



# A Comparative Clinical Study To Evaluate The Efficacy Of Vidangadi Loha And Nisha Amalaki Churna In The Management Of Madhumeha W.S.R.To Diabetes Mellitus Type-2

Dr Ganesh Vasant Rao Namade<sup>1</sup>, Dr Anand M Adi<sup>2</sup>,

<sup>1</sup> MD Scholar, Department of Kayachikitsa, Rajiv Gandhi Education Society's Ayurvedic Medical College, Hospital and Research Center for PG & PhD Studies, Ron, Karnataka, India

<sup>2</sup> Professor & HOD, PG Guide, Department of Kayachikitsa, Rajiv Gandhi Education Society's Ayurvedic Medical College, Hospital and Research Center for PG & PhD Studies, Ron, Karnataka, India

## ABSTRACT:

Madhumeha is one among the type of Vataja Prameha explained by Acharya Charaka. Madhumeha is a disease of Bastigata vikara. Nisha-Amalaki churna is mentioned in Ashtanga Hrudaya Chikitsa sthana and Vidangadi Loha is mentioned in Bhaisajya Ratnavali for Madhumeha. Thus, in the present study, two preparations Nisha-Amalaki churna and Vidangadi Loha are selected to evaluate their comparative efficacy on Madhumeha. The main objective of the present study was to compare the efficacy of Nisha Amalaki Churna and Vidangadi Loha in Madhumehi w.s.r to Type II Diabetes Mellitus. It was a comparative clinical study with pre and post-test design where in 40 patients of either sex diagnosed as Madhumeha w.s.r to type 2 Diabetes mellitus were selected and randomly assigned into two groups of 20 patients each. Group A were given Vidangadi Loha 250mg twice daily after food with Madhu for 90 days. Group B were given Nishaamalaki churna 1gm twice daily before food with Sukhoshnajala for 90 days. The statistical analysis after intervention showed statistically highly significant ( $p < 0.001$ ) Before Treatment to After Treatment and at after Follow up on all the parameters in both groups. On comparison, statistically there was no significant difference found between the two groups. However, the average improvement of group B 50.9% was slightly greater than group A 43.57%.

**Key words:** Diabetes Mellitus, Madhumeha, Nisha-Amalaki, Jambu Beeja churna

## INTRODUCTION:

Madhumeha is one of the Santarpanottha vyadhi<sup>1</sup> and Asta-Mahagada<sup>2</sup> which has been explained by Bruhatrayee and Laghutrayee. The nidana for madhumeha like asya-sukha, swapna-sukha, sedentary lifestyle, lack of physical exercise, obesity, stress improper diet habits etc. Diabetes mellitus is a clinical syndrome characterized by hyperglycemia due to absolute or relative deficiency of the insulin hormone<sup>3</sup>. The lack of the insulin affects the metabolism of carbohydrate, protein & fats can cause a significant disturbance of water & electrolyte homeostasis<sup>3</sup>. The classical signs and symptoms of diabetes mellitus are polydypsia, polyurea, polyphagia, lassitude, nocturia & rapid weight loss<sup>4</sup>.

According to the contemporary medical science the disease review is explained in all most all medicine books like Davidson's principles & practice of medicine<sup>3</sup>, Medicine for students A Reference book for the family physician<sup>4</sup>, Harrison's principles of internal medicine, & API textbook of medicine etc.

The formulation of Vidangadi Loha has been described in Bhaishajya Ratnavali<sup>5</sup> Prameha Chikitsa shloka no 191 and Rasendra Sara Sangraha<sup>6</sup> in Prameha Chikitsa shloka no 8 which contains vidanga, triphala, nagaramotha, pippali, sunthi, jeera & kalajeera all drugs are taken in 1 tola and loha 9 tola.

The formulation of Nisha Amalaki Churna has been described in Ashtanga hridaya<sup>7</sup> uttar sthana adhyaya no 40 Vajikaran Vidhi, sloka no 48 and in World Journal Of Pharmaceutical And Medical Research which is proved Standard drug for Madhumeha published by Dr.Prashant Beradkar Jamnagar Gujarat. [www.researchgate.net](http://www.researchgate.net)<sup>8</sup> wjpmr ,2017,3(9),101-105. based on all these, the present study was undertaken to compare the efficacy of Nishamalaki Churna and Vidangadi Loha in the management of Madhumeha.

