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## An open label, single arm prospective clinical study on the effectiveness of *Pugaarimeda Kashaya* in *Madhumeha* (Diabetes Mellitus Type 2)

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### ABSTRACT

**Background:** Diabetes mellitus (DM) is one of the most common non-communicable diseases globally. It is characterized by multiple metabolic disorders that results in hyperglycemia. Diabetes mellitus type-2 (DM2) is the most common type accounting almost 90% of cases of DM. *Madhumeha* on the basis of similar etiology, signs and symptoms can be co-related with Diabetes mellitus type-2. It is also described by the term *Kshoudrameha* or *Ojomeha*. *Pugaarimeda Kashaya* with *Madhu* as *Anupana* is mentioned in *Brihat Nighantu Ratnakara* in the management of *Madhumeha*. **Objective:** To clinically evaluate the effectiveness of *Pugaarimeda Kashaya* in *Madhumeha* (Diabetes mellitus type-2). **Materials and Methods:** Among 31 registered subjects, 28 of them completed the course of treatment. They were administered with *Pugaarimeda Kashaya* orally 100ml per day (50ml twice daily before food) with *Anupana* of *Madhu* 5ml for a period of 30 days. Blood and urine glucose test was done on 1<sup>st</sup>, 31<sup>st</sup> day of study initiation. For Statistical analysis subjective parameters were assessed by Cochran's Q test followed by McNemar test and objective parameters were assessed by Paired sample T Test. **Results:** There was statistically significant improvement observed in the signs and symptoms of *Madhumeha* with blood and urine glucose levels. ( $p < 0.05$ ) **Conclusion:** *Pugaarimeda Kashaya* was found effective in the management of *Madhumeha*.

**Key words:** *Madhumeha*; Diabetes Mellitus; *Pugaarimeda Kashaya*

### INTRODUCTION

Diabetes has been increasing at an alarming rate since the start of the 21<sup>st</sup> century, driven largely by obesity and sedentary life styles. The latest 2021 data from IDF Diabetes Atlas 10<sup>th</sup> edition estimated 537 million adults are living with Diabetes. This is predicted to rise

to 643 million by 2030 and 783 million by 2045.<sup>[1]</sup> India is projected to be home to 109 million individuals with Diabetes mellitus (DM) by 2035.<sup>[2]</sup> Among them Diabetes mellitus type-2(DM2) is the most common type accounting almost 90% of cases of DM.<sup>[3]</sup>

Diabetes mellitus type-2 is a chronic disorder which primarily occurs due to abnormal metabolism of glucose, fat and protein.<sup>[4]</sup> The high incidence is found to have association between age, family history, obesity, urbanization, lower socio-economic status, high calorie food and lack of physical activity. The increase in the prevalence of Diabetes mellitus type-2 across the world has become an important public health problem.<sup>[3]</sup> DM2 clinically presents with polyuria, polydipsia, polyphagia, paresthesia, loss of weight, weakness of unknown cause and glucosuria.<sup>[4]</sup> The etiology, signs and symptoms of Diabetes Mellitus are found to be similar with of *Madhumeha*.

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*Madhumeha* is included under the *Vimshati Prameha* and is explained as one among the *Vataja Prameha*.<sup>[5]</sup> *Madhumeha* is one of the *Ashta Mahagadas*.<sup>[6]</sup> It is also described by the term *Kshoudrameha*.<sup>[7]</sup> *Madhumeha* is classified into two types such as *Dhatukshayajanya* and *Avaranajanya*.<sup>[6]</sup> In *Samprapti* of *Avaranajanya Madhumeha Kapha, Pitta, Meda* and *Mamsa* are excessively increased. The vitiated *Kapha* and *Pitta* obstruct the path of *Vata* causing its provocation. This obstructed *Vata* transforms *Madhurata of Ojas* into *Kashaya* and expels *Ojas* through *Basti* causing *Madhumeha* with *Lakshanas* being *Madhuryata* of both *Mutra* and *Sharira*.<sup>[8]</sup>

All other *Prameha* can be called as *Madhumeha* and all other *Meha* would end up in *Madhumeha* when left untreated.<sup>[6,7]</sup> *Madhumeha* is *Krichrasadhya* or *Yapya* or *Asadhya* in nature.

