



**Research Article**

**A SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KATANKATERIYADI KWATHA* IN THE MANAGEMENT OF *MADHUMEHA* (DIABETES MELLITUS TYPE-2)**

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**ABSTRACT**

*Madhumeha* is known to Indian system of medicine since time immemorial. Almost all texts available, however old contain one or another very lucid hint of *Prameha*. This along with all of its causes, etiopathogenesis, symptomatology, treatment and complications are mentioned in all Ayurvedic texts written centuries ago. It's inclusion in eight major diseases (*Astamahagada*) indicates the significance and gravity attributed to it. Here 40 cases of newly diagnosed type 2 diabetes mellitus in a patient who underwent 3 follow up i.e., 30<sup>th</sup>, 60<sup>th</sup>, 90<sup>th</sup> of *Katankateriyadi kwatha* delivered in 3 months is reported. The patient's fasting blood glucose and post plasma blood glucose levels, as well as HbA1C level were decreased after treatment. Further-more, no adverse effects were observed. The results of this clinical study are encouraging and provide evidence supporting the effectiveness of *Katankateriyadi Kwatha* in reducing *Madhumeha* (Diabetes Mellitus Type-2) in a patient.

**INTRODUCTION**

The 21<sup>st</sup> century is the age of science, technology, computer and atomic energy. The expansion of science and technology has been observed in every field including modern medical science. Besides the miraculous achievements of modern medical science humanity is passing through a horror of disease and drug phobia particularly in developing countries like "India". Sedentary lifestyle increase all causes of mortality, double the risk of cardiovascular diseases, Diabetes Mellitus, obesity, and increase the risk of high blood pressure and lipid disorders. Ayurveda described various *Pathyas* to maintain health, ultimately which is the first aim of Ayurveda. But at present due to several causes people does not follow that type of lifestyle in proper way which leads to several life threatening problems and the *Madhumeha* is one of them.

Today contemporary science develops so many drugs for management of diabetes mellitus type II. The common drawback of contemporary medicine is drug

resistance because the drugs are used for life long period.

To avoid such types of problems the world look now a day towards the herbal medicines which are safe in use for long period of time.

The research on Ayurvedic medicines and their natural products have significant importance in demands and use in few decades and increasing the demand of Ayurvedic drugs worldwide.

**OBJECTIVE**


To determine the efficacy of *Katankateriyadi kwatha* in the management of *Madhumeha* (Diabetes Mellitus Type 2).

**METHODOLOGY**

For the present study 40 patients of either sex of group 25-70 yrs and the newly diagnosed subjects of *Madhumeha* (diabetes mellitus type 2) according to classical sign and symptoms. The patient will be selected strictly abiding to the inclusion and exclusion criteria. The patients thus selected will be Convenience sampling method. *Katankateriyadi kwatha* 25ml twice a day before meal for the period of 90 days is effective in *Madhumeha*.

**Inclusive Criteria**

1. The newly diagnosed Subjects of *Madhumeha* (diabetes mellitus type 2) according to classical sign and symptoms.

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- Subjects having any three of seven subjective criteria will be included.
- Subjects having any two of three objective criteria will be included.
- Subjects of *Madhumeha* with age group of 25 to 65 years with irrespective of sex, religion and socio-economical conditions.
- Blood sugar fasting  $\geq 125$ mg/dl and  $<$  than 200mg/dl.
- Blood Sugar PP $\geq 200$ mg/dl and  $<$  275mg/dl.
- HbA1c more than 5.7% up to 7%.

**Exclusion Criteria**

- Known cases of insulin dependent diabetes mellitus type 1 and gestational diabetes mellitus.
- Known case of diabetes mellitus with renal failure and other Diabetic complications (neuropathy, nephropathy).

- Subjects known case of other systemic diseases like AIDS and Cancer, VDRL etc.