## OBJECTIVES OF STUDY:

- ✓ To evaluate the efficacy of Vidangadi Loha in the management of Madhumeha.
- ✓ To evaluate the efficacy of Nisha Amalaki Churna in the management of Madhumeha.
- ✓ To compare the efficacy of Vidangadi Loha and Nisha Amalaki Churna in the management of Madhumeha.

## REVIEW OF LITERATURE:

The disease Madhumeha is explained under the types of prameha, its nidana, samprapti, lakshana, chikitsa are explained in Caraka Samhita Nidana Sthana & Chikitsa Sthana<sup>9</sup>, Susrutha Samhita Nidana Sthana & Chikitsa Sthana<sup>10</sup>, Ashtanga Hridaya Nidana Sthana & Chikitsa Sthana<sup>11</sup>,

Bhavaprakasha Madhya khandam<sup>12</sup>.

The formulation of Vidangadi Loha has been described in Bhaishajya Ratnavali<sup>13</sup> Prameha Chikitsa shloka no 191 and Rasendra Sara Sangraha<sup>14</sup> in Prameha Chikitsa shloka no 8 which contains vidanga, triphala, nagaramotha, pippali, sunthi, jeera & kalajeera all drugs are taken in 1 tola and loha 9 tola.

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## MATERIALS AND METHODS

**Study design:** A Simple comparative clinical Prospective study and sampling technique is purposive or deliberate.

**Sample size and grouping:** 40 patients suffering from Madhumeha were selected and divided into 2 groups, 20 patients in each group.

**Group A-** 20 patients were administered with Vidangadi Loha for 90 days

**Group B-** 20 patients were administered with Nisha amalaki Churna for 90 days

### Source of Data:

Patient suffering from Madhumeha were selected from Kayachikitsa O.P.D and I.P.D. of R.G.E.S.A.M.C & Hospital Ron after fulfilling the Inclusion and Exclusion criteria.

### Selection Criteria:

The cases were selected strictly as per the pre-set inclusion and exclusion criteria.

### Inclusion Criteria:

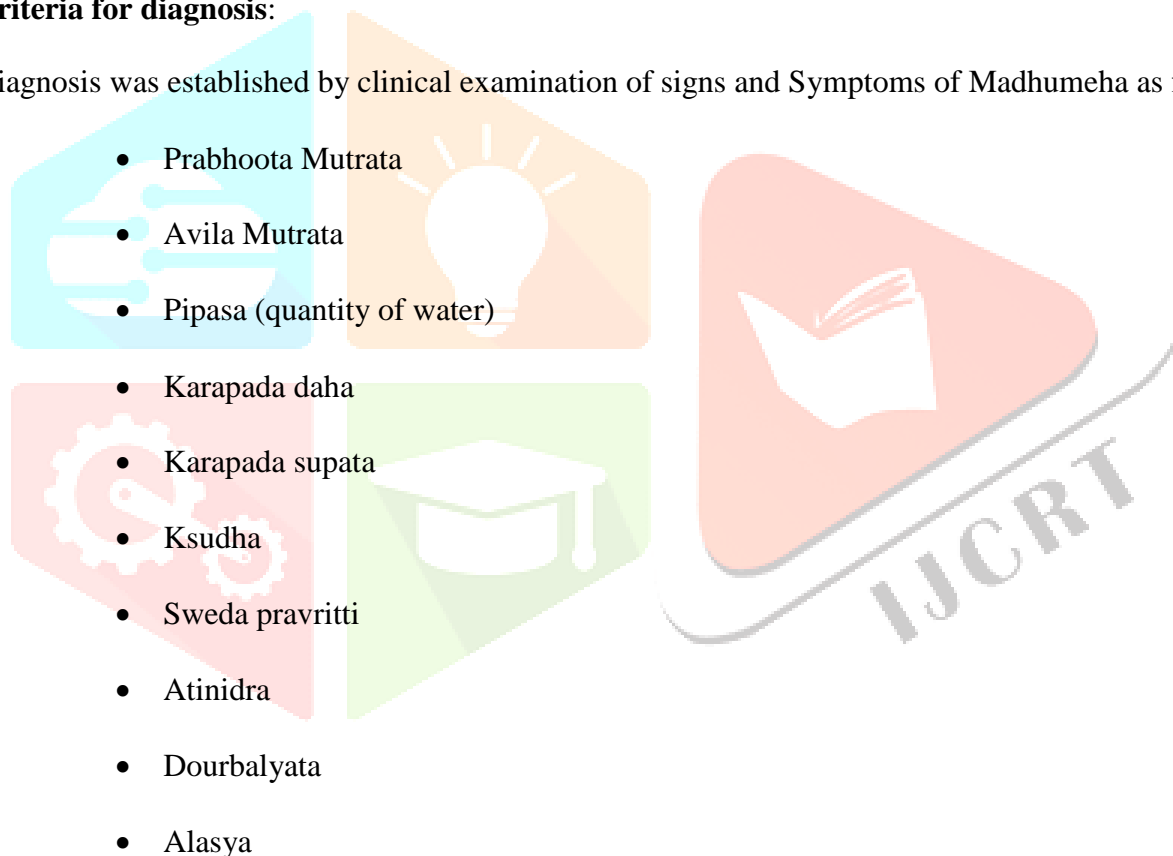
- Patients presented with classical signs & symptoms of Madhumeha.
- The patients suffering from Diabetes Mellitus less than 10 years.
- Age group between 30-60 years of both sex.
- Non Insulin Dependent Diabetes Mellitus.
- FBS above 130mg/dl & below 200mg/dl & PPBS above 180mg/dl & below 300mg/dl.

