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A randomized clinical study to evaluate the effect of *Saptachakra* in management of *Madhumeha* w.s.r. to type 2 diabetes mellitus

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ABSTRACT

Background: Non-communicable diseases are posing major health and development threats. The Worldwide, approximately 200 million people currently have type 2 DM, a prevalence that has been predicted to increase to 366 million by 2030. Diabetes Mellitus comprises a group of common metabolic disorders that share the phenotype of hyperglycemia, with an increase incidence worldwide. The Indian subcontinent has a higher prevalence of DM than any other region in the world, and two to three times the reported prevalence in western countries. Recent surveys say that diabetes is affecting 10-16% of urban population**.** The disease *Madhumeha* described in Ayurveda bears close resemblance to Diabetes Mellitus. **Objectives:** To evaluate the effect of *Saptachakra Choorna* in the management of *Madhumeha* w.s.r. to type 2 DM and to compare it with drug taken in the control group. **Materials and Method:** In the present study, two groups were taken each comprising of 20 patients who fulfilled the diagnostic and inclusion criteria. Subjects of group A were administered *Saptachakra Choorna* 6gms twice daily and subjects of group B were administered tablet Metformin 500 mg one tablet twice daily, both before food and for a period of 45 days. **Observation and Results:** In the present study, majority of the symptoms showed clinically significant improvement by *Saptachakra Choorna* and metformin 500 mg, however it was not statistically significant. In the glycemic parameters like FBS, PPBS, FUS and PPUS within the group administered *Saptachakra Choorna* 6 gms only FBS and PPBS showed significant improvement where as parameters like FUS and PPUS there was no much improvement and within the group administered tablet Metformin 500 mg significant improvement in all the parameters were observed. On comparing the results between the two groups, the group administered tablet Metformin 500 mg showed a better result than the group administered *Saptachakra Choorna.* **Conclusion:** By seeing overall improvement and applying Chi Square Test, tablet Metformin 500 mg showed a better result than *Saptachakra Choorna.*

Key words: *Madhumeha, Saptachakra Choorna, Type 2 Diabetes Mellites.*

INTRODUCTION

The physician from Greece, Aretaeus who coined the term 'Diabetes' said "life with Diabetes is short disgusting and painful''.

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The 21st century is the age of science, technology and computer, which is showing an unbalanced and faulty diet pattern and sedentary lifestyle. In studies conducted by ICMR – INDIA it shows that a large percentage of people in India are inactive with fewer than 10% engaging in recreational physical activity. Hence, showing an upward trend of lifestyle disorders in India at present. This has led to a drastic increase in several health problems, especially non-communicable diseases among which Diabetes Mellitus (D.M) tops the list and has become a global public health concern.

The features of *Madhumeha* mentioned in Ayurvedic *Granthas* can be correlated to D.M. A detail explanation of various *Nidanas* are coined which also show similarity like diet including *Gramya, Udaka,*

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Anupa, Dadhini etc. and lifestyle such as *Asyasukham Swapna Sukham*.

According to contemporary science along with oral hypoglycemic agents dietic and lifestyle modification is stressed upon D.M comprises a group of common metabolic disorders that share the phenotype of hyperglycemia, with an increase incidence worldwide. D.M will be a leading cause of morbidity and mortality for the foreseeable future. Hyperglycaemia is mainly caused by absolute or relative deficiency of insulin, this deficiency effects the metabolism of carbohydrates, protein, and fats further leading to significant disturbance of normal functioning of body.[1]

Long standing metabolic degeneration is linked with functional and structural changes in various organs mainly effecting the eye, kidney, nervous system etc. Hence this condition needs to be given utmost importance from the beginning to avoid complications.

Among the classification of OHA, Metformin comes under the biguanides and is currently the most commonly used oral agent to treat type 2 D.M. It is generally accepted as the first line treatment for this condition. The most frequent adverse effects of Metformin are gastrointestinal like anorexia, nausea, vomiting, abdomen discomfort, diarrhea and reduced absorption of vitamin B12.[2] This drug is meant to show hypoglycemic action but for the other adverse effects caused the patient needs to repeatedly see medical attention again which adds on to the burden of the patient.