**Diagnostic Criteria**

**Subjective Criteria<sup>[1]</sup>**

- Prabhoota mutrata*
- Pipasadhikya*
- Karapada daha*
- Kshudhadhikya*
- Dourbalya*
- Alasya*
- Atinidra*

**Objective criteria<sup>[2]</sup>**

- BSL Fasting
- BSL Post Prandial
- HbA1c

**Table 1: Gradation of Subjective Criteria<sup>[3]</sup>**

S.No	Lakshana	Grade 0	Grade 1	Grade 2	Grade 3
1	a. Quantity of urine b. Frequency of Urine	1.5 to 2.5 lit/day 3 to 5 times/day and 1-2 times at night	2.5 to 3 lit/ day 5 to 7 times/day and 1-2 times at night.	3 to 3.5 lit/day 7 to 10 times/ day, 3-4 times at night.	3.5 and above lit/day 10 to 12 times/day, more than 5 times at night.
2	<i>Pipasa Adhikya</i> Quantity of water intake	2 to 3 lit/day (24 hrs).	3 to 4 lit/day.	4 to 5 lit/day	More than 5 litres/day
3	<i>Karapadadaha</i>	No <i>Daha</i> Present	Occasional <i>Daha</i>	<i>Daha</i> mild but continuous	<i>Daha</i> severe and continuous
4	<i>Ksudhadhikya</i>	Normal appetite (3 meals/day)	Mild increased (1-2 more meals than normal)	Moderately increased (2-3 meals than normal)	Markedly increased (4-5 meals than normal)
5	<i>Daurbalya</i>	Can do routine physical activity without any difficulty	Can do routine physical activity with little difficulty	Can do mild physical activity only	Can do mild physical activity with difficulty

**BSL Fasting**

$\leq 125$	<b>Grade 0</b>
126 to 150	<b>Grade 1</b>
151 to 175	<b>Grade 2</b>
176 to $> 200$	<b>Grade 3</b>

**BSL Post Prandial**

$\leq 200$	<b>Grade 0</b>
201 to 225	<b>Grade 1</b>
226 to 250	<b>Grade 2</b>
251 to $> 275$	<b>Grade 3</b>

**Drug review/Properties**

कटङ्कटेरीमधुकत्रिफलाचित्रकैः समैः ।

सिद्धः कषायः पातव्यः प्रमेहाणां विनाशनः॥२३॥ (चक्रदत्त 28/23) <sup>[4]</sup>

The formulation *Katankateriyadi Kwatha* is taken from *Chakradatta Prameha chikitsa Adhyaya his Rasa, Virya and Vipaka* is as explained below:

**Table 2: Dravya and its Properties<sup>[5]</sup>**

S.no	Draya	Latin Name	Part Used	Quantity	Swarup
1	<i>Daruharidra</i>	<i>Berberis aristata</i>	<i>Kand</i>	1 Part	<i>Bharad Choorna</i>
2	<i>Yashtimadhu</i>	<i>Glycyrrhiza glabra</i>	<i>Kand</i>	1 Part	<i>Bharad Choorna</i>
3	<i>Haritaki</i>	<i>Terminalia Chebula</i>	<i>Phala</i>	1 Part	<i>Bharad Choorna</i>
4	<i>Bibhitaki</i>	<i>Terminalia Belirica</i>	<i>Phala</i>	1 Part	<i>Bharad Choorna</i>
5	<i>Amalaki</i>	<i>Emblica Officinalis</i>	<i>Phala</i>	1 Part	<i>Bharad Choorna</i>
6	<i>Chitrak</i>	<i>Plumbago zeylanica</i>	<i>Mula</i>	1 part	<i>Bharad Choorna</i>

**Kashaya Preparation (Decoction)**

Each drug taken 2gm *Bharad churn.*

Total=12gm

6gm - Morning dose and 6gm - Night dose

6gm *Bharad Choorna* + 100ml of *Jala* = 1/4<sup>th</sup> *Shesha Kwatha* (25ml)

**Interventions**

<b>Name</b>	<i>Katankateriyadi Kwatha</i>
<b>Dose</b>	25ml <i>Kwatha</i>
<b>Aushadhi Sevan Kala</b>	<i>Pragbhakta</i> (before 15 min of meal) BID (two times in a day.)
<b>Route of Administration</b>	Orally
<b>Duration</b>	90 days
<b>Follow up</b>	After every 30 days i.e., 30 <sup>th</sup> , 60 <sup>th</sup> and 90 <sup>th</sup> days.