**Exclusion Criteria:**

- The Patients suffering from Diabetes Mellitus more than 10 years.
- Prameha Pidikas.
- Insulin Dependent Diabetes Mellitus.
- Pregnancy.
- FBS more than 200mg/dl & PPBS more than 300mg/dl.
- Any other severe systemic disorder such as cardiac disease, chronic renal failure, HIV, TB etc
- Patients on Corticosteroid therapy.

**Criteria for diagnosis:**

Diagnosis was established by clinical examination of signs and Symptoms of Madhumeha as follows:

**Investigations:**

- Blood Glucose -FBS & PPBS
- Urine Glucose - Fasting & Post Prandial
- HbA1C
- Renal profile – if necessary
- Lipid profile – if necessary

## INTERVENTIONS

- Group A

<b>Sample size</b>	20
<b>Drug</b>	<i>Vidangadi Loha</i>
<b>Dose</b>	250 mg twice daily after meal
<b>Anupana</b>	<i>Madhu</i>
<b>Duration of treatment</b>	90 days
<b>Follow up</b>	30 days

- Group B

<b>Sample size</b>	20
<b>Drug</b>	<i>Nisha amalaki churna</i>
<b>Dose</b>	1 gram twice daily before meal
<b>Anupana</b>	<i>Ushna jala</i> q.s. (if required)
<b>Duration of treatment</b>	90 days
<b>Follow up</b>	30 days

Assessment was done before treatment (BT), on 90<sup>th</sup> day (AT) and 120<sup>th</sup> (AF) day.

### ASSESSMENT OF THE RESULTS:

The subjective and objective parameters of base line data to post medication were compared for assessment of the results. All the result was analysed statistically for 'p' value using paired - t test and Anova

#### Subjective parameters:

1. Prabhoota Mutrata			
a) Quantity:		b) Frequency:	
1.5 to 2.5 lit/day	0	3-5times/day rarely at night	0
2.5 to 3 lit/day	1	5-7 times/day 1-2times at night	1
3 to 3.5 lit/day	2	7-10 times/day 3-4times at night	2
3.5 lit more than par day	3	<10 times/day <4times at night	3

2. Pipasa (quantity of water)		3. Karapada daha	
1.5 to 2.5 lit/day	0	No daha	0
2.5 to 3 lit/day	1	Karapadatala daha intermittent	1
3 to 3.5 lit/day	2	Karapadatala daha continuous but not severe	2
<3.5 lit/day	3	Karapadatala daha continuous but severe	3

