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Comparative Clinical Study to Evaluate the Effect of *Nishakatakadi Kashaya* and *Nishamlaki Kashaya* in Madhumeha W.S.R Type 2 Diabetes Mellitus

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Abstract: ***Diabetes is a disease known to mankind since long and diabetes known as silent killer needs be take prevention as early as possible to stop onset of complications. Diabetes mellitus is the leading case of morbidity and mortality the world over and now India is a "Diabetes Capital of the world". It is estimated that approximately 1% of the population suffers from DM. The incidence is rising in developed countries of the world at the rate of about 10% per year, especially of type-2 DM, due to rising incidents of obesity and reduced activity levels. Madhumeha is one of the types of vataja Prameha in Ayurveda, its etiopathogenesis, clinical symptoms, and prognosis are similar to Diabetes mellitus. Madhumeha is caused by lack of exercise, excessive consumption of food containing Snigdha, and Guru Guna, bad dietary habits, and food that induces Kapha Dosha vitiation. In Ayurveda several plant based drugs have been advocated to manage hyperglycemia. The are many plants showing potential anti-diabetic properties, but in this study used Ingredients of Nishakatakadi Kashaya and Nishamlaki Kashaya are having majorly Laghu, Tikshna guna, Katu rasa and Ushna Veerya and are Kapha-Vata shamaka. They act as Mootrala and has Rasayana Property.***

Keywords: Type-2 Diabetes, Madhumeha, Prameha, Vataja Prameha, kashaya

1. Introduction

In present era people are busy in their lifestyle. The Sedentary life style, lack of exercise, faulty food habits and improper medication and urbanization precipitate the disease. Diabetes mellitus is a common chronic metabolic disorder prevalent all over the world. At least 171 million people worldwide have diabetes, this figure is likely to be more than double by 2030. Around 3.2 million deaths every year are attributable to complication of diabetes, six death every minute. The top 10 countries, in numbers of sufferers are, India, China, USA, Indonesia, Japan, Pakistan, Russia, Brazil, Italy and Bangladesh. According to statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation in the world. Current estimation in the country is about 62 million-an increase of over 10 million from 2011 when estimates suggested that about 50.8 million people in the country were suffering from the disease. By the year 2030, over 100 million people in India are likely to suffer from diabetes[1].

Ayurveda has described that it is not rational treatment where medicine modifies one disease, on the other hand it provokes new complains. So, effort has been made here to search the safe and effective medicine, without any side effects. The ancient *Ayurvedic* classics texts namely the *Samhita's of Charak*, S*ushruta* and *Vagbhata* and the subsequent treatises have invariably given detailed description of the disease diabetes, its causes, types, pathology and the line of management and treatment both preventive and curative.[2]

In *Charak Prameha Nidana* & *Chikitsa and Susruta Prameha Nidana*, *krodha* (anger) is among one of the etiological factors in *paittika prameha* and shoka (grif), *bhaya* (fear), *udvega* (anxiety) and *chinta* (worry) for the *vatika prameha* (*madhumeha* is among *vatika prameha*)[3] which leads to derailment of glucose metabolism According to *Sushruta Ajiranadhikar* and *Charak Trividhakushiya Vimana*, disturbed state of psyche (manas) is not able to digest the food even if taken in normal quantity and leads to formation of *Ama*. The above description is related with the gastric digestion, but it is said that the jataraagni only nourishes the dhatavagni and bhootugni. So the disturbed psychological state also disturbs the dhatavagni and bhootugni. In anxiety and stress prone individuals the samprapti starts from the vitiation of *agni* leading to amotpatti and that *ama* when settles in Basti leads to *Prameha* as mentioned in *Grahani* roga.