**OBSERVATION**

The analyses of observation of clinical study were done by using the appropriate statistical data. The observation documented during the present study with respect to demographic data, clinical data were present in the tables.

**Demographical Data**

**Table 3: Distribution of subjects as per Age**

Age	Frequency	Percentage
30-40 Years	5	12.50%
41-50 Years	15	37.50%
51-60 Years	11	27.50%
61-70 Years	9	22.50%
Total	<b>40</b>	100.00%

In the study maximum patients were seen in the age group 41-50 years.

**Table 4: Distribution of subjects as per sex**

Sex	Frequency	Percentage
Female	16	40.00%
Male	24	60.00%
Total	40	100.00%

In the study maximum patients were male (60.00%), rest (40.00%) were female.

**Table 5: Distribution of subjects as per religion**

Religion	Frequency	Percentage
Hindu	38	95.00%
Muslim	2	5.00%
Total	40	100.00%

In our study group out of 40 subjects, 38 (95.007%) subjects were form Hindu community, 02 (5.00%) subjects were form Muslim community.

**Table 6: Distribution of subjects as per Education**

Educational Status	Frequency	Percentage
Illiterate	7	17.50%
Literate	33	82.50%
Total	40	100.00%

In the study maximum patients were seen 33 (82.50%) literate and 7 (17.50%) was illiterate.

**Table 7: Distribution of subjects as per socioeconomic status**

Socio Economic Status	Frequency	Percentage
Moderate	29	72.50%
Poor	6	15.00%
Rich	5	12.50%
Total	40	100.00%

In the study maximum patients were seen moderate class 29 (72.50%) and 5 (15.00%) was from rich class, 6 (12.50%) was from poor class.

**Table 8: Distribution of subjects as per Occupation**

Occupation	Frequency	Percentage
Business	2	5.00%
Housewife	11	27.50%
Job	8	20.00%
Reporter	1	2.50%
Worker	18	45.00%
Total	40	100.00%

In the study maximum patients were seen out of 40 subjects 8 (20.00%) were doing job, 11 (27.50%) were housewives, 2 (5.00 %) were from business, 18 (45.00%) were worker, 1 (2.50%) were reporter.

**Table 9: Distribution of subjects as per Addiction**

Addiction	Frequency	Percentage
Alcohol	1	2.50%
Nil	33	82.50%
Tobacco	6	15.00%
Total	40	100.00%

In the study maximum patients were seen out of 40 subjects 6 (15.00%) subjects were addicted with tobacco and 1 (2.50%) subjects were addicted with alcohol.

**Table 10: Distribution of subjects as per Diet**

Diet	Frequency	Percentage
Mix	15	37.50%
Veg	25	62.50%
Total	40	100.00%

In this present study, Out of 40 subjects 15 (37.50%) subjects were taking mixed diet and 25 (62.50%) subjects were taking vegetarian diet.

**Table 11: Difference between before and after treatment in BSL (Fasting)**

BSL (Fasting)	Mean	N	SD	SE	t-Value	P-Value	% Change	Result
BT	158.10	40	26.11	4.13	7.920	0.0000	23.92	Sig
AT	120.28	40	26.59	4.20				

Since observations are quantitative, we have used paired t-Test to test significance. From above table, we can observe that P-Value is less than 0.05. Hence, we can conclude that, there is significant change observed in BSL (Fasting).

