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Research Article

A CLINICAL STUDY EVALUATING THE EFFICACY OF NISHA KATAKADI KASHAYA IN MADHUMEHA (DIABETES MELLITUS)

Shrilatha kamath¹*, U. N. Prasad²

¹Associate Professor, PG Department of Kayachikitsa, S. D. M. College of Ayurveda, Udupi, Karnataka, India ²Principal and Professor, PG Department of Kayachikitsa, S. D. M. College of Ayurveda, Udupi, Karnataka, India

	ABSTRACT
*Correspondence	The objective of the study is to have a conceptual review of the disease madhumeha and its treatment, in
Dr. Shrilatha kamath	particular to the use of shamana chikitsa using nisha katakadi kashaya in the disease madhumeha.
Associate Professor, PG Department of	Diabetes (Madhumeha) is one of the types of Vataja Prameha; that has been considered as an incurable
Kayachikitsa, S. D. M. College of Ayurveda,	disease (Mahagada). Due to the indulgence in etiological factors it results in the incomplete formation of
, , , , , , , , , , , , , , , , , , ,	kapha and meda which further proceeds downward through the channels of Mutravaha Srotas and get
Udupi, Karnataka, India	localized at Basti Mukha leading to the symptoms like polyuria (prabhoota mutrata), turbidity (avila
	mutrata). As the disease is chirakari, it requires an effective treatment which can be continued for a long
	time without any ill effects. Among the many treatment measures mentioned, Shamana using nisha
DOI: 10.7897/2321-6328.02241	katakadi kashaya has been selected in this study and the effect is evaluated. This clinical study has a
	single group pretest and post test design where the patients were assessed before, during and after the
	treatment. Therapeutic effect of the treatment was observed using the subjective and the objective
	criteria's which were graded and analyzed statistically using the paired't' test. The study showed a
	marked remission of the symptoms of madhumeha and in the urine and blood sugar levels in almost all
Article Received on: 07/03/14	patients in this study. The response by the treatment was statistically significant in terms of all the
Accepted on: 09/04/14	parameters of the disease. Thus the usage of nisha katakadi kashaya is proved to be useful in the
	condition madhumeha.
	Keywords: Madhumeha, Nisha katakadi kashaya, Diabetes Mellitus.

INTRODUCTION

Madhumeha identified as mahagada is a malady troubling the the mankind since ancient age till today and evidence is increasing day by day with their complications¹. Diabetes mellitus is similar to Madhumeha which is one among the Vataja Prameha. In which the patient voids excessive quantity of urine having Madhura rasa, Rooksha Sparsha and Kashaya Varna. Diabetes Mellitus is a metabolic disorder in which carbohydrate utilization is reduced and that of lipid and protein enhanced; it is caused by deficiency of insulin and is characterized by Hyperglycemia². The mortality rate due to Diabetes mellitus is high and is ranked fifth amongst the ten major causes of death in southern part of India. The rising prevalence of diabetes is associated with industrialization and socio-economic development. The prevalence of Diabetes in adults globally is estimated to be 150 million and this Figure is expected to double by 2025^3 . Although the prevalence of Type I and Type II D. M. is increasing worldwide, the prevalence of Type II D. M. is expected to increase more rapidly in future because of increasing obesity and reduced physical activity. The WHO estimates that 75 percent of the 300 million adults with diabetes in 2025 will live in developing countries. Over 20 million people are reported to be suffering from this Sweet Disease⁴. Nisha Katakadi Kashaya⁵ is explained in Sahasra