The disease is classified as *Santarpana Nimittaja* and *Apatarpana Nimittaja*[4], *Sahaja* and *apathya Nimittaja*, *Krisha and sthool*, *Shuddha vata* and *avrit vata*, *Durbal* and *Balwan*a. Presently the disease is classified as Primary i.e. (1) Autoimmune (type) 1) diabetes mellitus (1) Non- insulin dependent diabetes mellitus (type I NIDDM transient), (ii) Insulin dependent diabetes mellitus (type 1 IDDM) and (2) Non- autoimmune (type 2) diabetes mellitus (1) Insulin dependent diabetes mellitus (type 2 IDDM transient), (ii) Non- insulin dependent diabetes mellitus (type 2 NIDDM) and Maturity onset diabetes of young, Secondary diabetes may be due to pancreatic disease, hormonal abnormalities, Drug and chemical induced diabetes, insulin receptors abnormalities, associated with genetic syndrome.

Diabetes mellitus can very well be taken care of by ayurvedic drug without any hazardous side effects. *Madhumeha* (diabetes mellitus) is among the 20 sub type. of *Prameha* and is predominantly a vatika disease[5]. It is believed that Diabetes

mellitus occurs when insulin is not able to metabolize glucose (derailment of glucose metabolism). Here *Ayurveda* believes that it occurs mainly due to *Medo dusti*. This *Medo dusti vitiate Mansa, Rakta, Kleda and Ojas*. All the *dhatus* and *malas* & all three *doshas* are involved in the disease procedure. In sutra 17, charak says that the disease leads due to o*jodus*ti also (when a person eats a rich diet with lack of exercise, it leads to vitiation of *Ojas*, which avrits the *Mutravaha srotas*. precipitating *to Prameha*).[6]The management of *Madhumeha* is described in classical texts according to the peculiarities *of Dosha and Dushya* etc[7]. Currently, a number of anti-diabetic agents are available to control hyperglycaemia but due to long term or lifelong applications, their use is restricted because of the risk profile. Therefore, there is a need of satisfactory therapeutic modalities free from side effects.

Objectives of the Study

- To evaluate the therapeutic efficacy of *Nishakatakadi Kashaya* in *Madhumeha.*
- To evaluate the therapeutic efficacy of *Nishamlaki Kashaya* in *Madhumeha.*
- To evaluate the comparative efficacy of *Nishakatakadi Kashaya* and *Nishamlaki Kashaya* in *Madhumeha*.

2. Materials and Methods

a) Literary source

Literary aspects of the study was be collected from Ayurveda classical text books and modern text book, medical publication and internet.

b) Sample source

Patients who fulfills the inclusion criteria was randomly selected from OPD& IPD of Karnataka Ayurveda Medical collage & Hospital Mangalore and from various special medical camps conducted after fulfilling the inclusion and exclusion criteria.

c) Pharmaceutical source

The raw drugs for Kashaya preparation was be collected from GMP Certified Pharmacy and kashya churna prepared in Rashashatra department of Karnataka Ayurvedic Medical College Mangalore.

d) Method of collection of data

The subjects suffering from Madhumeha is screened under strict diagnostic inclusion and exclusion criteria and selected for the study. Eligible subjects then is invented to participate in the study after signing a detailed informed consent and then registered for this clinical trail. Thus registered participants is treated with the medication as per the plan of intervention. The outcome measures is assessed at baseline by comparing the efficacy of Nishakatakadi kashaya and Nishamalaki kashaya in Madhumeha.

Inclusion Criteria:

1) Patients representing signs and symptoms of Madhumeha
2) Patients age group between 18 to 60 years.
3) Patients with
   - FBS 110 mg/dl to 200 mg/dl
   - PPBS 160mg/dl to 300 mg/dl
4) Patients willing to participate in the study will be selected explaining them details about study.

Exclusion Criteria:

1) Patients belonging to below 18 and above 60 years**.**
2) Patients of Insulin Dependent Diabetes Mellitus.
3) Patients presenting with complications like severe renal disease, retinopathy, and ischemic heart disease.
4) Patients associated with other systematic diseases.
5) Juvenile diabetes
6) Any other patient considered not fit for trial.

