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EFFICACY OF *KATANKATERYADI KWATH* ON *MADHUMEHA* (DIABETES MELLITUS TYPE 2): A RANDOMISED OPEN-LABELED CLINICAL TRIAL

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ABSTRACT

According to *Ayurveda, Madhumeha* is a classical metabolic disorder of tissue and cellular level. In *Ayurveda* this condition may correlate with *Dhatvagnimandya*. The present study is humble effort to treat patients of *Prameha* as per classics. Diabetes mellitus is one of the most important metabolic disorders manifested by hyperglycemia and impaired insulin secretion. According to the Diabetes Atlas 2015 published by the International Diabetes Federation, Diabetes affects 69.9 million people in India, with the number estimated to climb to 123.3 million by 2040 unless immediate preventive measures are done. The rapid epidemiological transformation linked with changes in eating patterns and decreased physical activity, as seen by the greater prevalence of diabetes in the urban population, is the fundamental cause of the diabetes epidemic. In the present clinical trial '*Katankateryadi Kwath*' given orally, administered for 2 month twice a day after food. 50 clinically diagnosed patients of Diabetes mellitus were selected randomly. Blood Sugar Fasting, Blood Sugar PP, Blood Sugar Random, CBC, Urine Complete, RFT, LFT, HbA1c (Optional) were done before and after the clinical trial. After completion of study signs and symptoms were controlled significantly and also there were significant changes in laboratory findings.

KEYWORDS: *Madhumeha, Dhatvagnimandya,* Diabetes mellitus, Insulin, *Katankateryadi Kwath.*

INTRODUCTION

In *Ayurveda, Madhumeha* is one of the twenty type of *Prameha* described in Ayurvedic literature, In Madhumeha the patient passes urine which is sweet and astringent in taste, whitish pale in color & unctuous. Madhumeha is related primarily with *Mutravaha* and *Medovaha Srotasa* but along with these many other Srotasa are also involves. So it is multisystem disorder as it involves various types of dushyas and doshas, According to etiological factors, Clinical features and pathogenesis, *Madhumeha* is linked to diabetes mellitus (DM), the most common endocrine and metabolic illness characterised by high blood glucose levels caused by abnormalities in insulin secretion, glucose synthesis, and utilisation.

In spite of tremendous advancement of modern system of medicine i.e. oral hypoglycemic agent and insulin till date, an ideal drug which can cure diabetes is not yet available and still scientists are struggling to search an effective and harmless therapy. 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 Ayurveda classics texts namely the Samhitas of *Charak*, *Sushruta* and *Vagbhata* and the subsequent treatises have in variably given detailed description of the disease diabetes, its causes, types, pathology and the line of management and treatment both preventive and curative.

In Ayurveda *'Madhumeha'* is considered as disease of vitiated *Vata* and *Kapha Dosha* and *Agnimandya* is present in *Madhumeha.* The phrase *"bahudrava shleshma tathaavabadhameda*" was coined by *Aacharya Charaka* to describe *Prameha,* and the Dushyas involved include *Meda, Mamsa, Kleda, Shukra, Shonita, Vasa, Majja,* and others, are all *Kaphavargiya*. So ideally in *Shamana Chikitsa* such drugs should be used in its treatment which possess Agnideepana properties and should pacify the effects of aggravated Dosha like Katu, Tikta, Kashaya and Ruksha Dravya.

Ayurveda recommends a medicine or dietary supplement that reverses or breaks the Samprapti. In Ayurvedic texts

our Acharyas have described use of drug combinations rather than single drug use. An effort is made here to study the aetiopathogenesis and *Samprapti vighatana* of Madhumeha through "Katankateryadi Kwath". It can be a major relief to the patient.

AIMS AND OBJECTIVES

1. To collect, compile and analyze the literary materials regarding *Madhumeha* (Diabetes Mellitus Type 2).
2. To evaluate of the *"Katankateryadi Kwath"* in the management of *Madhumeha* (Diabetes Mellitus Type 2).
3. To evaluate the adverse drug reaction of the trial drug.

MATERIALS AND METHODS

A. Selection of Patients

50 diagnosed and clinically confirm patients of Diabetes Mellitus will be selected from OPD of PG department of Kayachikitsa, Dr. S. R. Rajasthan Ayurveda University and hospital Jodhpur randomly.

