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Research Article

Role and Efficacy of "Katankateriyadi Kwatha" in Patients of Madhumeha (Diabetes Mellitus Type 2): A Clinical Trial

Vandana Singh *, Bhuwal Ram

Department of Dravyaguna, Faculty of Ayurveda, IMS, BHU, Varanasi, 221005, India

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Abstract

Madhumeha (Diabetes Mellitus) is a by-product of urbanization, proclaimed thousands of years back by *Acharya Charaka*. India has a high prevalence of diabetes which is increasing in number at an alarming rate. The introduction of oral hypoglycaemic drugs in modern therapeutics materialize to be a breakthrough in the treatment of Diabetes Mellitus initially but subsequently, it was experienced that most of the hypoglycaemic drugs were inadequately effective and were associated with many major side effects. To get rid of this problem, here we aimed to find out an effective and safe remedy to control the disease. This study is an Open-label, standard control, randomized and comparative clinical study with the 3-month assessment of the response of the trial drug "*Katankateriyadi Kwatha*" on the diabetic patients through subjective and objective parameters.

Keywords: Diabetes mellitus, Clinical study, *Madhumeha, Katankateriyadi Kwatha*.

*Address for Correspondence:

Dr. Vandana Singh, Research scholar, Department of Dravyaguna, Faculty of Ayurveda, IMS, BHU, Varanasi, 221005, India

INTRODUCTION

In the field of research, though experimental studies provide a better understanding regarding the efficacy, mode, and site of action of the drugs, the evaluation of the drugs is incomplete until they tried clinically. As a part of research work, the clinical study is very much essential to establish the effect of the drug.

Madhumeha (Diabetes mellitus-2) is worldwide a stubborn disease condition recognized by ancient scholars of ancient India. The *Ayurvedic* classical texts namely the *Samhitas* of *Charaka, Susruta, Vagbhata* and the subsequent treatises have invariably given a detailed description of the disease *Prameha*, its causes, types, pathology and the line of management in both preventive and curative aspects. *Acharya Charaka* has classified it into two groups i.e. *Sthula Pramehi* and *Krisha Pramehi* and *Santarpanajanya* and *Aptarpanajanya Prameha* at the other places [1]. It can be paralleled with the classification given by *Vagbhata* i.e. *Dhatukshayajanya Madhumeha* and *Avaranajanya Madhumeha* respectively. The factor which elicits *Vata* directly causes *Aptarpanajanya Madhumeha* while the factor which elicits Kapha and Pitta causes *Santarpanajanya Madhumeha*. In *Avaranajanya Madhumeha*, *Kapha* is the prevailing *dosha* while the important *dushyas* are *Meda* and *Kleda*. In *Avaranajanya Samprapti* the vitiated *Kapha* and *Pitta* obstruct the *patha* of *Vata* causing its aggravation [2]. *Acharya Susruta* mentioned that in *Madhumeha* the vitiated *doshas* remains situated in the lower part of the body owing to the inefficiency of various *Dhamanis* [3].

As Diabetes is not merely a metabolic syndrome, it gives rise to lethal complications too, that is why health authorities of all over the world and in all countries are trying best to take control over the spread of this disease. Research on remedies of diabetes mellitus is a continuous process being adopted by all countries. Our work was instigated to explore the possibility of better control over diabetes.

Ayurveda has described that it is not rational treatment where medicine modifies one disease; on the other hand, it provokes new complaints. So the effort has been made here to search the safe and effective medicine, without any side effects.

Considering the above-stated fact, a compound formulation of plant-derived, which has been used since ancient times to alleviate this disorder, i.e. *Madhumeha* (Diabetes mellitus-2) is selected. The formulation composed of six medicinal herbs namely; *Daruharidra* (stem), *Yastimadhu* (stem), *Chitraka* (root), *Haritaki* (Fruit), *Bibhitaka* (Fruit) and *Amalaki* (Fruit) and is known as "*Katankateriyadi Kwatha*". After the collection of the useful parts of the plants following the guidelines, the drug was prepared.