As Ayurvedic medications show a holistic approach there is a need to search a safe and effective medication for D.M over synthetic / chemical preparations. *Saptachakra* drug belongs to the family Celastraceae and is distributed across the world. Specially in India this plant is widely used and is a species which is widely known for its antidiabetic properties. Many studies regarding the roots are either chewed directly or taken in dried powdered form or as decoction are available.

Prevalence of diabetes

There will be at least 629 million people living with D.M by 2045. The proportion of people with type 2 D.M is increasing in most countries. 79% of adults with Diabetes were living in low- and middle-income countries.[3]

Recent surveys say that Diabetes is affecting 10-16% of urban population and 5-8 % of rural population.[4]

Thus, this study is put forward focusing on evaluating the effect of *Saptachakra Choorna* in management of *Madhumeha* (type 2 D.M)

Aims and Objectives

1. To evaluate the effect of *Saptachakra Choorna* in the management of *Madhumeha* w.s.r to type 2 D.M in the study sample.
2. To evaluate the effect of tablet Metformin 500 mg in the management of *Madhumeha* w.s.r. to type 2 D.M in the study sample.
3. To compare the effect of *Saptachakra Choorna* and tablet Metformin 500 mg in the management of *Madhumeha* w.s.r to type 2 D.M in the study sample.

Materials and Methods

For the present study patient were selected randomly from OPD, IPD and special camp conducted at Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.

Ethical Clearance and Consent

The study was approved by the institutional ethical committee and signed informed consent was obtained from all the patients.

Sampling Method and Research Design

Total 40 patients were randomly selected and assigned into two groups of 20 each as Group A and B respectively.

Diagnostic Criteria

Subjective criteria

Subjects presenting with *Prabhuta Mutra, Avila Mutra* and any of the classical signs and symptoms of *Madhumeha* such as *Karapadadaha,*

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Karapadasuptata, Trishna, Atisweda, Dourbalya were selected.

Objective Criteria

Subjects with F.B.S greater than 126 mg/dl less than 160 mg/dl and P.P.B.S greater than 200 mg/dl less than 300 mg/dl were selected.

Inclusion Criteria

- The subjects irrespective of gender and of age group between 30 to 70 years.
- Subjects presenting with classical signs and symptoms of *Madhumeha* such as *Prabhuta Mutra, Avila Mutra* and *Karapadadaha, Karapadasuptata, Trishna, Atisweda, Dourbalya* were selected.
- Subjects with F.B.S greater than 126 mg/dl less than 160 mg/dl and P.P.B.S greater than 200 mg/dl less than 300 mg/dl were selected.

Exclusion Criteria

- I.D.D.M patients.
- Subjects under insulin therapy.
- Gestational diabetes.
- Type 2 D.M subjects under insulin therapy due to secondary failure.
- Secondary D.M cases were excluded.

Laboratory Investigation

FBS, PPBS, FUS and PPUS were assessed on 0^{th} day before treatment, 15^{th} day, 30^{th} day and 45^{th} day.

Intervention

Group A: *Saptachakra Choorna* was administered with dosage of 6gms twice daily administered orally *(*before food) with warm water for 45 days.

Group B: Metformin 500mg was administered with dosage of 1 tablet twice daily orally *(*before food) with water for 45 days.

Assessment Criteria

- *Prabhutamutrara*
- *Avilamutrata*
- *Trishnadhikya* (polydipsia)
- Kara pada tala daha
- *Dourbalyata*
- FBS
- PPBS
- FUS
- PPUS

Assessment was done on 0^{th} day, 15^{th}day, 30^{th} day and 45^{th} day.

Statistical Analysis

Statistical Analysis was done with - Unpaired T test, Paired T test for parametric data and Mann-Whitney U Test and Wilcoxon Sign Rank test for non-parametric data.

OBSERVATIONS

In the present study maximum number of patients belonged to the age group 40-49 years, this shows more prevalence of D.M in middle and later decade of life. Risk of diabetes increases as age advances. (Table No 1).

The incidence of female are more affected than males. This may be due to the demographic facts. (Table No 2)

Incidence of *Madhumeha* in this study is most common in house wives followed by businessmen, this group contribute to a sedentary life style, lack of change of position for long which may have contributed to the disease process.(Table No 3).

More urbanization and lifestyle changes leading to physical inactivity and consumption of diet rich in fat, sugar and calories along with mental stress contributes the disease process, which is true with a maximum patient belonging to middle class group.(Table no 4)

Diseases including type 2 D.M, occur at lower BMI levels in Asian Indians compared to other ethnic groups,[5] here maximum patients have normal BMI index. (Table no 5)

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Table 1: Showing the incidence of disease with relation to age.

