipravritti			3				
	BT	2.1	0.7881	0.1762	190	19	3.8229	<0.001
	AT	0.3	0.4702	0.1501	170	17	3.0227	V0.001
	Diff	1.8	0.8944	0.2	//			
9	Kshudha vruddhi							
	BT	1.65	0.5971	0.1313	210	20	3.9201	
	AT	0.2	0.4104	0.0917	210	20	3.7201	< 0.001
	Diff.	1.45	0.5104	0.1141				

| 1.45 | 0.5104 | 0.1141 | | (BT=Before Treatment; AT= After Treatment; Diff= Difference)

Table 3: Showing Effect on Symptoms Of 40 Patients Of Diabetes Mellitus Of Control Group By Wicoxson-Matched-Pairs-Signed-Ranks Test

	Tan Signed Ranks Test										
No.	Symptom	Mean	SD	SEd	Sum of all Signed Ranks	No. Of Pairs	Z	P			
1	Daurbalya										
	BT	1.8	0.6959	0.1556	210	20	3.9201	<0.001			
	AT	0.4	0.5062	0.1124	210	20	3.9201	<0.001			
	Diff	1.4	0.5982	0.1337							
2	Pipasati Pravrutti										
	BT	1.7	0.6569	0.1469	190	19	3.8229	<0.001			
	AT	0.6	0.5026	0.1123	190	19	3.0229	<0.001			
	Diff.	1.1	0.4472	0.1							
3	Nakta mutrata										
	BT	1.85	0.6708	0.15	210	20	3.9201	<0.001			
	AT	0.5	0.5129	0.1147	210	20	3.9201	<0.001			
	Diff.	1.35	0.9880	0.2209							
4	Hasta-padatala daha										
	BT	1.95	0.6863	0.1534	153	17	3.6213	< 0.001			
	AT	0.9	0.6048	0.1352							

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	Diff.	5 1	0.5619	0.1256				
5	Pippilika Sancharvaat							
	prachiti	1.7	0.8645	0.1933				
	BT	0.85	0.6708	0.15	171	18	2 7220	<0.001
	AT	0.85	0.5871	0.1312	1/1	10	3.7238	<0.001
	Diff.							
6	Prabhuta Avila mutrata							
	BT	1.6	0.7539	0.1685				
	AT	0.45	0.6048	0.1352	171	18	3.7238	< 0.001
	Diff.	1.15	0.8127	0.1337				
7	Pindikodweshtan							
	BT	1.6 0.7	0.5982	0.1337				
	AT	0.9	0.5712	0.1277	136	16	3.5160	< 0.001
	Diff.		0.5525	0.1235				
8	Swedatipravritti							
	BT	2.15	0.7451	0.1666	171	18	3.7238	< 0.001
	AT	1.05	0.7591	01697	171	10	3.7 230	10.001
	Diff.	1.1	0.5525	0.1235				
9	Kshudha vruddhi							
	BT	1.7	0.5712	0.1277	190	19	3.8229	< 0.001
	AT	0.7	0.5327	0.1638	170	1	0.022	.0.001
	Diff.	1	0.5619	0.1256				

(BT=Before Treatment; AT= After Treatment; Diff= Difference)

Table 4: Showing Comparison between Two Groups with Respect to Symptoms Score By Mann-Whitney Test

							- ,	
Sr. No.	Symptoms	R ₁	Mean	U	SD	Mean <u>+</u> 1.96 SD	Z	P
1	Daurbalya	419.5	200	190.5	38.97	123.63 -276.38	0.2309	>0.05
2	Pipasati Pravrutti	351	152	89	30.2	92.8-211.19	2.069	< 0.05
3	Nakta mutrata	307.2	142.5	167.8	28.83	85.99-119	0.8602	>0.05
4	Hasta-padatala daha	460.5	170	89.5	32.81	105,69-234.3	2.42	< 0.05
5	Pippalika Sancharvaat prachti	416	150	94	30	91.2-208.8	1.85	< 0.05
6	Prabhuta Avila mutrata	385.84	160	143.5	31.41	98.43-221.56	1.068	>0.05
7	Pindikodweshtan	320.5	144	138.25	28.98	87.199-200.8	0.1725	>0.05
8	Swedatipravritti	441	171	91	32.9	106.51-235.48	2.214	< 0.05
9	Kshudha vruddhi	426.5	170	123.5	32.81	105.69-234.31	1.4	< 0.05