Table 1: The individual properties of the trial drug (*Katankateriyadi Kwatha*) are intervened as:

Rasa - Katu, Tikta, Kashaya (Madhura rasa in Yastimadhu)
Guna – Laghu, Ruksha
Vipaka – Katu (Daruharidra & Chitraka) and Madhura
Virya – Ushna (shita virya in Yastimadhu & Amalaki)
Dosha Karma – Tridoshaghna

AIMS AND OBJECTIVES

- To evaluate the role of *Katankateriyadi kwatha* in *Madhumeha* (Diabetes Mellitus-2).
- To determine the symbiotic relationship between *Katankateriyadi kwatha* and anti-hyperglycemic drug (Gliclazide SR).

MATERIAL AND METHODS

Selection of Patients: 75 cases of DM II (out of 85, 10 were drop out) registered from the O.P.D. of Department of *Dravyaguna*, Sir Sundarlal Hospital, Banaras Hindu University, and Varanasi. Some of these cases were already known diabetics while some cases were diagnosed for the first time when they visited with other complaints.

Pre-Treatment Observation: All the patients were studied at the time of registration considering their age, sex, religion, marital status, occupation, habitat, family history, dietary habits (diet habit-1 and diet habit-2), appetite, bowel habit, addiction, duration of illness and physical activity. After preliminary registration, patients were subjected to document their detail case history taking and physical examination including general and systemic examination.

Diagnostic Criteria: All the patients were examined clinically for signs and symptoms of Madhumeha (type 2 Diabetes mellitus) i.e; *Prabhuta mutrata* (polyuria), *Kshudhadhikya* (polyphagia), *Trishnadhikya* (polydipsia), *Daurbalya* (weakness), *Karapadatala Suptata* (numbness of limbs), *Karapadatala Daha* (tingling and burning sensation in sole and palm) and *Pindikodweshtana* (cramps in legs) over few months [4]. The entire patients were subjected to their fasting and postprandial blood sugar, HbA_1C, and lipid profile, etc.

- **Inclusion Criteria**

1. Male and female patients within the age limit 25-60 yrs.
2. Newly diagnosed patients with type 2 diabetes mellitus (*Madhumeha*).
3. Patients already taking oral hypoglycaemic drugs.

- **Exclusion Criteria**

1. Patients having age more than 60 yrs.
2. Patients having type1 DM.
3. Patients with severe complications of Diabetes (Nephropathy, Cardiomyopathy, Retinopathy, Neuropathy, etc.).
4. Patients having a superinfection.
5. Any other chronic diseases like Tuberculosis, Rheumatic Heart disease, Rheumatoid arthritis, etc.
6. Patients of type 2 DM taking insulin were also not included in the study.
7. Pregnant women and patients advised any surgical interventions.

Laboratory Investigations: The entire patients were subjected to their following biochemical investigations.

1. Fasting Blood sugar (FBS)
2. Post-Prandial Blood sugar (PPBS)
3. HbA1C
4. Lipid profile

Study Design: An Open-label, standard control, randomized and comparative clinical trial.

- Sample Size – 75 patients registered divided into 3 groups
- Dropouts – 10 patients
- Duration of Treatment – 3 months
- Follow Up – 30 days interval with 3 follow-ups
- Source of Formulation: The *yavkuta churna* of *katankateriyadi kashaya* was prepared in *Ayurvedic* pharmacy of Faculty of *Ayurveda*, Institute of Medical Sciences, Banaras Hindu University.
- Interventions

1. Drug & Dose:- The trial drug *Katankateriyadi kwatha* [5] was advised to the patients**.** Coarse powder of plant parts approx. 40g taken and four times water is added and boiled till one-fourth remain and this decoction is given two times. The standard drug i.e; Gliclazide SR 60 mg advised twice a day before meal.
2. Duration:- All the patients were followed up at an interval of every 15 days. The total duration of treatment was 3 months.