B. Inclusion Criteria

- Diagnosed & confirmed patients of Diabetes Mellitus on the basis of Modern texts.
- Patients of 30 to 70 years age having sign and symptoms of diabetes mellitus will be selected for the study.
- Patient having their Blood sugar level > 125mg/dl to < 180mg/dl for Fasting and > 200mg/dl to < 300 mg/dl for postprandial.
- Patients with presence symptoms of *Prabhuta mutrata*, *Aavil mutrata*, *Pipasadhikya*, *Kshudadhikya*, *Kara pada tala daha*, *Kara pada tala supti*, *Alasya*, *Pindiko-udveshatan*, *Mutramadhurya*, *Daurbalyta*, *Pandurvarna mutrata* etc.

C. Exclusion Criteria

- Patients who were addict drugs and drinking
- Age below 30 and above 70 years
- Insulin dependent diabetic patients
- DM with complications.
- The patients suffering from heart diseases, hemiplegia and other chronic disorders will be excluded from the study.
- Uncontrolled DM (>600 mg/dl)
- Pregnant woman

D. Criteria for Diagnosis of *Madhumeha* (DM) by American Diabetic Association, which is accepted by WHO

-Sign & Symptoms of *Madhumeha* (DM) plus
-Patients having random blood sugar level > 200 mg/dl.

	Fasting Plasma Glucose(FPG)	Post prandial Glucose	HbA1c
Normal	Less than 100 mg/dl	Less than 140 mg/dl	Less than 5.7%
Prediabetes	100 mg/dl to 125 mg/dl	140 mg/dl to 199 mg/dl	5.7% to 6.4%
Diabetes	126 mg/dl or higher	200 mg/dl or higher	6.5% or higher

E. Study Design

- **Type of study**: Randomised Open labelled clinical trial
- **No. of Patients**: 50
- **Trial Duration**: 2 Months
- **Follow up**: On every 15 days (Blood sugar fasting and post- prandial level will be check on ever follow up)
- **Dose of *Katankateryadi Kwath*** : 20 ml twice in a day

Criteria for Assessment

Subjective parameter

All patients will be registered for clinical trial and will be looked for any changes in their clinical manifestations and growing feeling of well being, if any before and after treatment, and we will collect data of selected patients. The following sign and symptoms will be assessed for any improvement after the course of there by.

1) *Prabhuta Mutrata* (Polyuria): **Frequency of urine.**

S. No.	Details	Score
1.	3 – 5 times per day, no or rarely at night	0
2.	6 – 8 times per day, 1 – 2 times per night	1
3.	9 – 11 times per day, 3 – 4 times per night	2
4.	> 11 times per day, > 4 times per night	3

2) *Pipasadhikya* (Polydipsia).

S. No.	Details	Score
1.	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
2.	Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - - 9 times/ 24 hours with quantity 2.0 - 2.50 liter/24 hours	1

3.	Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11 times/ 24 hours with quantity 2.50 -3.00 liter/24 hours	2
4.	Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/ 24 hours with quantity >3.00 liter/24 hours	3

3) *Kshudhadhikya* (Excessive Appetite).

S. No.	Details	Score
1.	2 main meals + 1 breakfast	0
2.	Feeling of hunger after 6 hours of food	1
3.	Feeling of hunger after 4 hours of food	2
4.	Feeling of hunger after 2 hours of food	3

4) *Avila Mutrata* (Turbidity in urine).

S. No.	Details	Score
1.	Absence of albumin in urine	0
2.	Albumin in urine +	1
3.	Albumin in urine ++	2
4.	Albumin in urine +++	3

5*) Kara-Pada-Tala- Daha* (Burning sensation in palm and soles).

S. No.	Details	Score
1.	No *daha*	0
2.	Mild *Kara-pada-tala-daha*	1
3.	Moderate *Kara-pada-tala-daha*	2
4.	Severe *Kara-pada-tala-daha*	3

6*) Kara-Pada-Tala Supti* (Numbness in palm and soles).

S. No.	Details	Score
1.	No *Supti*	0
2.	Mild *Kara-pada-tala- Supti*	1
3.	Moderate *Kara-pada-tala- Supti*	2
4.	Severe *Kara-pada-tala- Supti*	3

7) *Alasya*/*Utsahahani* (General Debility).