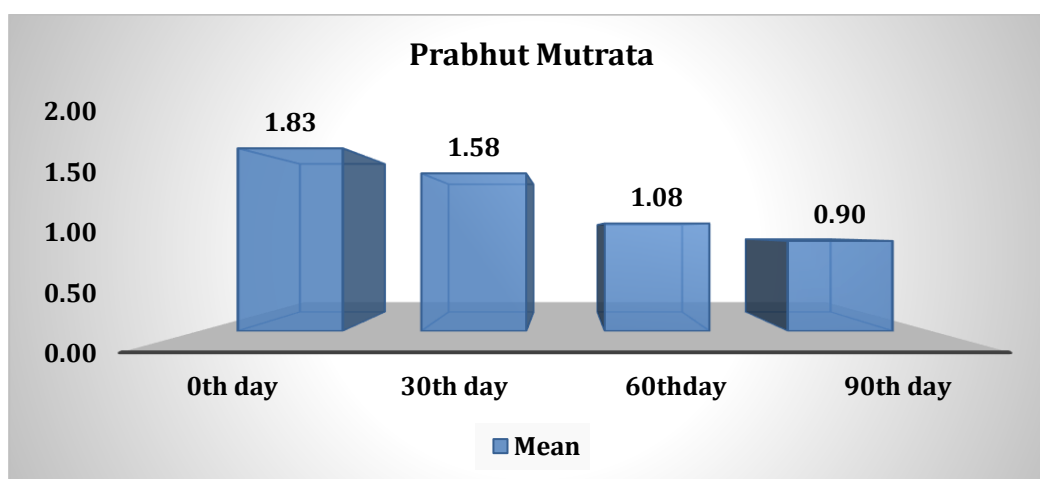
**Table 12: Difference between before and after treatment in BSL (PP)**

BSL (PP)	Mean	N	SD	SE	t-Value	P-Value	% Change	Result
BT	231.93	40	38.38	6.07	7.107	0.0000	24.20	Sig
AT	175.80	40	48.27	7.63				

Since observations are quantitative, we have used paired t-Test to test significance. From above table, we can observe that P-Value is less than 0.05. Hence, we can conclude that, there is significant change observed in BSL (PP).

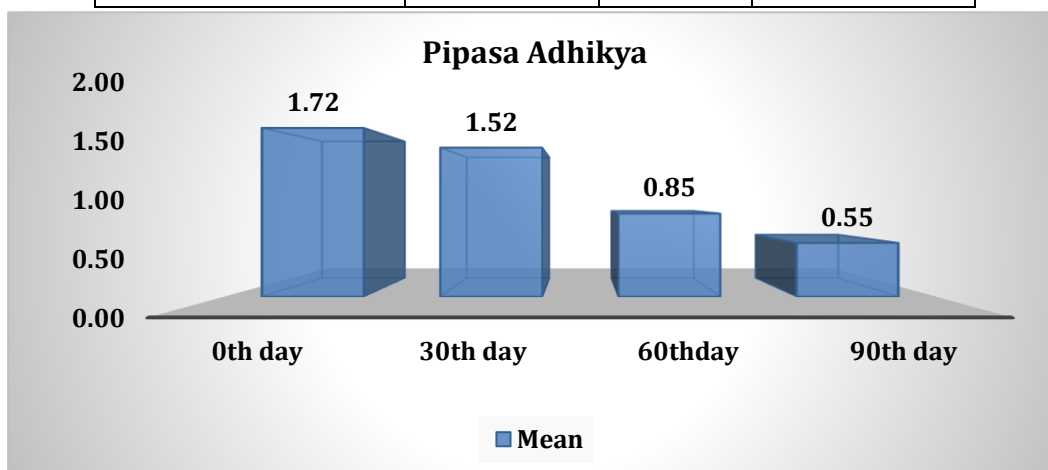
**Table 13: Follow up effect of *Prabhut mutrata***

11 <i>Prabhut Mutrata</i>	Mean	SD	% Effect
0 <sup>th</sup> day	1.83	0.75	-
30 <sup>th</sup> day	1.58	0.75	13.70
60 <sup>th</sup> day	1.08	0.76	41.10
90 <sup>th</sup> day	0.90	0.74	50.68