- Criteria of Assessment of Overall Effect of Treatment: Selected patients were counseled to come for follow-ups at every one-month interval for three months. The assessment was done under the headings subjective and objective parameters.

i. The clinical symptomatology of the selected patients was divided into four grades (0-3) and changes in gradations of each symptom were assessed at each follow-up.

ii. Control on sugar levels for both fasting and after-meal was focused at each follow-up.

iii. Improvement in HbA1C level and lipid profile was analyzed after the last follow-up i.e, 3 months.

Table 2: Composition of Trial Drug *Katankateriyadi Kwatha*.

S.No.	Drug name	Botanical name	Useful part	Part used
1.	***Daruharidra***	*Berberis aristata* DC.	Stem	1 part
2.	***Yastimadhu***	*Glycyrrhiza glabra* Linn.	Stem	1 part
3.	***Chitraka***	*Plumbago zeylanica* Linn.	Root	1 part
4.	***Haritaki***	*Terminalia chebula* Retz.	Fruit	1 part
5.	***Bibhitaki***	*Terminalia bellirica* Roxb.	Fruit	1 part
6.	***Amalaki***	*Emblica officinalis* Gaertn.	Fruit	1 part

Treatment Protocol

Group A: *Katankateriyadi kwatha* group; Mild to moderate cases of *madhumeha* (type 2 diabetes) were advised with *Katankateriyadi kwatha* along with *pathya-apathya* as per protocol.

Group B: Control group; Known patients of *madhumeha* (type 2 diabetes) were administered with oral hypoglycaemic drug (Gliclazide SR-60 mg) along with recommended *pathya-apathya* as per protocol.

Group C: Integrative group; Known patients of *madhumeha* (type 2 diabetes) already taking the Gliclazide SR (60 mg BD) but not well under control were advised with *Katankateriyadi kwatha* additionally along with *pathya-apathya* as per protocol.

Patients of all the groups were counseled to follow *patha-apathya* as given [6]:

Pathya

- *Ahara* – *Yava* (barley), green gram, *moong dal*, all green and leafy vegetables, anyone seasonal fruit daily, 2 *chapattis* each meal.
- *Vihara* – daily 2-3 km brisk walking in the morning

Apathya

- *Ahara* – milk and milk products, dried fruits, chocolates, sugar, rice, bakery products, potatoes and oily and fried food.
- *Vihara* – avoid sleeping in the day time.

Ethical Clearance

A detailed research proforma was prepared to incorporate all the points from *Ayurvedic* as well as a modern aspect to study the patients as well as disease. The study had received prior approval from the Institutional ethics committee. (ECR/526/Inst/UP/2014 Dt. 31.1.14).

Statistical Analysis

Significant enhancement in the subjective criteria in a single group was assessed by the Friedman test and to compare the effect of the drug between the groups was done by the Chi-square test**.** Similarly for the improvement of the clinical parameters within the group was judged by paired t-test and comparison between the groups was carried out by one way ANOVA**.**

OBSERVATION AND RESULTS

Statistical analysis of their general profile evidenced the majority of cases belongs to the age group 41-60 yrs. (65.3%) asserting that disease *Madhumeha* has a predominance of occurrence at middle age group whereas, the onset of the disease was also observed in the younger age group i.e, 20-30 yrs. (9.3%). Also, more male cases (65.3%) were registered as compared to female cases (34.7%). Married cases (68%) were in more incidences and Hindu cases (80%) were registered in a large number. Prevalence of disease was remarked more in-service class individuals (38.7%) contribute to the fact that a sedentary lifestyle (*Asyasukhama*) [7] and work stress is one of the causes of *Madhumeha*, followed by housewife (28.0%) indicating altered food habits to be one of the dominating cause. Highly marked cases belonged to urban areas (81.3%) illuminating diabetes to be a modern lifestyle disorder. Out of which mostly belongs to middle economic status, it shows its more prevalence in the middle socioeconomic status group. As people of the middle socioeconomic group have to face more stress in their daily lives, diabetes seems to be closely related to stress.