Table 5: Showing Variance Ratio Test Before treatment on Hematological Parameter

Sr. No.	Hematological	Before Tr	eatment SD	F ratio	P Value	
31. NO.	parameter	Trial Group SD ₁	Control Group SD ₂	riadio		
1	BSL(F)	50.5109	52.5439	1.0821	> 0.05	
2	BSL(PP)	57.2458	67.0478	1.3717	> 0.05	
3	Total Cholesterol	37.0352	42.4600	1.3144	> 0.05	
4	USL	0.8825	0.8207	1.1562	> 0.05	

Variance Ratio Test Before Treatment

Variance ratio test was evaluated in this study to see the difference between mean values of hematological parameters.

Variance ratio for Blood sugar level fasting, Post prandial, total Cholesterol and Urine sugar levels presented in the table showed that there was no significant difference between two groups with respect to these Hematological parameters.

Therefore further statistical evaluation was done to see the difference between two groups with respect to these character only by unpaired 't' test.

Table 6: Showing Comparison between two Groups by Unpaired 't' Test on Hematological Parameters

Sr.No	Hematological	Mean of Dif	SEd	t	P	
31.10	parameter	Trial Group	Control Group	SEU		
1	BSL(F)	16.2 <u>+</u> 34.75	61.65 <u>+</u> 4.40	10.9335	4.1569	< 0.001
2	BSL(PP)	27.1 <u>+</u> 7.78	76.75 <u>+</u> 53.95	17.6776	2.8086	< 0.05
3	USL	0.75 <u>+</u> 1.0195	1 <u>+</u> 0.6488	0.2702	0.9251	> 0.05
4	Total Cholesterol	18.35 <u>+</u> 27.681	32.85 <u>+</u> 32.4885	9.5439	1.5193	> 0.05

Table 7: Showing total effect of therapy in 40 Patients of Madhumeha

Sr. No.	Total effect of	f Trial Group		Control Group		Total	
31. NO.	therapy	No of Pts	%	No of Pts	%	No of Pts	Percentage
1	Cured	0	0%	0	0%	0	0%
2	Markedly improved	12	60%	13	65%	25	62.5%
3	Improved	8	40%	7	35%	15	37.5%
4	Unchanged	0	0%	0	0%	0	0%
5	LAMA	0	0%	0	0%	0	0%

Total Effect of Therapy

In case of trial group 12 patients (60%) were markedly improved and 8 patients (40%) were improved. In case of control group 13 patients (65%) were markedly improved and 7 patients (35%) were improved.

Table 8: Showing Comparison between two Groups by Chi-Square test

Sr. No	Group	Improved	Marked Improved	Total	Chi-Square value
1	Trial Group	(0)=8	(0)=12	20	0.1067 P > 0.05
		(E)=7.5	(E)=12.5	20	
2	Combust Cusum	(0)=7	(0)=13	20	
_ Z	Control Group	(E)=7.5	(E)=12.5	20	
	Total			40	

CONCLUSION

It is observed that there was significant improvement in symptoms in both the groups. Comparison between two groups with respect to symptom score was statistically evaluated by Mann - Whitney test. There was significant difference found between Trial and control group in Hasta Paadatala Daha, Pipilika Sanchaarvat Prachiti, Swedatipravrutti, Kshudha vrudhhi symptoms. That Difference is significant at P<0.05 level of confidence. As the means of difference of these symptoms in the trial group was more than control group, it can be concluded that the drug under trial (Mamajjak choorna) acts better with respect to these symptoms than control.

Blood sugar level (fasting), blood sugar level (Postprandial), total cholesterol and urine sugar level were significantly decreased in both trial and control groups. Comparison between two group was done by unpaired 't' test. There was highly significant in BSL (F) and BSL (PP). Hence it can be concluded from the mean that drug in the control group act significantly on these hematological parameters than the trial medicine.

In case of urine sugar level and total cholesterol the unpaired 't' comes out to be insignificant.

In case of trial group out of 20 patients 12 patients were markedly improved and 8 patients were improved. While in case of control group, out of 20 patients 13 were markedly improved and 7 were improved. Comparison between two groups was done by Chi-square test. It was

found that there was no significant difference between the two groups.

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