Age	Group A	Group B	Total
30-39	4	4	8 (20%)
40-49	8	8	16 (40%)
50-59	4	4	8 (20%)
60-70	4	4	8 (20%)

Table 2: Showing the incidence of disease with relation to gender.

Gender	Group A	Group B	Total
Male	12	7	19 (47.5%)
Female	8	13	21 (52.5%)

Table 3: Showing the incidence of disease with relation to occupation.

Occupation	Group A	Group B	Total
House wife	4	8	12 (30%)
Businessmen	3	3	6 (15%)
Cashier	2	2	4 (10%)
Retired	1	2	3 (7.5%)
Engineer	2	0	2 (5%)
Others	8	5	13 (32.5%)

Table 4: Showing the incidence of disease with relation to socio-economic status.

Socio economic status	Group A	Group B	Total
Middle class	14	13	27 (67.5%)
Lower middle class	6	6	12 (30%)
Upper middle class	0	1	1 (2.5%)

Table 5: Incidence of observation of patients according to their B.M.I

B.M.I	Group A	Group B	Total%
Normal index	13	17	30 (75%)
Under weight	0	0	0 (0%)
Over weight	5	3	8 (20%)
Obesity	2	0	2 (5%)

RESULTS

In the current study it was observed that there was a reduction in symptoms like *Prabutamutrata, Trishnadhikya, Karapadataladaha* and *Dourbalya* in both the groups, except for *Avilamutrata* which remained the same in the group administered *Saptachakra Choorna* and reduced in group administered tablet Metformin 500 mg. There was improvement in the PPBS values in both the groups which was statistically significant (p value <0.01) and reduction in FBS, FUS and PPUS values but was not statistically significant (p value >0.05) before and after treatment.

Over all clinically in the symptom of *Trishnadhikya Saptachakra Choorna* showed better results than tablet Metformin 500 mg, but statistically it was not significant (p value >0.005).

In the other parameters like *Prabhutamutrata, Avilamutrata, Karapadatala, Dourbalya* group tablet Metformin 500 mg showed better results which was clinically significant but statistically not significant (p value>0.05).

In the parameters like FBS, PPBS, FUS and PPUS group B (standard group) showed better results than group A (trial group) which was statistically significant (p value <0.01).(Table No 6 &7).

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Table 6: Effect of medicine on chief complaints in the patients of *Madhumeha* in Group A

Symptoms	Mean Score		P value
	B.T	A.T	
Prabhuta Mutrata	0.65	0.10	0.008
Avilamutrata	0.10 ±0.308	0.10 ±0.308	1.000
Trishnadikya	0.90 ±0.718	0.20 ±0.410	0.005
Kara Pada Tala Daha	0.85 ± 0.875	0.30 ± 0.470	0.005
Dourbalya	0.95 ± 0.605	0.25 ±0.00	0.001
FBS	149.15	144.90	0.478
PPBS	250.25	202.10	0.001
FUS	0.05	0.10	0.330
PPUS	0.18	0.28	0.408

Table No: 7 Effect of medicine on chief complaints in the patients of madhumeha in Group B

Symptoms	Mean Score		P value
	B.T	A.T	
Prabhuta Mutrata	0.15	0.10	0.577
Avilamutrata	0.10 ± 0.308	0.00 ±0.000	0.157
Trishnadikya	1.05 ± 0.224	0.40 ± 0.503	0.000
Kara Pada Tala Daha	0.55 ± 0.686	0.20 ± 0.410	0.070
Dourbalya	0.95 ±0.510	0.10 ± 0.308	0.000
FBS	151.85	136.35	0.019
PPBS	253.85	193.80	0.000
FUS	0.05	0.00	0.330
PPUS	0.70	0.13	0.005

By assessing overall improvement through Chai Square Test Group B shows better result compared to Group A as shown in the table below (Table No 8).

Table 8: Showing the Over All Improvement

Symptoms	Group	UN	ML	MD	MR
Prabhuta Mutrata	A	13	3	0	4
	B	18	0	0	2
Avilamutrata	A	18	0	0	2
	B	18	0	0	2
Trishnadikya	A	7	1	0	12
	B	7	3	0	10
Kara Pada Tala Daha	A	11	2	0	7
	B	13	0	0	7
Dourbalya	A	8	0	0	12
	B	5	0	0	15

UN=unchanged, ML= mild, MD= moderate, MR= marked Relief. A=Group A, B= Group B.