Nearly about 33.3% of cases were having a family history of diabetes contributed to the fact that disease has a genetic predisposition.

The personal profile of the patients elucidates statistical incidence with more cases having a non-vegetarian diet (54.7%) which contributed to the fact that overindulgence in *Mansa* [8] is one of the causes of *madhumeha* and the majority with altered bowel habits (50.7%). Maximum cases had no addiction (62.7%) with an average 4-10% cases was observed with alcohol, Tobacco, smoking and other addiction. It also reveals that *apathya ahara*, *vihara* contribute to the development of disease in diabetic prone peoples. Marked cases were having a history of diabetes for >6 yrs (40%) with a moderately active lifestyle (62.7%) followed by 16% of patients with a sedentary lifestyle which again supports the review data that showed decreased physical activity (*ekasthanarati*) [9] as the leading cause of increasing type-2 diabetes mellitus prevalence.

The demography of the clinical profile of the patients was statistically analyzed in each group and also between the groups. About 64% of cases in group A had mild to moderate grade of *Prabhuta mutrata* (Polyurea) induced due to excess of vitiated *kleda* initially before treatment as compared to 76% in group B and 48% in group C. Nearly 40% cases in group A were observed with mild to moderate *Trishnadhikya* (polydipsia) occurs due to *Pitta vriddhi* and *udaka kshaya* initially before treatment followed by 72% in group B and 56% in group C. Nearly 60%, 68% and 48% cases in group 1st, 2nd and 3rd group respectively had mild to moderate *Kshudhadhikya* (polyphagia) caused due to *Tikshna* and *ushna guna* of *Pitta* initially before treatment. The majority of cases were observed with 0-4 kg loss of weight/year i.e; 88% in group 1st initially before treatment followed by 74% and 88% in group 2nd, 3rd respectively. In the etiopathogenesis of *Prameha*, the *Dhatus* get vitiated, resulting in *Dhatukshaya* responsible for the manifestation of *Daurbalya* (weakness),

Pindikodweshtana (cramps in legs). Approximate 45-55% cases in all the groups suffered from mild to moderate *Pindikodweshtana* (leg cramps) before treatment. *Karapadatala Daha* and *Karapadatala Suptata* (burning sensation and numbness in the palm and foot) are both reported as *Purvarupa* of *Prameha in the Ayurvedic literature*. About 50-60% of cases in all groups had mild to moderate *Karapadatala Daha* (tingling and burning sensation) initially before treatment. Nearly 60% of cases suffered from mild to moderate *Karapadatala Suptata* (numbness) in group 1st initially before treatment followed by 44% and 48% in group 2nd and 3rd respectively.

All the groups have shown significant relief in all the symptoms in successive follow-ups. Intergroup comparison was found statistically highly significant in symptoms polyuria, polyphagia and tingling & burning sensation. The absence of symptoms was higher in group C as compared to other groups. The overall improvement was determined based on the percentage of presence and absence of symptoms after treatment as compared to before treatment.

1. If no. of symptoms absent is up to 50%, the improvement is considered mild.
2. If no. of symptoms absent is >50 & <75%, the improvement is considered as moderate.
3. If no. of symptoms absent is >75%, then it is considered as a marked improvement.

Table 3: Overall Improvement based on the presence of eight symptoms before and after treatment:

Improvement	No. & (%) of cases			X^2
	Group 1	Group 2	Group 3	
No change (0%)	2 (9.52)	0 (0)	0 (0)	χ^2=8.40, df=2, p=0.015
Mild (≤50%)	5 (23.80)	7 (36.84)	3 (14.28)	
Moderate (51-74.9%)	4 (19.04)	8 (42.10)	4 (19.04)	
Marked (≥75%)	10 (47.61)	4 (21.05)	14 (66.66)	
Total	21 (100)	19 (100)	21 (100)	

The above table shows marked improvement in overall symptoms in patients of group 3rd nearly 66.66% as compared to group 1st, and 2nd after the last follow-up which is statistically highly significant.