4. Karapada suptata		5. Ksudha	
No suptata	0	Normal appetite	0
Karapadatala suptata intermittent	1	2 meals/day slightly increased	1
Karapadatala suptata continuous but not severe	2	2-3 meals/day moderately increased	2
Karapadatala suptata continuous but severe	3	4-5 meals/day markedly increased	3

6. Sweda pravritti		7. Atinidra	
Only after strenuous work	0	6-7 hrs satisfactory	0
After doing normal work	1	7-9 hrs satisfactory	1
Just after walking little distance	2	9-10 hrs satisfactory	2
On rest also	3	> 10 hrs & always feeling sleepy	3

8. Dourbalyata		9. Alasya	
Can do routine exercise/work	0	No alasya	0
Can do mild exercise with difficulty	1	Doing satisfactory work/late initiation	1
Can do moderate exercise with difficulty	2	Doing unsatisfactory work/late initiation	2
Can not do mild exercise also	3	Do not want to work/no initiation	3

10. Avila mutrata	
Crystal clear urine	0
Faintly cloudy or smoky slight turbidity	1
Turbidity clearly present(news print easily read through tube)	2
Turbidity more, news print not easily read	3

Turbidity more news print can not read	4
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**Objective parameters**

1.Fasting blood glucose (FBS)		2. Post prandial blood glucose (PPBS)	
90 – 130 mg/dl	0	140 - 180 mg/dl	0
131 – 150 mg/dl	1	181 – 220 mg/dl	1
151 – 170 mg/dl	2	221 -260 mg/dl	2
171 – 200 mg/dl	3	261 -300 mg/dl	3

3. Urine Glucose FUS & PPUS (Mutramadhuryata)	
Blue ppt	0
Green ppt.	1
Yellow ppt.	2
Orange ppt.	3
Brick red ppt.	4

**Assessment of Response to Treatment:**

For subjective analysis gradation of cardinal symptoms are the Parameters. Every patient was observed **BT**-before treatment(Day 1), **AT**-After Treatment (90th day), and **AF**-After follow up(120th day) for clinical response.

**RESULTS:**

**Comparison Between Group A and Group B**

PARAMETER	GROUP	Mean	% of Improv	T-Value	P-Value	Remarks
Prabhoota Mutrata	A	0.8	35.5	1.14	>0.05	NS
	B	0.95	40.4			
Pipasa (quantity of water)	A	0.8	45.71	1.16	>0.05	NS
	B	1	45.94			
Karapada daha	A	0.65	44.82	1.92	>0.05	NS
	B	1	52.63			
Karapada suptata	A	0.9	54.5	2.04	>0.05	NS
	B	1.2	52.17			
Ksudha	A	0.95	45.23	0.71	>0.05	NS
	B	1.1	50			

Sweda pravritti	A	0.35	29.6	2.10	>0.05	NS
	B	0.7	53.84			
Atinidra	A	0.9	48.64	0.90	>0.05	NS
	B	1.05	60			
Dourbalyata	A	0.9	42.85	1.67	>0.05	NS
	B	1.2	52.17			
Alasya	A	0.8	45.71	1.16	>0.05	NS
	B	1	45.94			
Avila mutrata	A	0.65	44.82	1.92	>0.05	NS
	B	1	52.63			
Fasting blood glucose (FBS)	A	0.9	54.5	2.04	>0.05	NS
	B	1.2	52.17			
Post prandial blood glucose (PPBS)	A	0.95	45.23	0.71	>0.05	NS
	B	1.1	50			
Urine Glucose FUS & PPUS (Mutramadhurya ta)	A	0.35	29.6	2.10	<0.05	S--
	B	0.7	53.84			

For comparison between Group A and Group B, Un paired t test is used. From above table we can observe that P-Values for all parameters are more than 0.05. Hence we conclude that statistically there is no significant difference between Group A and Group B in the management of Madhumeha.

Further we can observe that Average percentage of improvement of Group B is 50.90% which is greater than Average percentage of improvement of Group A- 43.59%. Hence we conclude that effect observed in Group B is more than Group A.