Diagnostic Criteria:

1) Patients will be diagnosed as per clinical features of *Madhumeha* explained in classics.
   - FBS 110 mg/dl to 200 mg/dl
   - PPBS 160mg/dl to 300 mg/dl

Intervation:

60 Patients of *Madhumeha* was selected and randomly assigned into two equal groups, as Group -A and Group – B

Group A: 30 patients was treated with *Nishakatakadi Kashaya* 96ml (2 Pala) daily in two equal divided doses i.e. morning and evening before food with Luke warm Water was be given for 30 days

Group B: 30 patients was treated with *Nishamalaki Kashaya* 96ml (2 Pala) daily in two equal divided doses i.e. morning and evening before food with Luke warm Water was be given for 30 days.

Study Duration:

Treatment	-	30 days
Follow up	-	15 days
Total duration	-	45 days

Patient will be assessed clinically on 0th,15th, 30th ,45th day. FBS & PPBS will be assessed on 0th,15th, and 45th day.

Scoring Pattern of Subjective Criteria

Subjective Symptoms	Grade	B.T	A.T	A.F

1) Prabhuta Mutrata (Polyuria)

Quantity of urine

• 1.50 to 2.00 liters / 24 hrs.	**0**				
• >2.00 to 2.50 liters / 24 hrs.	**1**				
• >2.50 to 3.00 liters / 24 hrs.	**2**				
• >3.00 liters/24 hrs.	**3**				

Frequency of urine

• 3-5 times per day, no or rarely at night	**0**				
• 6-8 times per day, 1-2 times per night.	**1**				
• 9-11 times per day, 3-4 times per night	**2**				
• >11 time per day >4 times per night	**3**				

2) AVILA MUTRATA

• Crystal clear fluid	**0**			
• Faintly cloudy or hazy with slight turbidity.	**1**			
• Turbidity clearly present and newsprint easily read through test 2 tube	**2**			
• Newsprint not easily read through test tube	**3**			
• Newsprint cannot be visualized through test tube	**4**			

3) Dourbalya

• Can do routine exercise/work	**0**			
• Can do moderate exercise with hesitancy	**1**			
• Can do mild exercise only, with difficulty	**2**			
• Cannot do mild exercise too	**3**			

4) Atisweda

• Sweating after some strenuous or heavy work or in hot & humid weather	**0**			
• Profuse sweating after moderate work and movement	**1**			
• Sweating after little extra work than routine and movement	**2**			
• Profuse sweating after routine work	**3**			
• Sweating even at rest or in cold climate	**4**			

5) Pipasa (Polydipsia)

• Feeling of thirst 7-9 times/24 hours, either/or Intake of water 5-7 times/24 hours with quantity 1.5-2.0 liter/24 hours	**0**			
• Feeling of thirst 911 times/24 hours, either/or Intake of water 7-9 times/24 hours with quantity 2.0-2.50 liter/24 hours	**1**			
• Feeling of thirst 11 13 times/24 hours, either/or Intake of water 911 times/24 hours with quantity 2.50 -3.00 liter/24 hours	**2**			

6) Kshudha adika (Appetite)

• As usual/routine	**0**			
• Slightly increased (1-2 meals)	**1**			
• Moderately increased (3-4 meals)	**2**			
• Markedly increased (5-6 meals)	**3**			

Objective parameters:

Objective parameters	B.T	A.T (30^{th} day)	A.F (45^{th} day)
FBS			
PPBS			
URINE SUGAR			

Ingredients of Nishakatakadi kashaya [8]

Drugs	Botanical name	Proportion
Haridra	Curcuma longa	1 part
Kataka	Strychons potatorum	1 part
Pranati mula	Ixora coccinea	1 part
Amalaki	Emblica officinalis	1 part
Lodhra	Symplocos recemosa	1 part
Bhadarika	Zizipush sativa	1 part
Meharimula	Salacia reticulate	1 part
Usira	Vetiveria zizanioides	1 part

Ingredients of Nishamalaki kashaya [9]

Drugs	Botanical name	Proportion
Haridra	Curcuma longa	1 part
Amalaki	Emblica officinalis	1 part

Statistical Analysis

For assessing the improvements of symptomatic relief and to analyse Stastiscally the observation was recorded before and after the treatment. The mean percentage S.D, S.E and t-value was calculated from the observation recorded .the data obtained was be analysed statistically with unpaired t test.