Effect of Trial Drug on FBS: All the groups have shown a highly significant ($p \leq 0.001$) decrease in mean FBS by 69.126, 62.963 and 89.519 in group 1st, 2nd, and 3rd respectively at the last follow-up. The intergroup comparison was not statistically significant after treatment indicating that all the groups are equally effective in reducing fasting blood sugar.

Table 4 Showing effect of treatment on FBS level

Groups	FBS (mean±std.deviation)				Comparison within the group Paired t-test (BT-AT)
	BT	F1	F2	F3	
Group 1	179.14 ± 47.119	149.86 ±43.160	123.90 ±32.168	106.90 ±16.742	69.126 ± 35.828 t=8.842 p=0.000
Group 2	171.75 ±21.835	141.89 ±19.591	120.73 ±17.473	106.41 ± 13.823	62.963 ± 21.028 t=13.052 p=0.000
Group 3	191.67 ±50.007	146.58 ±34.795	121.92 ±32.511	103.66 ± 16.381	89.519 ± 43.976 t=9.329 p=0.000
Comparison between the group One-way ANOVA	F=1.463 p=0.238	F=0.348 p=0.708	F=0.069 p=0.934	F=0.254 p=0.776	

Effect of Trial Drug on PPBS: Decrease in mean PPBS at 3rd follow-up as compared to before treatment is 124.756, 106.353 and 127.024 in 1st, 2nd and 3rd group respectively; which were statistically highly significant. All the groups are equally effective in reducing post-prandial blood sugar as the intergroup comparison shows insignificant results.

Table 5 Showing effect of treatment on PPBS level

Groups	PPBS (mean±std.deviation)				Comparison within the group Paired t-test (BT-AT)
	BT	F1	F2	F3	
Group 1	294.27 ±42.070	229.64 ±48.170	183.91 ±25.002	160.29 ±16.378	124.756 ± 38.526 t=14.840,p=0.000
Group 2	277.29 ±18.149	217.62 ±32.169	188.18 ±23.556	171.26 ±14.163	106.353 ± 21.028 t=21.151,p=0.000
Group 3	289.05 ±61.485	223.51 ±46.673	181.22 ±33.579	165.80 ±32.546	127.024 ± 49.753 t=11.700,p=0.000
Comparison between the group One-way ANOVA	F=0.966 p=0.386	F=0.490 p=0.615	F=0.342 p=0.712	F=1.156 p=0.322	

Effect of Trial Drug on HbA1C: Decrease in mean HbA_1C after treatment as compared to before treatment is 1.8095, 1.3158 and 2.1095 in group 1st, 2nd, and 3rd respectively; which were statistically highly significant. Intergroup comparison was not found significant after the treatment.

Table 6 Showing effect of treatment on HbA1C level

Groups	HbA1C (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	8.576 ± 1.5791	6.686 ± 0.4328	1.8095 ± 1.3323 t=6.224,p=0.000
Group 2	7.928 ± 0.5842	6.711 ± 0.4677	1.3158 ± 0.5659 t=10.134,p=0.000
Group 3	8.612 ± 2.1324	6.638 ± 0.3866	2.1095 ± 2.0557 t=4.703,p=0.000
Comparison between the group One-way ANOVA	F=1.505 p=0.229	F=0.149 p=0.862	

Effect of Trial Drug on Lipid Profile: All the groups have shown significant improvement in their lipid profile levels after treatment. Total cholesterol level (Decrease in mean after treatment is 82.938, 63.316 and 64.476 in groups 1st, 2nd and 3rd respectively) and triglyceride (Decrease in mean after 3rd follow-up is 56.400, 24.579 and 34.524 in groups 1st, 2nd and 3rd respectively) was statistically highly significant within the group & not significant in intergroup comparison. In both cases group 1st shows significant improvement as compared to other groups.