On the overall assessment when done by simple percentile calculation the group administered tablet Metformin 500 mg showed better results than the group administered *Saptachakra Choorna*.

DISCUSSION

Prabutamutrata

In this study, when we compare the effect of medicines given in group A and B, there was no difference and it is statistically not significant with p value 1.00. This shows that both group A and group B

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show similar effect on the symptom of *prabutamutrata*.

The gradation results within each group are tabulated below (Table No 9&10).

Saptachakra Choorna has the properties of *mutrasangrahaniya*[6] which may be the reason for reduction in symptoms of *Prabutamutrata.*

The most common cause of polyuria is uncontrolled D.M, which causes osmotic diuresis, when glucose level is high that glucose is excreted in urine, tablet Metformin has hypoglycaemic effect[7] which could be the reason for reduction in the symptom of *Prabutamutrata*.

Avilamutrata

When we compared the effect of medicines given in group A and B, group B showed better results than group A, but it is statistically not significant with p value 0.602

The gradation results within each group are tabulated below (Table No 9&10). The reduction in *Avilamutrata* may be due to improved blood glucose levels brought about by the antidiabetic action of the drug which further helps kidneys to filter urine appropriately.

Trishnadhikya

Group A showed better results than group B but it is statistically not significant with p value 0.289 on the symptom of *Trishnadhikya*.

Trishnadhikya is mainly caused by the involvement of *Pitta* and *Vata*, the medicine administered in group A has a *Karma* of *Pitta Shamaka*.[6] This might have reduced this symptom. The gradation results within each group are tabulated below. (Table No 9&10)

Kara Pada Tala Daha

Group B showed better results than group A but it is statistically not significant with p value 0.602.

The *Dāha* in patients of *Madhumeha* may be due to vitiation of *Vāta* and *Pitta*. *Saptachakra* drug has a property of *Pitta Shamaka* and the root bark contains 1,3 diketones as one of its chemical composition.[8] Which directly reduces symptoms of neuropathy along with the action of reduced glucose level.

Kara Pada Tala Daha may have indirectly reduced by a good glycemic control which prevented further damage to the nerves. The gradation results within each group are tabulated below. (Table No 9&10)

Dourbalyata

Group B showed better results than group A but it is statistically not significant with p value 0.583.

Metformin enhances the insulin - mediated glucose uptake and disposal in skeletal muscles and fat thus overcoming insulin resistance and further helping the cell to utilize glucose to produce energy therefore reducing this symptom.The gradation results within each group are tabulated below. (Table No 9&10)

FBS

Group B showed better results than group A and it is statistically significant with p value 0.041. The value range results within each group are tabulated below (Table No 11 & 12). *Saptachakra Choorna* is indicated as *Madhumehahara*[6] hence showing its action. Metformin suppresses hepatic gluconeogenesis and glucose output from liver, this may be the reason for reducing the blood glucose level.

PPBS

Group B showed better results than group A and it is statistically significant with p value 0.021. The value range results within each group are tabulated below.(Table No 11& 12)

FUS

Group B showed better results than group A and it is statistically highly significant with p value 0.002. *Saptachakra Choorna* has action on *Muratravahasamsthana* along with *Madhumehahara* property.[6] Metformin suppresses gluconeogenesis and glycose out put from liver which reduces the glucose level circulating in blood which may be the reason for reduction in FUS. The value range results within each group are tabulated below.(Table No 11& 12)

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PPUS

Group B showed better results than group A and it is statistically highly significant with p value 0.021. Metformin has a property to retards glucose absorption from the intestine which may be the reason for glycemic control hence leading to reduction in PPUS.

The value range results within each group are tabulated below.(Table No 11 & 12)

Table 9: Showing the results of interventions on Symptoms in Group A

C.F	B.T				45th Day (A.T)			
	GR 0	GR 1	GR 2	GR 3	GR 0	GR 1	GR 2	GR 3
Prabhuta Mutrata	11	5	4	0	18	2	0	0
Avilamutrata	18	2	0	0	18	2	0	0
Trishnadikya	6	10	4	0	16	4	0	0
Kara Pada Tala Daha	9	5	6	0	14	6	0	0
Dourbalya	4	13	3	0	16	3	1	0

GR - Grade , BT - Before Treatment, AT - After Treatment, C.F - Clinical Features.