yoga as one of the remedy for Madhumeha as these drugs are available in plenty, in all the seasons, easy to prepare and cost effective. All the eight drugs of this formulation have the property of mitigating Kapha and as Madhumeha is a Kapha dominated disease this medicine will be useful in this disease. So, to get a better management in patients of Madhumeha by palliative management (Samshamana Chikitsa), this clinical study is planned. Observing the different nidana quoted for the disease prameha and madhumeha in specific, it is seen that most of the nidanas like adhyasana, guru snigdha madhura ahara, Dadhi, anoopa, audaka, gramya mamsa⁶ etc have been referred which are kapha meda vardaka which are responsible for the production of Avarana type of Madhumeha. This type of madhumeha is considered the Apathyanimithaja variety. Few nidanas like katu, tikta, kashaya rasa, laghu ruksha ahara, ativyayama, vegadharana, sodhana atiyoga⁷ etc are Vata vardhaka nidana producing Dadhukshayaja Madhumeha. According to Sushruta, the excessive indulgence in the etiological factors related to Prameha results in Aparipakva Vata, Pitta, Kapha and vitiates meda as meda and kapha have similar properties. Meda, further proceed downward through the Mutravaha Srotas to get localized at Basti Mukha and thus leading to disease Prameha. Excessive kleda dushti leads to ati mutra pravritti and further mamsa gets vitiated and ends up in mamsa pidaka

utpatti⁸. Sushruta also asserted that, if all the Pramehas are treated improperly or ignored terminates into Madhumeha. The clinical differentiation of the types is essential as prognosis as well as treatment differs in the different types of Prameha. Depending upon the physical strength it is again classified in to Sthoola Pramehi and Krusha Pramehi⁹. Based upon the etiological factors, it is classified into Sahaja and Apathya Nimittaja¹⁰. According to the pathogenesis, it is classified into Dhatukshayaja and Avaranaja variety. Most of the patients of Avaranaja variety are Apathyanimittaja and Sthoola pramehi. The Diabetes mellitus has been broadly classified as type 1 and type 2. The type 1 Diabetes mellitus patients are usually asthenic in body constitution and suffer from it in the early years of life, while the type 2 Diabetes mellitus patients are obese and suffer from their age of 40 years. The type 2 Diabetes mellitus patients can be managed easily by hypoglycemic drugs whereas in type 1 Diabetes mellitus patients besides hypoglycemic drugs, the Insulin therapy is needed¹¹. So, the type 1 Diabetes mellitus is almost nearer to Dhatukshayajanya Madhumeha while the type 2 Diabetes mellitus resembles to Avaranajanya Madhumeha.

Madhumeha chikitsa

The line of treatment of Madhumeha is Nidana Parivarjana and Apakarshana Chikitsa in Margavarana janya Madhumeha. Prakruti Vighatana Chikitsa is preferred in Dhatu kshaya janya Madhumeha. Avastha Anusara Chikitsa, Santarpana Chikitsa is given in Krusha and Durbala Pramehi¹². Apatarpana Chikitsa considered in Sthoola and Balavan Pramehi and shamana prayoga is used according to the suitability. Samshaman Chikitsa includes deepana (appetizers), Pachana, (enhancing digestion), Kshut (Hunger maintenance), Trit (Maintenance of thirst), Vyayama (Exercise), Atapa (Having exposed to sunlight) and Maruta (Exposing oneself to wind). According to the condition of vitiated doshas and dushyas, vaidya has to suggest proper Shaman Chikitsa to the patient. Kashaya yogas should be enriched with sneha and used in vatika mehas¹³. Usage of shilajatu, tuvaraka rasayanas¹⁴ has been referred in the disease, which will help in the rejuvenation of destructed cells responsible for the production of Insulin. Ample mentioning of different types of vyayama¹⁵ is seen which will help in the balancing the calorie intake and usage. Different eatables prepared of yava, mudga and amalaka¹⁶ should be given to the patient to eat.

MATERIALS AND METHODS

Madhumeha is one among the Vataja Prameha that has been considered as Mahagada. The present study is focused on clinical study of Madhumeha (NIDDM) in evaluating the effect of Nisha katakadi kashaya. This study was carried out on 20 patients who attended the OPD and IPD sections of SDM Ayurveda Hospital, Udupi, Karnataka, India.

Aim of study

To study the therapeutic effect of Nisha Katakadi Kashaya in patients suffering from Madhumeha

Source of data

Patients of either sex diagnosed as Madhumeha were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka, India. The ethical clearance number of the clinical study is SDMCAU/ACA 15/ IEC-51/ 2008-09.

Inclusion Criteria

- Patients presenting with cardinal signs and symptoms of Madhumeha (NIDDM) such as prabhuta mutra, avila mutra, mootra madurya, with Fasting Blood Sugar greater than 126 mg/dl and Postprandial serum glucose level of greater than 200 mg/dl.
- Patients aged 16-70 years.