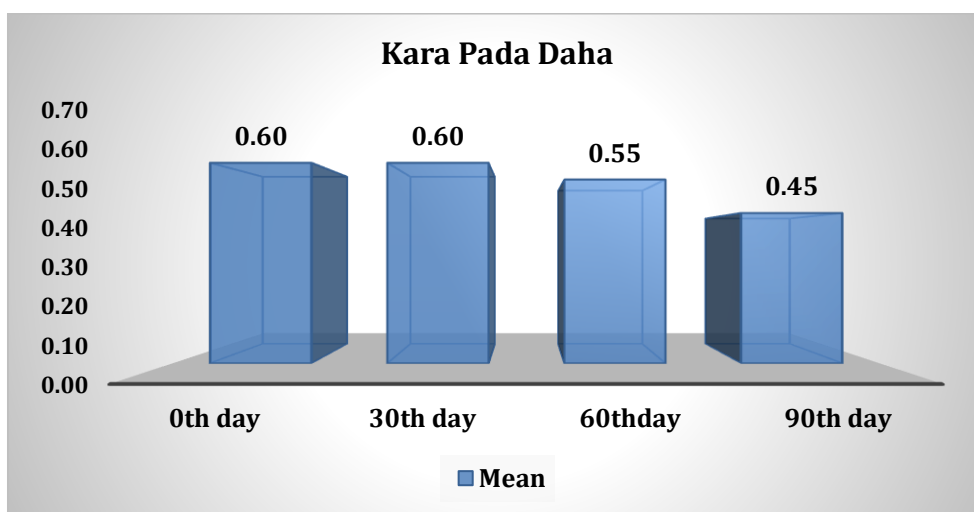
**Table 14: Follow up effect of *Pipas Adhikya***

<i>Pipasa Adhikya</i>	Mean	SD	% Effect
0 <sup>th</sup> day	1.73	0.72	-
30 <sup>th</sup> day	1.53	0.82	11.59
60 <sup>th</sup> day	0.85	0.70	50.72
90 <sup>th</sup> day	0.55	0.71	68.12



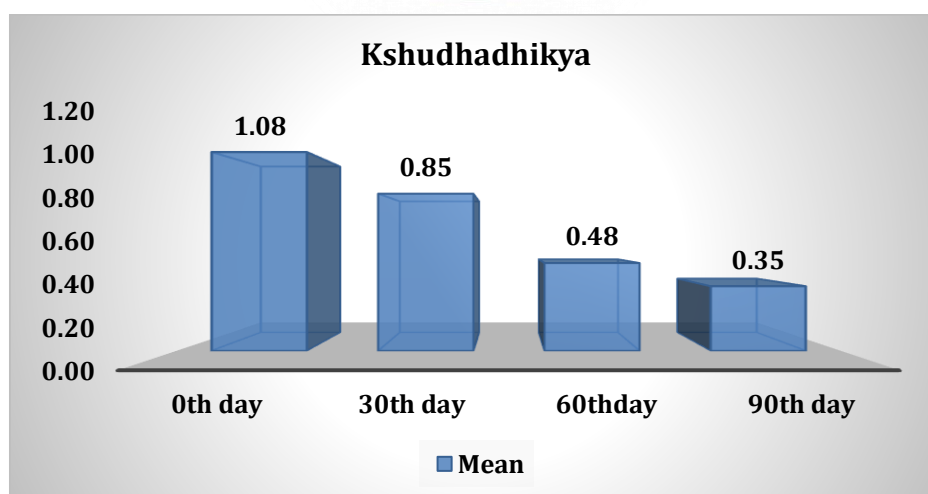
**Table 15: Follow up effect of Kara Pada Daha**

<i>Kara Pada Daha</i>	Mean	SD	% Effect
0 <sup>th</sup> day	0.60	1.01	-
30 <sup>th</sup> day	0.60	0.98	0.00
60 <sup>th</sup> day	0.55	0.90	8.33
90 <sup>th</sup> day	0.45	0.75	25.00