*Pugaarimeda Kashaya* with *Madhu* as *Anupana* is mentioned in management of *Madhumeha*.<sup>[9]</sup> It has two ingredients *Puga* and *Arimeda*. *Puga* and *Arimeda* are having *Ruksha Guna, Tikta Kashaya Rasa, Katu Vipaka, Ushna Virya, Kapha-Pittahara* and *Medoshoshana* properties which is essential in *Samprapti Vighatana* of *Madhumeha*.<sup>[10,11]</sup> Experimental studies on *Puga* has showed antidiabetic activity by suppressing the action of intestinal glucosidase enzymes, reduction of blood glucose level, improved glycogen content and *Arimeda* has showed inhibitory activity against  $\alpha$ -glucosidase type-4 enzyme.<sup>[12,13,14]</sup>

This study was intended to validate the effectiveness of *Pugaarimeda Kashaya* in *Madhumeha* (Diabetes mellitus type-2).

## OBJECTIVE

To evaluate the effect of *Pugaarimeda Kashaya* in the management of *Madhumeha* (Diabetes Mellitus type 2).

## MATERIALS AND METHODS

### Source of Data

31 participants of *Madhumeha* fulfilling the diagnostic and inclusion criteria were recruited from outpatient

department of Sri Dharmashtala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

### Methods of collection of data

31 participants were screened at outpatient department and Data were collected using specially prepared case report form (CRF) by incorporating all aspects of *Madhumeha* and Diabetes mellitus type-2.

### Diagnostic Criteria

1. Signs and symptoms of *Madhumeha* like *Prabhoota Mutrata, Pipaasa Adhikya, Kshudha Adhikya, Karapada Daha, Karapada Suptata* or *Angasaada*
2. Fasting blood glucose >126 mg/dl or
3. Postprandial Blood Glucose >200mg/dl or
4. HbA1c >6.5%

### Inclusion Criteria

1. Fresh cases and diagnosed cases of Diabetes mellitus type-2 on Ayurvedic treatment
2. Participants of either gender of age between 30-70 years
3. Participants who are ready to sign the informed consent form

### Exclusion Criteria

1. Participants of Diabetes mellitus type-2 on insulin
2. Participants of Diabetes mellitus type-2 with HbA1c >10%
3. Participants with known case of cardiac illness, impaired kidney and liver function
4. Pregnant and lactating women

### Laboratory Investigations

- Fasting blood glucose
- Post prandial blood glucose
- Fasting urine sugar
- Post prandial urine sugar
- HbA1c

### Study design

The study was an open label, single arm, prospective clinical study on 31 participants of *Madhumeha* using convenience sampling technique.

### Intervention

**Medicine - Pugaarimeda Kashaya**

### Source and authentication of raw drug

*Arimeda* stem bark was purchased and authenticated from CKKM Pharmacy, Kerala (GMP certified pharmacy). *Puga* fruit was purchased from market and authenticated from the Department of Dravyaguna of Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hassan.

### Plan of Treatment

*Pugaarimeda Kashaya*: 100ml/day in divided dose of 50ml twice daily before food for 30 days.

*Anupana*: 5ml of *Madhu*

**Follow up:** Starting from the first day of treatment, follow up was done on 15<sup>th</sup> and 31<sup>st</sup> day (for primary outcome measures) and before treatment and on 31<sup>st</sup> day for secondary outcome measures

### Assessment Criteria

**Primary outcome measures:** The assessment of effect of treatment was done based on the changes in signs and symptoms of *Madhumeha* such as:

*Prabhoota Mutrata*, *Pipasa Adhikya*, *Kshudha Adhikya*, *Karapada Daha*, *Karapada Suptata*, or *Angasaada*

**Secondary outcome measures:** Effect was assessed with changes in;

- Fasting blood glucose - Before and after treatment.
- Post prandial blood glucose - Before and after treatment
- Fasting urine sugar - Before and after treatment
- Post prandial urine sugar - Before and after treatment

### OBSERVATION

**Table 1: Before treatment symptom wise distribution of 31 subjects of *Madhumeha***

Symptoms	Parameter		Total	%
	Present	Absent		
<i>Prabhoota Mutrata</i>	19	12	31	61.3
<i>Kshudha Adhikya</i>	4	27		12.9
<i>Pipasa Adhikya</i>	8	23		25.8
<i>Karapada Daha</i>	6	25		19.4
<i>Karapada Suptata</i>	18	13		58.1
<i>Angasaada</i>	22	9		71.0

### RESULTS

A total of 31 participants of *Madhumeha* were registered for the study, 28 participants completed the trial and 3 drop outs.