Exclusion Criteria

- IDDM patients
- Gestational diabetes.
- Diabetes Mellitus produced due to other illnesses like Acromegaly, Cushing's syndrome, pancreatic disorders etc.

Investigations

- Blood: FBS, PPBS
- Urine: Sugar

Design of the study

An open labeled clinical study with pre-test and post-test design

Intervention

All 20 patients selected for the study were subjected to Nisha Katakadi Kashaya 50 ml BD for 28 days.

Method of Preparation

The drugs Nisha, Kataka, Dathri, Lodra, Paranti, Bhadraka, Meharimula and Ushira were taken in an equal quantity. All the individual drugs were checked for their identity, quality and quantity. The individual drugs were mixed and subjected to size reduction in a pulverizer to get coarse powder. The coarse powder (Kwatha Choorna) 50 g was packed and the 7 same packets are sealed in a single pack. This pack can be used for a week¹⁷.

Assessment criteria

In this clinical study which was conducted on 20 patients suffering from Madhumeha shamana with Nisha Katakadi Kashaya was given 50 ml twice a day before food. Scores were given to the different assessment criteria's before treatment, after first week, after second week, after third week and after treatment. The effect of the treatment on the symptoms and laboratory tests were statistically analyzed.

Statistical test

For the statistical analysis of results, paired t test was applied on the parameters of the study on patients treated with Nisha kathakadi kashaya to compare the results within the group before and after the treatment. Assessment criteria of subjective and objective parameters with their scoring¹⁸ are shown in Table 1.

RESULTS

In this clinical study which was conducted on 20 patients suffering from Madhumeha Nisha Katakadi Kashaya was given 50 ml twice a day before food. Scores were given to the different symptomatic assessment criteria's before treatment weekly and after treatment. The blood and urine sugars were assessed and compared before treatment with that of 28th day. The effect of the treatment on the symptoms and laboratory tests were statistically analyzed. All the parameters taken for assessment showed statistically significant response on the

 28^{th} day of assessment. This shows that Nisha kathakadi kashaya has marked effect on the disease. All the parameters taken for assessment in this study such as prabhuta mutrata (polyuria), muhurmhur mutra tyaga (frequency), avila mutrata, pipaasa, kshudha, swedhadhikya, dourbalya, karapada daha, supti, FBS, PPBS and fasting urine sugar had a significant change in the scores after treatment with a P value of < 0.001. The details of the above are given in tables and illustrations.

Overall assessment of the treatment

The overall assessment of the symptoms like prabhootha mootrata is 77.96 %, avilamootrata is 72.41 %, pipaasa is 73.46 %, kshuda is 83.92 %, FBS is 75 %, PPBS is 76.08 %, Urine sugar is 76.19 %, swedadhikya is 86.78 % and daurbhalya is 84.32 %. The overall assessment of the whole treatment is 78.4 %.

DISCUSSION

Observing the scores given to the individual symptoms and tests before and after the treatment in the 20 patients the results is statistically analyzed. The maximum reduction in the symptom prabhoota mootrata is seen during second week to fourth week of medication. This shows that the treatment is helpful only when it is continued for more than two weeks. The mean value of avila mutrata during the first week of the treatment shows not much reduction but after second, third and fourth week there is significant reduction in the symptom. The mean value of Pipaasa after one week of the treatment didn't show much reduction but by continuing medication after second and third week it showed good reduction in the symptom. The mean value of Kshudha after the second week showed significant reduction in the symptom.