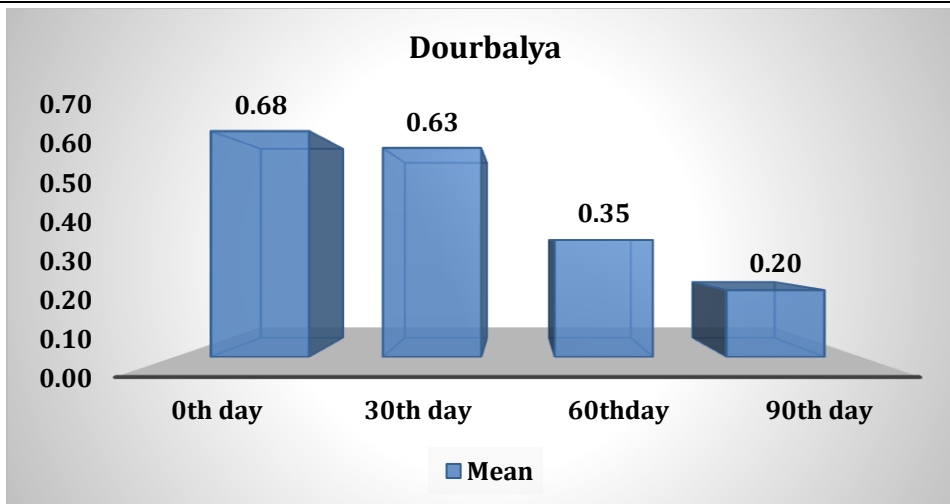
**Table 16: Follow up effect of Khudhadhikya**

<i>Kshudhadikya</i>	Mean	SD	% Effect
0 <sup>th</sup> day	1.08	0.97	-
30 <sup>th</sup> day	0.85	0.89	20.93
60 <sup>th</sup> day	0.48	0.64	55.81
90 <sup>th</sup> day	0.35	0.58	67.44



**Table 17: Follow up effect of Dourbalya**

<i>Dourbalya</i>	Mean	SD	% Effect
0 <sup>th</sup> day	0.68	0.76	-
30 <sup>th</sup> day	0.63	0.74	7.41
60 <sup>th</sup> day	0.35	0.62	48.15
90 <sup>th</sup> day	0.20	0.52	70.37



**Table 18: Lakshan wise Distributions of patients**

S.no	Subjective Criteria	% Relief
1.	<i>Prabhuta mutrata</i>	50.68
2.	<i>Pipasa adhikya</i>	68.12
3.	<i>Karapada daha</i>	25.67
4.	<i>Kshutadhikya</i>	66.7
5.	<i>Dourbalya</i>	70.37

**Probable Mode of Action of Katankateriyadi Kwatha in Madhumeha (type 2 DM)**

*Katankateriyadi kwatha* contains most of drugs which belongs to *Lekhaniya Gana* (substances that reduced excess body tissue). *Lekhaniya gana* reduces *Dushta kapha, Meda* as well as *Kleda* consequently having *Pramehghna* properties. According to *rasa*, *Katankateriyadi Kwatha* contains the maximum drugs which are *Kashay, Tikta,* and *Katu rasa* present in it act *Kapha shamak* and *Agni deepak* in nature and facilitates *Srotodushti* while *Kasaya rasa* hinders the movement of *Shariragata kleda* towards *Basti*. Presence of *Ruksha guna* directly pacifies *Kapha* due to opposite in property. The *Laghu guna* of this *Kwatha* aids in digestion of *Amadosha* by increasing *Vayu* and *Agni mahabhuta*. *Tikshna guna* of this drug is responsible of *Sroto suddhi* and also perform *Lekhana karma* to eliminate *Meda, Kaphanashak karma* and *Sodhan karma* to remove *Mala rupa dosha*. The

**According to Rasa**

majority of this *Kwatha's* compounds have *Ushna virya*, which balances the *Kapha* and *Vata doshas*.