The value of HDL (Increase in mean after treatment is 9.586, 7.474 and 8.905 in groups 1st, 2nd and 3rd respectively) was statistically highly significant within the group and also found significant in intergroup comparison showing significant control in HDL with trial drug in synergistic action with standard drug as compared to the standard drug i.e; value of HDL was increased in group C after taking treatment.

In all groups reduction in LDL (Decrease in mean after 3rd follow-up is 23.862, 15.158 and 23.895 in groups 1st, 2nd and 3rd respectively) and VLDL level (Decrease in mean after 3rd follow-up is 18.9238, 13.0526 and 10.2571 in groups 1st, 2nd and 3rd respectively) was statistically highly significant within the group & not significant in intergroup comparison. The trial drug was found more effective in controlling LDL and VLDL as compared to the standard drug.

Table 7 Showing effect of treatment on Cholesterol level

Groups	Cholesterol (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	241.35 ± 5.247	166.48 ±32.816	82.938 ± 47.629 t=7.980,p=0.000
Group 2	226.00 ± 44.032	169.11 ±25.166	63.316 ± 39.798 t=6.935,p=0.000
Group 3	232.48 ± 55.540	167.81 ±33.397	64.476 ± 51.733 t=5.711,p=0.000
Comparison between the group One-way ANOVA	F=0.536 p=0.587	F=0.036 p=0.964	

Table 8 Showing effect of treatment on Triglyceride level

Groups	Triglyceride (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	190.86 ±92.843	139.43±40.185	56.400 ± 64.268 T=4.022, P=0.001
Group 2	148.80 ±17.673	123.68 ± 7.048	24.579 ± 17.995 T=5.954, P=0.000
Group 3	174.24 ±52.113	141.14±31.257	34.524 ± 31.406 T=5.037, P=0.000
Comparison between the group One-way ANOVA	F=2.889 p=0.062	F=2.000 p=0.145	

Table 9 Showing effect of treatment on HDL level

Groups/Tests	Hdl (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	32.95 ± 6.375	43.10 ± 6.147	-9.586 ± 4.769 t=-9.211, p=0.000
Group 2	31.20 ± 4.796	37.95 ± 3.188	-7.474 ± 5.976 t=-5.452, p=0.000
Group 3	34.00 ± 11.937	44.48 ± 10.759	-8.905 ± 5.431 t=-7.517, p=0.000
Comparison between the group One-way ANOVA	F=0.728 p=0.486	F=4.153 p=0.021	
Post Hoc test **1 vs 2** **1 vs 3** **2 vs 3**		 p=0.102 p=1.000 p=0.024	

Table 10 Showing effect of treatment on LDL level

Groups	Ldl (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	132.44 ± 22.237	106.19 ± 18.471	23.862 ± 13.350 t=8.191, p=0.000
Group 2	128.12 ± 17.259	117.21 ± 9.295	15.158 ± 16.025 t=4.123, p=0.001
Group 3	137.03 ± 22.016	111.14 ± 19.767	23.895 ± 16.882 t=6.486, p=0.000
Comparison between the group One-way ANOVA	F=1.166 p=0.317	F=2.171 p=0.123	

Table 11 Showing effect of treatment on VLDL level

Groups	VLDL (mean±std.deviation)		Comparison within the group Paired t-test (BT-AT)
	BT	F3	
Group 1	52.4448 ±19.7489	32.467 ± 8.7712	18.9238 ± 15.7547 t=5.504, p=0.000
Group 2	45.160 ± 11.0517	34.316 ± 5.2605	13.0526 ± 11.2915 t=5.039, p=0.000
Group 3	42.856 ± 12.2087	33.619 ± 8.1699	10.2571 ± 9.0382 t=5.201, p=0.000
Comparison between the group One-way ANOVA	F=2.844 p=0.065	F=0.302 p=0.740	