Table 1:	Grading	of assessment	of parameters
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S. No	Criteria	Details	Score
1	Prabhoota Mootrata (Polyuria)	1.50 to 2.00	0
	Quantity of urine (in liter)	2.00 to 2.50	1
		2.50 to 3.00	2
		3.00 onwards	3
2	Prabhoota Mootrata (Polyuria)	3-6 times per day, rarely at night	0
	Frequency of urine	6-9 times per day, $0-2$ times per night	1
		9-12 times per day, 2-4 times per night	2
		More than 12 times per day, more than 4 times per night	3
3	Pipasa (Polydypsia)	Feeling of thirst 7 – 9 times/24 hours, either/or Intake of water 5 – 7	0
		times/24 hours with quantity $1.5 - 2.0$ liter/24 hours	
		Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9	1
		times/24 hours with quantity 2.0 - 2.50 liter/24 hours	
		Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11	2
		times/24 hours with quantity 2.50 -3.00 liter/24 hours	
		Feeling of thirst >13 times/24 hours, either/or Intake of water >11	3
		times/24 hours with quantity >3.00 liter/24 hours	
4	Bahu Ashee (Appetite)	As Usual	0
		Slightly increased (1-2 meals)	1
		Moderately increased (3 – 4 meals)	2
		Markedly increased $(5 - 6 \text{ meals})$	3
5	Kara-Pada-Tala-Daha / Supti	No Daha	0
	(Neuropathy)	Kara-pada-tala-daha / Supti is continuous	1
		Kara-pada-tala-daha / Supti continuous but not severe	2
		Kara-pada-tala-daha / Supti continuous and severe	3
6	Avila Mootrata (Turbidity)	Crystal clear fluid	0
	× 57	Faintly cloudy or smoky (turbidity barely visible)	1
		Turbidity clearly present but newsprint easily read through test tube	2
		Newsprint not easily read through test tube	3
		Newsprint cannot be seen through test tube	4
7	Mootramadhurya (Glycosuria)	Absence of Glucose in urine	0
,	(orycoound)	<0.5 % Glucose in urine	1
		0.05 - 1.0% of Glucose in urine	2
		1.0 - 2.0% of Glucose in urine	3
		> 2.0 % Glucose in urine	4
8	Ati Sweda (Perspiration)	Sweating after heavy work and fast movement or in hot weather	0
0	r ti Swedu (i eispitution)	Profuse sweating after moderate work and movement	1
		Sweating after little work and movement (stepping ladder etc.)	2
		Profuse sweating after little work and movement	3
		Sweating even at rest or in cold weather	4
9	Dourbalya (Weakness)	Can do routine exercise/work	0
	Dourbarya (weakiess)	Can do noderate exercise with hesitancy	1
		Can do mild exercise only, with difficulty	2
		Cannot do mild exercise too	3
10	FBS (mg/dl)	75 – 110	0
10	rbs (ing/ui)	111 - 125	1
		111 - 125 126 - 180	2
	PPBS (mg/dl)	> 180	3
11	PPBS (mg/dl)	Up to 140	
11		141 - 160	1
	1	160 - 300	2

Parameter Mean Urine quantity Difference in Mean			Paired 't' test				
	BT (± SE)	AT (± SE)		S.D	S.E.M	't'	Р
Urine quantity	2.950	0.650	2.300	0.657	0.147	15.657	< 0.001
	(± 0.0500)	(± 0.150)					
Frequency	2.950	0.650	2.300	0.675	0.147	15.657	< 0.001
	(±.0500)	(±.150)					
Avila mutrata	2.900	0.800	2.100	0.641	0.143	14.658	< 0.001
	(± 0.228)	(±.156)					
Pipasa	2.450	0.650	1.800	0.616	0.138	13.077	< 0.001
	(± 0.153)	(±.109)					
FBS	2.600	0.650	1.950	0.605	0.135	14.419	< 0.001
	(± 0.112)	(± 0.109)					
PPBS	2.300	0.550	1.750	0.444	0.0993	17.616	< 0.001
	(± 0.128)	(±.114)					
Sweating	3.118	0.412	2.706	0.588	0.143	18.978	< 0.001
N = 17	(± 0.080)	(±.123)					
Dourbalya	2.800	0.450	2.350	0.813	0.182	12.931	< 0.001
N = 18	(± 0.117)	(±.135)					
?	2.833	0.444	2.389	0.608	0.143	16.678	< 0.001
	(± 0.090)	(±.121)					

Table 2: Effect of treatment on different Parameters

Table 3: Effect of treatment on daha/supti

Kara-Pada Tala-Daha /	Assessment In 5 Patients			Assessment In 5 Patients		
Supti N = 6	Initial	AT1	AT2	AT3	AT4	
Mean score	1.6	1.2	1.0	0.8	0.6	