S. No.	Details	Score
1.	No Alasya (doing satisfactory work with proper vigor and in time)	0
2.	Normal capacity of doing work / late initiation	1
3.	Less capacity of doing work / late initiation	2
4.	No initiation of doing work	3

8) *Pindiko-udveshatan* (Cramps).

S. No.	Details	Score
1.	No cramps	0
2.	Cramps after walking more than 1 km	1
3.	Cramps after walking ½ km	2
4.	Inability in walking even ½ km	3

9) *Mutramadhurya* (Glycosuria).

S. No.	Details	Score
1.	Absence of Glucose in urine	0
2.	Glucose in urine +	1
3.	Glucose in urine ++	2
4.	Glucose in urine +++	3

10) *Daurbalyta* (Weakness).

S. No.	Details	Score
1.	Absence of weakness	0
2.	Mild weakness	1
3.	Moderate weakness	2
4.	Severe weakness	3

11) *Pandurvarna mutrata* (yellowish white coloured urine).

S. No.	Details	Score
1.	Normal pale yellow urine	0
2.	Mild pale urine	1
3.	Pale urine	2
4.	Colorless or watery colored urine	3

Objective parameter

Following investigations will be assessed for objective parameter-

Laboratory investigation-

- Blood sugar fasting
- Blood sugar PP
- Blood sugar random
- CBC
- Urine Complete
- RFT
- LFT
- HbA1c (Optional)

Data Documentation and Statistical Analysis

Data collected in various stages of the clinical trial were analyzed using Graph Pad Instat (version 3.10, 32 bit for windows created July 10, 2009).

Trial Drugs

Katankateryadi Kwath

"Katankateryadi Kwath" is mentioned in *Chakradatta*, 35th Chapter, *"Prameha Chikitsa Prakaram"* 23rd *Shloka*.

Table 1: Ingredients of *Katankateryadi Kwath.*

Sr. No	Sanskrit Name	Part used	Proportion	Latin name
1.	*Daruhaldi*	Bark	1 Part	***Berberis aristata***
2.	*Madhuyasthi*	Stem	1 Part	***Glycyrrhiza glabra***
3.	*Haritaki*	Fruit	1 Part	***Terminalia chebula***
4.	*Vibhitak*	Fruit	1 Part	***Terminalia bellirica***
5.	*Aamlaki*	Fruit	1 Part	***Emblica officinalis***
6.	*Chitrak*	Root	1 Part	***Plumbago zeylanica***

Observation

Wilcoxon Matched Pair Signed Rank Test in individual group comparing before & after scores.

Table 2: For subjective (Non-parametric) variables.

Sr. No	Variables	Mean		Mean Diff.	% Relief	S.D.	S.E.	P	S
		BT	AT						
01.	***Prabhuta Mutrata*** *(Polyuria) Frequency of urine)*	2.380	0.6600	1.72	72.26	0.7835	0.1108	<0.0001	**HS**
02.	***Pipasadhikya*** *(Polydipsia)*	2.380	0.5800	1.80	75.63	0.7284	0.1030	<0.0001	**HS**
03.	***Kshudhadhikya*** (Excessive Appetite)	1.800	0.733	1.067	59.27	1.387	0.3581	0.0166	**S**
04.	***Avila Mutrata*** (Turbidity in urine)	1.533	0.666	0.866	56.49	1.302	0.3362	0.0273	**S**
05.	***Daurbalyta*** (Weakness)	2.000	1.133	0.866	43.33	1.187	0.3065	0.0156	**S**
06.	***Kara-Pada-Tala- Daha*** (Burning sensation in palm and soles)	2.400	0.6400	1.76	73.33	0.7709	0.1090	<0.0001	**HS**
07.	***Kara-Pada-Tala Supti*** (Numbness in palm and soles)	2.220	0.6000	1.62	72.97	0.7530	0.1065	<0.0001	**HS**
08.	***Alasya/Utsahahani*** (General Debility)	2.000	0.6800	1.32	66.00	0.7407	0.1047	<0.0001	**HS**
09.	***Pandurvarna mutrata*** (Yellowish	1.800	0.933	0.866	48.11	1.060	0.2737	0.0122	**S**

	white coloured urine)								
10.	***Pindiko-udveshatan*** (Cramps)	2.200	0.6200	1.58	71.81	0.8593	0.1215	<0.0001	**HS**
11.	***Mutramadhurya*** (Glycosuria)	1.667	0.733	0.933	55.98	1.163	0.3003	0.0039	**S**

Paired t test (P = Two tailed 'p' value) - in individual group comparing before and after measurements.