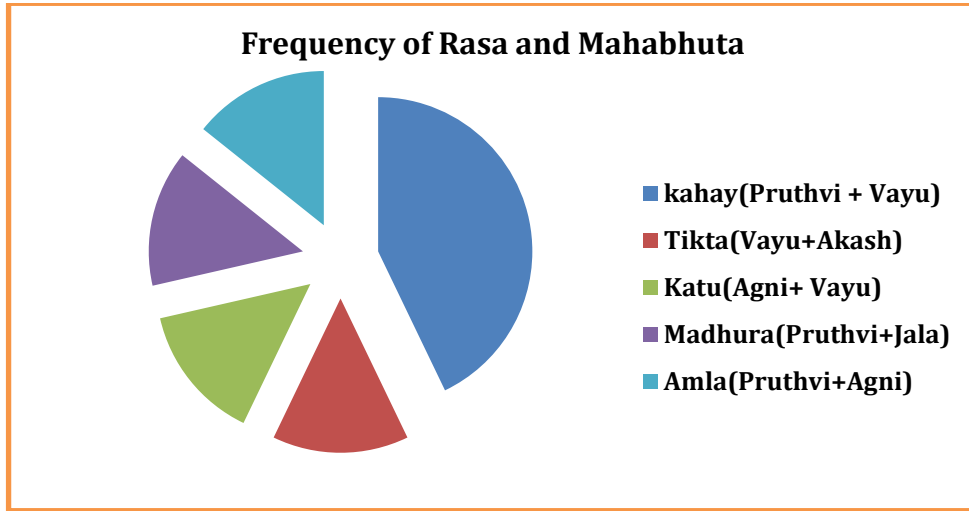
**According to the Dravyas**

*Katankateriyadi Kwatha* contain *Daruharidra, Yashtimadhu, Haritaki, Bibhitaki, Amalaki* and *Chitrak*. The primary pharmacological action of these herbs contribute to the disruption of the disease progression (*Samprapti vighatan*) through the following mechanisms:

- *Daruharidra- Dipana, Grahi, Kaphapittahara.*
- *Yastimadhu- Vatapittashamak, Dahashamak, Mutravirajaniya, Ojovardhak.*
- *Haritaki- Tridoshahara, Rasayan, Anulomak.*
- *Bibhitaki- Tridoshahara, Bhedak*
- *Amalaki- Pittashamak, Tridoshahara, Rasayan*
- *Chitrak- Dipan, Pachan, Lekhan, Bhedaan, Kledanashak*

**Table 20: Distribution of Rasa and its Mahabhut**

Rasa and Mahabhut	Frequency	Percentage
<i>Kahay (Pruthvi + Vayu)</i>	3	50.00%
<i>Tikta (Vayu + Akash)</i>	1	16.66%
<i>Katu (Agni + Vayu)</i>	1	16.66%
<i>Madhura (Pruthvi + Jala)</i>	1	16.66%
<i>Amla (Pruthvi + Agni)</i>	1	16.66%