No.	Overall assessment of symptoms	ent of symptoms %		
1.	Prabhootha mootrata	77.96 %		
2.	Avilamootrata	72.41 %		
3.	Pipaasa	73.46 %		
4.	Kshuda	83.92 %		
5.	FBS	75 %		
6.	PPBS	76.08 %		
7.	Urine sugar	76.19 %		
8.	Swedadhikya	86.78 %		
9.	Daurbhalya	84.32 %		
Overal	assessment of the whole treatment	78.4 %		

Table 4: Overall assessment of parameters

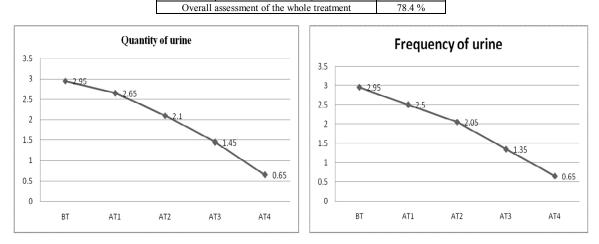


Figure 1 and 2: Effect on Prabhuta mutrata and muhur muhur mutra tyaga in patients of Madhumeha during weekly follow up

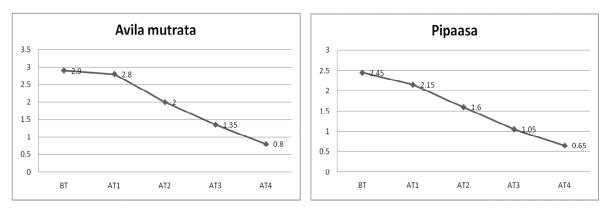


Figure 3 and 4: Effect on Avila mutrata and pipasa in patients of Madhumeha during weekly follow up

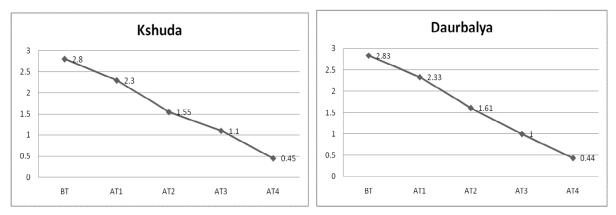
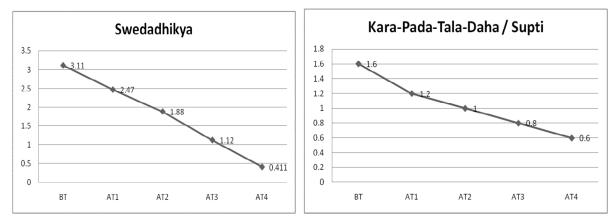


Figure 5 and 6: Effect on Kshudha and Daurbalya in patients of Madhumeha during weekly follow up