**Table 2: Effect of *Pugaarimeda Kashaya* in *Prabhoota Mutrata***

Parameter	Value		N	Cochran's Q	P value	Remarks
	Present	Absent				
BT	18	10	28	19.500	<.05	S
15 <sup>th</sup> day	15	13				
31 <sup>st</sup> day	6	22				

Cochran's Q test, BT – Before Treatment, S – Highly Significant, N – number of objects

**Table 3: Effect of *Pugaarimeda Kashaya* in *Kshudha Adhikya***

Parameter	Value		N	Cochran's Q	P value	Remarks
	Present	Absent				
BT	4	24	28	.000 <sup>a</sup>	>.05	NS
15 <sup>th</sup> day	4	24				
31 <sup>st</sup> day	4	24				

Cochran’s Q test, BT – Before Treatment, S – Significant, N – number of objects

**Table 4: Effect of Pugaarimeda Kashaya in Pipasa Adhikya**

Parameter	Value		N	Cochran’s Q	P value	Remarks
	Present	Absent				
BT	7	21	28	2.000 <sup>a</sup>	>.05	NS
15 <sup>th</sup> day	7	21				
31 <sup>st</sup> day	6	22				

Cochran’s Q test, BT – Before Treatment, S – Significant, N – number of objects

**Table 5: Effect of Pugaarimeda Kashaya in Karapada Daha**

Parameter	Value		N	Cochran’s Q	P value	Remarks
	Present	Absent				
BT	5	23	28	4.000 <sup>a</sup>	>.05	NS
15 <sup>th</sup> day	5	23				
31 <sup>st</sup> day	3	25				

Cochran’s Q test, BT – Before Treatment, S – Significant, N – number of objects

**Table 6: Effect of Pugaarimeda Kashaya in Karapada Suptata**

Parameter	Value		N	Cochran’s Q	P value	Remarks
	Present	Absent				
BT	17	11	28	20.42 <sup>a</sup>	<.05	S
15 <sup>th</sup> day	13	15				
31 <sup>st</sup> day	4	24				

Cochran’s Q test, BT – Before Treatment, S – Highly Significant, N – number of objects

**Table 7: Effect of Pugaarimeda Kashaya in Angasaada**

Parameter	Value		N	Cochran’s Q	P value	Remarks
	Present	Absent				
BT	19	9	28	26.235 <sup>a</sup>	<.05	S
15 <sup>th</sup> day	8	20				
31 <sup>st</sup> day	2	26				

Cochran’s Q test, BT – Before Treatment, S – Highly Significant, N – number of objects

**Table 8: Effect of Treatment on Fasting Blood Glucose in 28 Subjects**

Pair	Mean	N	SD	P value	Remarks
FBS BT	223.39	28	47.62	<.05	S
FBS 31 <sup>st</sup> Day	148.57	28	52.69		

Paired T test, BT-before treatment, SD-standard deviation, N-no of subjects

**Table 9: Effect of Treatment on Post Prandial Blood Glucose in 28 Subjects**

Pair	Mean	N	SD	P value	Remarks
PPBS BT	300.86	28	48.21	<.05	S
PPBS 31 <sup>st</sup> Day	216.60	28	63.85		

Paired T test, BT-before treatment, SD-standard deviation, N-no of subjects

**Table 10: Effect of Treatment on Fasting urine sugar in 28 Subjects**

Pair	Mean	N	SD	P value	Remarks
FUS BT	1.250	28	0.54	<.05	S
FUS 31 <sup>st</sup> Day	0.4107	28	0.55		

Paired T test, BT - Before treatment, SD - Standard deviation, N – No. of subjects

**Table 11: Effect of Treatment on Post Prandial Urine Sugar in 28 Subjects**

Pair	Mean	N	SD	P value	Remarks
PPUS BT	1.75	28	0.319	<.05	S
PPUS 31 <sup>st</sup> Day	0.86	28	0.715		

Paired T test, BT - Before treatment, SD - Standard deviation, N – No. of subjects

## DISCUSSION

### Effect of Pugaarimeda Kashaya on Prabhoota Mutrata

There was statistically significant improvement in *Prabhoota Mutrata* after treatment with p value <0.05. *Prabhoota Mutrata* is *Mootra Vaha Sroto Dushti Lakshana* caused due to *Mandagni*, increase in *Bahu Drava Shleshma*, *Abadha Dhatus* leading to increased *Malas* and *Kledamsha*.

*Pugaarimeda Kashaya* having *Kashaya-Tikta Rasa*, *Ruksha Guna*, *Katu Vipaka*, *Kapha-Kleda Soshaka* property reduces the *Bahumutrata*. The *Deepana*, *Pachana Karma* of *Puga*, *Ushna Virya* of *Arimeda* improves *Agni*, so further formation of *Ama*, *Kleda* will be prevented.

### Effect of Pugaarimeda Kashaya on Kshudha Adhikya

There was no statistically significant improvement in *Kshudha Adhikya* after the treatment with p>0.05.

### Effect of Pugaarimeda Kashaya on Pipasa Adhikya

There was no statistically significant improvement in *Pipasa Adhikya* after the treatment with p>.05.