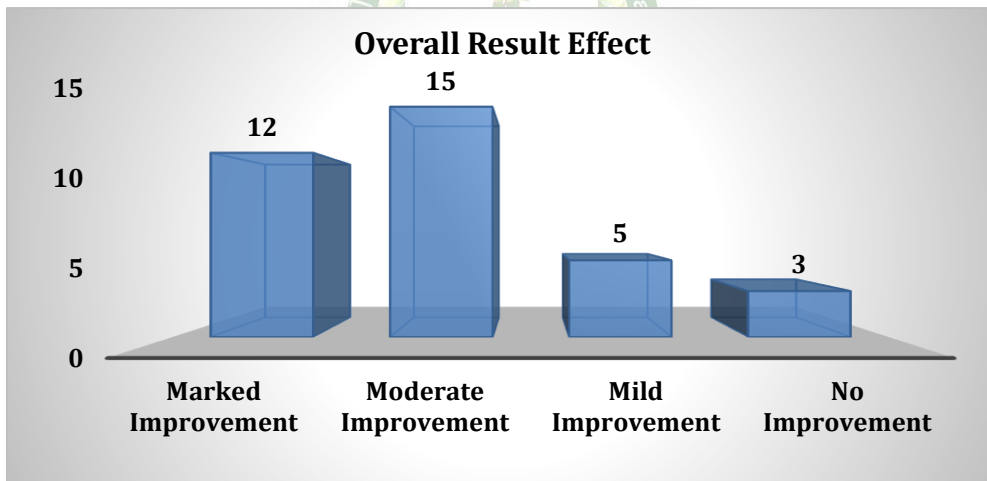


**RESULT**

**Result of treatment**

**Table 19: Overall Result Effect**

Overall Effect	Frequency	Percentage
Marked improvement	12	30.00%
Moderate improvement	15	37.50%
Mild improvement	5	12.50%
No improvement	3	7.50%
Total	40	100.00%



It observed that 12 subjects have marked improvement; 15 subjects have moderate improvement and 5 subjects have mild effect, 3 subjects have no improvement.

*Kashaya rasa* is *Shoshan* which helps in reducing excessive *Kleda* formed in the body. Hence, relieving the symptoms like *Prabhuta mutrata* and *Avil mutrata*. *Kashaya rasa* contains qualities such as *Sangrahi*, *Samshaman*, and *Stambhak*.

The main function of *Tikta rasa* is "*Kleda-medo-vasa-majja-lasika-puya-sweda-mootra-purish-pitta-shleshmo upshosana*" due to these properties it acts on *Dushya* of *Prameha*.

Action of *Katu rasa* increases the *Jatharagni* due to *Dipan* and *Ushna guna*. It reduces the *Mukha madhurya lakshana* due to *Mukha shudhi guna*. It decreases the *Strotorodha*. It also helps to reduce the *Dourbalya* of *Indriya*. *Mamsa*, *Kleda* and *Sweda-nashak*, *Mamsa vilekhan*, *Marganvivruti* these action of *Katu rasa* which helps to *Lakshanas samprapti bhang* the of *Madhueha*.

*Madhura rasa* of *Yashtimadhu* which helps *Vatashamak*, *Saptadhatuvaradhak*, *Ojovardhak*, *Trishnashamak* and *Dahashamak*.



## CONCLUSION

Hereby on the basis of data conclusion is:

1. Overweight, sedentary lifestyle, lack of physical exercise, unhealthy diet and family history are the factors contributory for the development of *Madhumeha*.
2. The study confirms that in the *Samprapti* of disease there is dominance of *Kapha dosha* and *Vata dosha*.
3. The maximum numbers of subjects observed in this study are between the age group of 40-65 years. So it can be concluded that incidence of *Madhumeha* is increasing in middle age.
4. There is no relation of religion for the causation of *Madhumeha*.
5. In entire study, it was observed that the subject with *Vishamagni* and *Vata kapha prakruti* is more prone to develop *Madhumeha*.
6. The overall cost of the treatment, availability of drugs and mode of administration is quite easy and effective.
7. Statistically the overall average efficacy rate of *Katankateriyadi Kwatha* from day 0 to day 90 is 64.10% due to which highly significant decrease observed in symptoms score value such as *Prabhut mutrata, Pipasa adhikya, Kara-pada daha, Kshudhadhikya, Dourbalya, Alasya* and *Atinidra*

after treatment of *Katankateriyadi Kwatha* on *Madhumeha* patients.

8. Statistically highly significant decrease ( $P < 0.05$ ) observed in BSL (F), BSL (PP) value after treatment of *Katankateriyadi Kwatha* on *Madhumeha* patients.
9. There is no any adverse effect of *Katankateriyadi Kwatha* in the management of *Madhumeha* on the general health of the patients.

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