3. Observation and Results

The Observation that were made in these patients will be explained in detail under the fallowing heading.

- Observation in personal history
- Observation in dashavidha pariksha
- Observation in disease history

Observation	Group A	Group B	Total
AGE			
20 - 40	09	07	16 (26.6%)
40 - 60	21	23	44 (73.3%)
Sex			
Male	13	18	31 (51.6%)
Female	17	12	29 (48.3%)
Religion			
Hindu	27	25	52(86%)
Muslim	03	04	07(11.6%)
Christians	00	01	01(1.6%)
Socio Economic			
Lower	03	04	07(11.6%)
Middle	04	19	43(71.6%)
Upper	03	07	10(16.6%)
Occupation			
Working Person	14	17	31(51.6%)
Housewife	16	13	29(48.3%)
Diet			
Veg	08	09	17(28.3%)
Non-Veg	22	21	43(71.6%)
Marital Status			
Married	29	28	57(97.3%)
Unmarried	01	02	03(3.6%)
Nidra			
Good	20	18	38(63.3%)
Disturbed	10	12	22(36.6%)
Bowel Habit			
Regular	23	22	45 (75%)
Irregular	03	03	06(10%)
Constipated	04	05	09(15%)

3.1 Result

Symptoms	Group A Mean Score	Group A t value	Group A P value	Group B Mean Score	Group B Mean Score	Group B T Value
PRABHUTA MUTRATA	BT: 0.30 AT: 0.07 AF: 0.03	AT: 2.16 AF: 2.58	<0.05 <0.05	BT: 0.53 AT: 0.27 AF: 0.10	AT: 2.15 AF: 4.01	<0.05 <0.05
AVILA MUTRATA	BT: 0.13 AT: 0.03 AF: 0.00	AT: 1.40 AF: 2.11	<0.05 <0.05	BT: 0.27 AT: 0.10 AF: 0.10	AT: 1.51 AF: 1.51	>0.05 >0.05
DOURBALYA	BT: 0.70 AT: 0.40 AF: 0.37	AT: 1.75 AF: 1.96	<0.05 <0.05	BT: 0.70 AT: 0.53 AF: 0.43	AT: 1.22 AF: 1.92	>0.05 <0.05
ATISWEDA	BT: 0.90 AT: 0.27 AF: 0.20	AT: 4.34 AF: 4.94	<0.05 <0.05	BT: 0.60 AT: 0.20 AF: 0.13	AT: 2.78 AF:3.59	>0.05 <0.05
KSHUDA ADIKA	BT: 0.83 AT: 0.20 AF: 0.10	AT: 4.29 AF: 5.27	<0.05 <0.05	BT: 0.73 AT: 0.10 AF: 0.03	AT: 5.75 AF: 6.95	<0.05 <0.05
FBS	BT: 135.43 AT: 104.37 AF: 108.47	AT: 6.74 AF: 5.91	<0.05 <0.05	BT: 139.70 AT: 111.37 AF: 117.17	AT: 8.18 AF: 6.12	<0.05 <0.05
PPBS	BT: 227.7 AT:181.37 AF:191.13	AT: 7.13 AF: 5.49	<0.05 <0.05	BT: 245.33 AT: 203.53 AF: 212.60	AT: 4.44 AF: 3.48	<0.05 <0.05
URINE SUGAR	BT: 0.23 AT: 0.00 AF: 0.05	AT: 2.35 AF: 1.62	<0.05 <0.05	BT: 0.10 AT: 0.02 AF: 0.16	AT: 1.20 AF :0.59	>0.05 >0.05

Overall effect of *Nishakatakadi Kashaya* Group-A

Result on Group- A

EFFECT OF TREATMENT IN GROUP – A		
Class	Grading	No of patients
0-25%	Minimal	1
26%-50%	Mild	4
51% - 75%	Moderate	9
76% - 99%	Marked	1
100%	Complete Remission	15