## DISCUSSION:

### • Probable Mode of Action (VIDANGADI LOHA)

The probable action on *Samprapti Ghataka* can understand from the properties of “*Vidangadi Loha*” as follows:

#### *Dosha*

In *Vidangadi Loha* 50% of drugs having ‘*Vata-Kaphahara Property*’ and remaining has *Tridoshhara* and *Pitta-Kaphahara*. So it can be used for *Madhumeha*. It has *Anulomaka* property to eliminate the vitiated *Dosha*.



### *Dushya*

Majority of drugs of *Vidangadi Loha* have *Katu Rasa, Laghu, Ruksha, Tikshna, Ushna Guna* which have *Deepan Pachana* property. They normalize the *Jathragni* and *Dhatvagni* and *Dhatu Nirmana* process gets toned up which results in to *Dhatu Pushti*.

### *Agni and Ama*

*Shadaushna*, contain of *Vidangadi Loha* have *Amapachna* and *Agni Deepana* property which diminishes *Mandagni* and breaks the pathogenesis of *Madhumeha Roga*.

### ❖ Srotasa

*Srotoshodhaka* property of maximum *Dravya* in *Vidangadi Loha* due to presence of *Katu, Tikta Rasa, Laghu, Ruksha, Tikshna, Ushna Guna* as a result it is able to clear the *Srotasa*. Also “*Vidangadi Loha*” has well known *Rasayana* drugs like *Triphala, Vidanga, Pippali* and *Loha bhasma*. *Dhatu* gets adequate nourishment with the help of *Rasayana* drugs and thereby *Dhatu* get increased.

Content of *Triphala, Amalaki* is well known drug for *Madhumeha*.

*Trikatu* is a well-known *Amapachaka*. So it is useful in *Amadosha*. Moreover *Yakrututtejaka* property of *Pippali* and *Maricha* improves liver function.

*Loha Bhasma* improves iron deficiency as well as the quality of blood. Thus from the ingredients described above it can be stated that all the *Dravya* used in “*Vidangadi Loha*” are effective on overall the conditions described in pathogenesis of *Madhumeha*.

Hence, it can be concluded that ‘*Vidangadi Loha*’ can be considered as very useful and a wonder drug in the treatment of *Madhumeha*.

### • Probable Mode of Action ( NISHA AMALAKI CHURNA):

#### Dosha:

Nisha-Amalaki Churna encounters vata & kapha dosha by virtue of its katurasa dominance & Ushna virya .Vata hara action is also achieved by Guru property and due to madhura vipaka vata-pitta shaman action has been appreciated.

**Dushya:**

Meda & kleda are the chief culprits in Apatyanumuthaja Madhumeha. Katu rasa performs medokledopa shoshana action. Madhura vipaka ensues sarvadhata vivardhan action. Sthairya guna of madhura rasa combats sharir shaithilya .Ushna virya also helps in kleda and meda vilayana action.

**Agni & Ama:**

Katu rasa and Ushna virya encounters dhatwagnimandya & potentiates the weakened dhatwagni. Madhura vipaka helps in alleviating agnivaishmya by samana vayu niyantrana. Katu rasa & Ushna virya helps in amapachana thereby alleviates aparipakwa and ama dhatu.

**Srotas:**

Due to katu rasa, all the involved channels are dilated i.e. 'Srotansi Vivrunoti action'.Katu rasa and ushna virya check over medovaha and mamsavaha srotodushti. Haridra with its mutrasangrahani does basti vishodhana by cleansing the basti ,thereby alleviates mutravaha srotodushti.

**Rupa :**

Since prabhutavila mutrata is the predominant symptom of the aforesaid ailment, Madhura & tikta rasa combats dominant symptom of this disease i.e. prabhutavila mutrata. Madhura vipaka performs rasadi dhatu vardhana and thereby encounters the ojas kshaya and daurbalya .

**CONCLUSION:**

- Vidangadi Loha is effective in the management of Madhumeha.
- Nisha Amalaki churna is effective in the management of Madhumeha.
- On comparison, statistically there is no significant difference found in the effect of Vidangadi Loha and Nisha Amalaki Churna on Madhumeha. However, Group B with Nisha Amalaki Churna is more effective having 50.9% overall improvement as compared to Group A with Vidangadi Loha having 43.57% overall improvement.

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