### Effect of Pugaarimeda Kashaya on Karapada Daha

There was no statistically significant improvement in *Karapada Daha* after the treatment with p>.05.

### Effect of Pugaarimeda Kashaya on Karapada Suptata

There was statistically significant improvement in *Karapada Suptata* after treatment with p value <0.05. *Karapada Suptata* may be due to *Prakopa* of *Kapha Dosh*. *Pugaarimeda Kashaya* is having *Kashaya*, *Tikta Rasa*, *Ushna Virya*, *Katu Vipaka* and *Kapha-Vatahara* property which pacifies *Kapha*, thus reduces *Karapada Suptata*.

### Effect of Pugaarimeda Kashaya on Angasaada

There was statistically significant improvement in *Angasaada* after treatment with p value <0.05. *Angasaada* may be caused due to vitiated *Kapha* and *Abadha Dhatus* particularly *Meda Dhatu* in *Madhumeha*. *Pugaarimeda Kashaya* is having *Kashaya Rasa*, *Tikta Rasa*, *Ushna Virya*, *Katu Vipaka* which does *Ama Pachana*, *Agni Deepana* and possesses *Kapha-Meda Hara* property which Reduces vitiated *Kapha* and *Meda*. Hence it reduces *Angasaada*. Fatigue or feeling tired is the most common presenting feature of Diabetes mellitus type2 resulting from hyperglycemia and glycosuria. Therefore, when hyperglycemia is corrected with hypoglycemic activity of ingredients of *Pugaarimeda Kashaya*, feels relief from this symptom.

### Effect of Pugaarimeda Kashaya on Biochemical parameters:

Experimental studies on *Puga* has showed antidiabetic activity by suppressing the action of intestinal glycosidase enzymes, reduction of blood glucose level, improved insulin secretion thus reducing blood glucose level. Experimental studies on *Arimeda* has showed inhibitory activity against  $\alpha$ -glucosidase type-iv enzyme, antihyperlipidemic and antioxidant activities thus reducing peripheral insulin resistance and blood glucose level.

### Probable mode of action of therapy related discussion

*Kashaya*, *Tikta Rasa* of *Puga* and *Arimeda* acts as *Kleda Soshana*, *Mutra Sangrahi* and does *Kapha-Meda Soshana*. *Laghu*, *Ruksha Guna* does *Shoshana* of *Kleda* and acts against *Madhura-Snigdhatu* of *Madhumeha*. *Katu Vipaka* does *Kapha Shamana*, *Meda Soshana*, *Deepana*, *Pachana* and *Kapha-Medahara* property helps in improving *Jatharagni* and *Meda Dhatvagni*, so

further formation of *Ama*, abnormal *Dhatu*s will be prevented. *Arimeda* is having *Kapha-Vata Hara*, *Meda Soshaka* and *Puga* is having *Kapha-Pittahara Karma*, which is the main action in *Madhumeha* as it is said to be *Tridoshaja*. It would be effective in *Samprapti Vighatana* of *Madhumeha*.

*Puga* contains tannins, polyphenols, arecoline which are found effective in reducing blood sugar levels by suppressing breakdown of starch into simple sugars and improving peripheral glucose metabolism in liver, muscle adipocytes and pancreatic beta cells. It also possesses antilipidemic and antioxidant effects. *Arimeda* contains tannins, catechin, fisetinidol (4 alpha 6,8) which has hypoglycemic activity and n-hexacosanol, beta-amyrin, beta-sitosterol possessing hypolipidemic (reduces cholesterol, LDL) activity which in turn reduces peripheral insulin resistance.

Both the drugs help in reducing blood sugar and improving insulin sensitivity. Hence *Pugaarimeda Kashaya* would be effective in *Samprapti Vighatana* of *Madhumeha*. It would be beneficial in *Avaranajanya Madhumeha*.

*Anupana* – *Madhu*, it is having *Laghu*, *Ruksha Guna*, *Deepana*, *Lekhana*, *Medahara*, *Grahi*, *Tridosha Shamana* property and is indicated in *Prameha Roga*.

## CONCLUSION

Administration of *Pugaarimeda Kashaya* in the dosage of 100m/day in divided dose of 50ml twice daily (morning and evening) before food with 5ml *Madhu* as *Anupana* for 1 month was found beneficial in improving symptoms of *Madhumeha*. Statistically significant improvement was observed in *Prabhoota Mutrata*, *Karapada Suptata* and *Angasaada*. Statistically significant improvement was observed in objective parameters - Fasting and Post prandial blood and urine glucose levels. Research hypothesis was thus accepted.

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