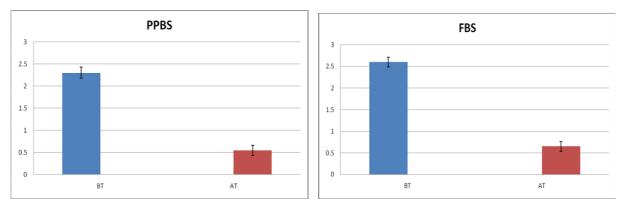


Figure 9 and 10: Effect on PPBS and FBS in patients of Madhumeha on 28th day

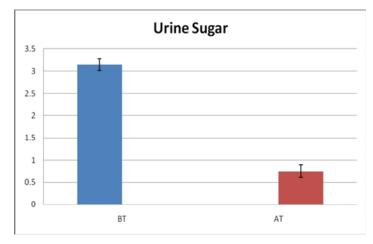


Figure 11: Effect on urine sugar in patients of Madhumeha on 28th day

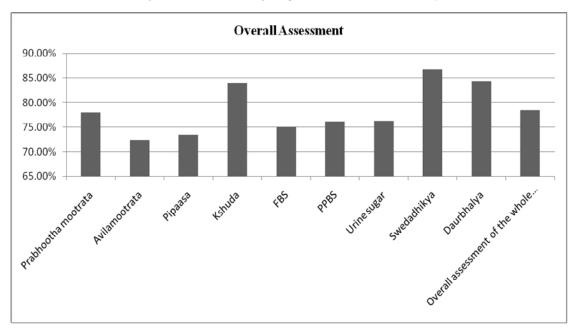


Figure 12: Effect on overall assessment in patients of Madhumeha on 28th day

The mean value of the symptom Swedadhikhya shows a gradual reduction in each week equally. The mean value of the symptom daurbalya didn't show much reduction in first week but after the second and third week it shows reduction of symptom. The difference in the mean of the symptom Kara-Pada-Tala-Daha / Supti shows that the formulation Nisha Katakadi Kashaya is helpful in reducing the symptom. It is observed that hyperglycemia has reduced well in both sthula and krusha pramehi and comparing the two the response was good in krusha pramehi.

Mode of action of Nisha kathakadi kashaya

In the pathogenesis of the Avaranajanya Madhumeha, the Kapha and Pitta are the main Dosha, and the most important Dushyas are Meda and Kleda. So, its management has to be against Meda and Kleda as well as having the Rasayana effect. Nisha Katakadi Kashaya having reference in Sahasrayoga, contains eight drugs. They are Nisha, Kataka, Dhatri, Lodra, Paranti, Bhadraka, Meharimula, Ushira. All these eight drugs have Kaphahara properties and as Madhumeha is a Kapha pradana vyadhi this medicine is useful. In the above mentioned drugs Nisha and Bhadraka are

considered as the cardinal feature of the disease madhumeha. Even the drugs like Nisha, Dathri and Meharimoola have a direct reference of anti-diabetic action. The drug Dathri has also got a specific action in Hypercholesterolemia, and Kataka has got the action of Lekhana so these two drugs will be helpful in the patients of Madhumeha who are Sthula. Lodra, Paranti and Nisha have the actions like rakthaprasadana, kushtahara, and sothahara. Because of these gunas it will be helpful for the skin lesions which are produced in the disease Madhumeha. Particularly the drug Dathri is having the actions rasavana and chakshusya, because of which it will be helpful in the madhumeha patients who will be having the symptoms of daurbalya. In a research study administration of turmeric or curcumin to diabetic rats reduced the blood sugar, Hb and HbA1c levels significantly.¹⁹ Curcuma longa rhizome extracts showed blood glucose lowering activity in experimental induced diabetic rats. After 3 and 6 h of curcuma injection (10 mg), 37.2 % and 54.5 % fall was observed respectively in glucose levels.²⁰ Dhatri has an anti hypercholestremic effect and

having the property Mootrasangrahana action which helps in

the reduction of the symptom prabhutamootrata, which is

kataka has got anti oxidant effect. Study of alcoholic extract of Bhadraka (*A. lanata*) leaves in alloxan-induced diabetic rats showed significant anti hyperglycemic activity. Study of the ethanol extract of the entire plant of *Aerva lanata* in cisplastin- and gentamicin-induced acute renal injury in albino rats showed it possessed marked nephroprotective activity with minimal toxicity and offers a potential role in the treatment of acute renal injury caused by nephrotoxins like cisplastin and gentamicin²¹. Meharimula Root, especially the root bark exhibits the potent hypoglycemic action. Salaretin attributed to its Intestinal a-glucosidase inhibition, this inhibition in turn leads to retardation in the digestion of carbohydrates. So there will be decreased absorption of the carbohydrate micro components in small intestine, this finally results in decreased blood glucose level²².

CONCLUSION

The maximum numbers of patients in this study are between the ages of 41-60 years. There is no relation of sex, marital status, religion for the causation of Madhumeha. Sedentary life style, increased stress and strain are main factors for the production of Madhumeha. The study confirms in the pathogenesis of the disease Madhumeha that there is a dominancy of kapha dosha, medo dushti, rasavaha and medovaha srotodushti. The study confirms that Nisha Katakadi Kashaya is effective in treatment of Madhumeha and definitely reduces the symptoms of the illness that include Prabhoota Mootrata, Avila Mootrata, Pippasa, Karapadatala Supta/daha, Dourbalya, FBS, PPBS and Urine sugar.

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