Effects of *Nishamalaki kashaya*

Overall effect of Group-B

Effect of Treatment in Group – B		
Class	Grading	No of patients
0-25%	Minimal	1
26%-50%	Mild	5
51% - 75%	Moderate	14
76% - 99%	Marked	3
100%	Complete Remission	7

Table 56: Comparative results of Group-A and Group-B

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	SD	SE	T Value	P Value
Prabhuta Mutrata	0.13	0.30	0.501	0.093	2.05	<0.05
Avila Mutrata	0.06	0.16	0.368	0.068	1.53	>0.05
Dourbalya	0.51	0.55	0.815	0.151	0.57	<0.05
Atisweda	0.44	0.32	0.572	0.106	1.37	>0.05
Pipasa	0.28	0.41	0.413	0.077	2.01	<0.05
Kshudha Adika	0.37	0.30	0.402	0.075	1.02	>0.05
FBS	116.31	122.53	17.541	3.257	2.05	<0.05
PPBS	199.67	221.14	41.937	7.787	2.81	<0.05
Urine Sugar	0.10	0.09	0.331	0.061	0.04	>0.05

Overall result of group A and Group B

Group A	Group B	Mean Difference	SE (±)	T value	P value
79.26	64.72	15.04	11.61	1.35	<0.09

4. Discussion

Discussion on Effect of Trial Drugs:

In present research work the effect of *Nishakatakadi kashaya* and *Nishamalaki kashaya* for 45 days in *Madhumeha* patients

was studied after 45 days of treatment with regular fallow up, it was observed that Fasting blood sugar and post prandial blood sugar & urine sugar levels in diabetes type -2 patients were significantly decreased. *Nishakatakadi kashaya* - It contains *Haridra, Kataka, Pranati mula, Amalaki Lodhra, Bhadarika, Meharimula, and Usira.* Drugs has tikta kashaya rasa in dominance and have *Laghu, Ruksha and Tikshna guna*. Drugs have ushna Veerya. They have *vata kapha shamaka, pitta shamaka, Mutrata, Rasayana* properties.

This data suggests that *Nishakatakadi kashaya* is a potent herbal antidiabetic.it control blood sugar levels. Normalizes symptoms and provides good health.*Nishakatakadi kashaya* thus can be considered as supplementary therapy for effective treatment of various complications of Madhumeha (type-2 diabetes mellitus).

Discussion on Result

Over all comparison of effect of the therapy in 60 patients of *Madhumeha*

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired t test. The test shows that the treatment is significant in Group A when compared to Group B. Group A overall result is 76.26% and Group B overall result is 64.72%.

5. Conclusion

Conclusion is the outcome of clinical research work carried out .the same has been depicted as under:

1) Regarding comparison of *Prameha* with disease of modern medicine two different views are observed. the most commonly practiced view is that 20 types of *Prameha* are different form of urinary / metabolic disorders, out of these *Madhumeha* is compared with diabetes mellitus
2) *Madhumeha* is rapidly progressive in India and its incidence is increasing every year.
3) Early manifestation of diabetes occurs in *Anupa Desha*. It may be due to *Anupa Desha* is a favorable condition for diabetes mellitus.
4) Most of the diabetes founds from middle age i.e. 40-60yrs.
5) Male were more prone to diabetes than female
6) Most of the diabetic male patients were from business, service class, Teachers and female patients were housewives indulge sedentary life style.
7) Analyzing the socio economical status of diabetes patients the incidence was higher in middle class & upper middle class having sedentary life style.
8) The people of vata-Kaphaja Prakriti are more prone to suffer from Madhumeha.
9) The majority of the patients were having positive family history of diabetes.
10) Meda Sara and mamsa Sara individuals are more prone to suffer from this disease.
11) The data reflects that defective diet and lifestyle including stress & obesity play an important role in Aetiopathogenesis of *Madhumeha*, hence avoidances of such dietary factors, sedentary life style & stress can contribute significantly for prevention of disease as well as promotion of health.
12) Most common Upadrava of *Madhumeha* was Neuropathy, Daha, & Padadaha.
13) *Nishakatakadi kashaya* is effective in the management of all symptomatic parameter of *Madhumeha.*

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