Therefore, the above-endorsed statistics signal that the test drug epitomizes to control the symptoms better than the standard drug. The study exemplifies that the trial drug is equally effective in controlling FBS, PPBS, and HbA1C as the standard drug, whereas the trial drug (in Group A) is more efficacious in the management of lipid profile as compared to other groups. These results materialize the *pramehahar* effect of the drugs *Haritaki* [10], *Amalaki* [11], *Bibhitaki* [12], *Daruharidra* [13], *Chitraka* [14] and *Yastimadhu* [15]. Also proposed actions of the drugs like antioxidant, antistress, immunomodulator, the anti-atherosclerotic activity must also oversee to withstand against the symptomatological effects and complications of the disease.

DISCUSSION

Prameha is described to have contrived after the consumption of "*havisha* of *yagya*" performed by *Daksha Prajapati*. Its inclusion in "*Ashta Mahagada*" by *Acharya Charaka*, *Susruta* and *Vagbhata* marked the dominancy of the disease. "*Prameho anusanginama*" [16], contemplated by *Acharya Charaka* intimates the cohesive nature and poor prognosis of the disease. Based on its etiology and symptoms *madhumeha* can be co-related with Diabetes Mellitus type-2 (NIDDM-non insulin-dependent diabetes mellitus).

Prameha is contemplated to be *kapha pradhan tridoshaja vyadhi*. Here, the term *kapha pradhan* reveals that if all the three *doshas* are involved to produce *prameha* then it is *kapha dosha* which make body favourable for the genesis of *prameha roga*. It also unfolds the fact that in initial stage maximum patients suffer with *kaphaja prameha* which later on changes into *vataja prameha & pittaja prameha*. The main *dushya* in any type of *prameha* are those components of body which can not only be vitiated by these *dosha* but could be brought to *basti* to vitiate *mutra* also i.e, '*Medo dhatu*' and watery components are main *dushya*.

Therefore the drugs possessing properties opposite to that of *kapha dosha* and *meda dhatu* and are proficient enough to break the *samprapti* of the disease by intensifying *agni*, digesting *ama*, and cleansing the *srotas* are competent in opposing the *prameha roga*.

Katankateriyadi kwatha is amidst such type of drug. Probably *katu* and *tikta rasa* present in it are *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. *Laghu guna* of this *kwatha* supports in digestion of *amadosha* by boosting *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*. *Ushna virya* of most of the compound of this *kwath* pacifies *kapha* and *vata dosha*.

Pathya is highly advised along with other drugs in *prameha* because almost every *dhatu* (except *asthi*) and *kleda* of body might be *dushya* in *prameha roga*. Therefore patency and health of *srotas* inside the body for *dhatusamyata* in *prameha rogi* is highly necessary.

CONCLUSION

1. Safe and effective treatment of *Madhumeha* (DM-II) is much more challenging since very beginning till now because all drugs have their own limitations, in this connection a poly herbal formulation may be a good choice.

2. *Katankateriyadi kwatha* (a poly herbal formulation) has been used by *Acharya Chakrpanidatta* (11th cent A.D.) for the treatment of *madhumeha*.

3. After scientific study (overall objective and subjective assessment) observation were found more effective in group C (treated by both *Katankateriyadi kwatha* & Gliclazide SR) than group A (treated by *Katankateriyadi kwatha*) and group B (treated by Gliclazide SR 60 mg) significantly due to synergistic effect.

4. Although the test drug epitomizes to control the symptoms better than the standard drug. No side effects were observed during treatment.

The aforesaid clinical trial gives positive output that *Katankateriyadi Kwatha* is effective in *Madhumeha* (DM-II), which needs a larger number of data to communicate *Katankateriyadi Kwatha* as one of the convalescent and potent compound formulation of vegetable origin drug in *madhumeha*. Therefore, appropriate *ahara-vihara* along with the *Ayurvedic* drugs solitarily or in combination with the modern drugs depending on the necessity provide enduring health benefits in the patients of *Madhumeha* (Diabetes mellitus).

Conflict of Interest - Nil

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