Table 10: Showing the results of interventions on Symptoms in Group B

C.F	B.T				45th Day(A.T)			
	GR0	GR 1	GR 2	GR 3	GR 0	GR 1	GR 2	GR 3
Prabhuta Mutrata	17	3	0	0	18	2	0	0
Avilamutrata	18	2	0	0	20	0	0	0
Trishnadikya	0	19	1	0	12	8	0	0
Kara Pada Tala Daha	11	7	2	0	16	4	0	0
Dourbalya	3	15	2	0	18	2	0	0

GR - Grade , BT - Before Treatment, AT - After Treatment, C.F - Clinical Features.

Table 11: Showing the results of interventions on Symptoms in Group A

C.F	B.T				45th Day (A.T)					
FBS Range	<125	126 to 137	138 to 149	150 to 161	>162	<125	126 to 137	138 to 149	150 to 161	>162
	0	6	8	6	0	6	2	4	2	6
PPBS Range	<199	200 to 225	226 to 250	251 to 275	276 to 300	>301	<199	200 to 225	226 to 250	251 to 275	276 to 300	>301
	0	5	7	1	7	0	10	3	3	2	1	1
FUS Range	Nil	P (0.5 %)	P (1%)	P (1.5%)	P (2%)	Nil		P (0.5%)	P (1%)	P (1.5%)	P (2%)	

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	19	0	1	0	0	18	0	2	0	0
PPUS Range	Nil	P (0.5 %)	P (1%)	P (1.5%)	P (2%)	Nil	P (0.5%)	P (1%)	P (1.5%)	P (2%)
	17	2	0	1	0	15	1	3	0	1

Table 12: Showing the results of interventions on Symptoms in Group B

C.F	**B.T**					**45th Day (A.T)**						
FBS Range	<125	126 to 137		138 to 149	150 to 161	>162	<125	126 to 137	138 to 149	150 to 161	>162	
	0	5		6	9	0	4	7	4	3	2	
PPBS Range	<199	200 to 225	226 to 250	251 to 275	276 to 300	>301	<199	200 to 225	226 to 250	251 to 275	276 to 300	>301
	0	6	2	4	8	0	8	9	3	0	0	0
FUS Range	Nil	P (0.5 %)	P (1%)	P (1.5%)	P (2%)	Nil		P (0.5%)	P (1%)	P (1.5%)	P (2%)	
	19	0	1	0	0	20		0	0	0	0	
PPUS Range	Nil	P (0.5 %)	P (1%)	P (1.5%)	P (2%)	Nil		P (0.5%)	P (1%)	P (1.5%)	P (2%)	
	8	3	3	5	1	16		3	1	0	0	

BT- Before Treatment, AT- After Treatment, C.F- Clinical Features, P- present

CONCLUSION

Madhumeha has been discussed in *Prameha Roga* as one among the *Vataja Prameha*. Further *Vataja Prameha* has two types, among them *Avaranajanya Madhumeha* can be corelated to type 2 D.M. An effort was made to evaluate the effect of *Saptachakra Churna* which has the property of *Madhumehahara* and was compared with the effect of tablet Metformin 500 mg which is the most commonly used OHA to treat type 2 DM. It was observed that most of the patient's nature of work was prolonged sitting and standing, which is also mentioned as one of the *Nidana* leading to *Madhumeha*.

There was a reduction in symptoms like *Prabutamutrata, Trishnadhikya, Karapadataladaha* and *Dourbalya* in both the groups before treatment and after treatment, except for *Avilamutrata* which remained the same in group A and reduced in group B. There was improvement in the PPBS values in both the groups which was statistically significant and reduction in FBS, FUS and PPUS values but was not statistically significant BT and AT. Over all clinically in the symptom of *Trishnadhikya* group A showed better results than group B, but statistically it was not significant. In the other parameters like *Prabhutamutrata, Avilamutrata, Karapadatala, Dourbalya* group B showed better results which was

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clinically significant but statistically non-significant. In the parameters like FBS, PPBS, FUS and PPUS group B showed better results than group A which was statistically significant. In the overall assessment group B showed better results than group A.

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