Table 3: For objective (Parametric) variables.

Variables	Mean		Mean Diff.	% Relief	S.D.	S.E.	P	Paired t-test	S
	BT	AT							
Fasting Blood Sugar (mg/dl)	145.6	115.0	30.6	21.01	7.286	1.030	0.0013	4.014	**HS**
Post Prandial Blood Sugar(mg/dl)	224.4	154.4	70.02	31.20	14.90	2.107	0.0142	2.800	**S**
Random Blood Sugar (mg/dl)	163.9	133.7	30.2	18.42	5.683	0.8037	0.0003	4.734	**HS**
S. Bilirubin Total	0.7942	0.6854	0.1088	13.69	0.09635	0.01363	0.1199	1.657	**NS**
S. Bilirubin Direct	0.3202	0.2332	0.087	36.80	0.04132	0.005843	0.1411	1.560	**NS**
S.G.O.T.	27.78	20.84	6.94	24.98	2.683	0.3795	0.5521	0.6093	**NS**
S.G.P.T.	28.96	22.22	6.74	23.27	3.231	0.4570	0.1047	1.735	**NS**
Blood Urea	28.92	21.42	7.50	25.93	4.258	0.6022	01149	0.1681	**NS**
Sr. Creatinine	0.9978	0.8676	0.13	13.02	0.1770	0.02503	0.1178	1.663	**NS**
Sr. Uric Acid	1.033	0.9036	0.1294	12.52	0.1000	0.01414	0.1163	1.674	**NS**
Alkaline Phasphatase	85.70	69.52	16.18	18.87	7.452	1.054	0.0373	2.135	**NS**
Specific Gravity of Urine	1.020	1.014	0.006	0.58	0.01221	0.001727	0.5521	0.6093	**NS**
Ph of Urine	6.412	5.584	0.828	12.91	0.5233	0.07401	0.6356	0.4844	**NS**
Total Protien	7.255	6.587	0.668	9.20	0.4645	0.06568	0.0399	2.265	**S**
Albumin	4.676	4.044	0.632	13.51	0.4237	0.05992	0.019	2.23	**S**
Globulin	3.428	3.056	0.372	10.85	0.4976	0.07037	0.0136	2.394	**S**
WBC Count	8.444	9.596	-1.152	1.36	0.8839	0.1250	0.4949	0.0128	**NS**
RBC Count	4.075	4.520	-0.445	10.92	0.7760	0.1097	0.0373	2.135	**NS**
Platelat Count	276.8	327.9	-51.10	18.46	57.33	8.108	0.1178	1.663	**NS**

Discussion on Effect of Treatments on Chief Complaints

Table 3: For average % relief of therapeutic trial.

Sr. No.	Variables	% Relief
01.	*Prabhuta Mutrata (Polyuria) Frequency of urine)*	72.26
02.	*Pipasadhikya (Polydipsia)*	75.63
03.	*Kshudhadhikya* (Excessive Appetite)	59.27
04.	*Avila Mutrata* (Turbidity in urine)	56.49
05.	*Daurbalyta* (Weakness)	43.33
06.	*Kara-Pada-Tala- Daha* (Burning sensation in palm and soles)	73.33
07.	*Kara-Pada-Tala Supti* (Numbness in palm and soles)	72.97
08.	*Alasya/Utsahahani* (General Debility)	66.00
09.	*Pandurvarna mutrata* (Yellowish white coloured urine)	48.11
10.	*Pindiko-udveshatan* (Cramps)	71.81
11.	*Mutramadhurya* (Glycosuria)	55.98
Average % Relief		**63.19**

Table no. 4 reveals that symptomatically, 63.19% relief was observed in present clinical trial. So it can be say that significant / satisfactory relief was found during this research.

Discussion regarding probable mode of action of *Katankateryadi Kwath*

S. No	Constituents	*Rasa*	*Guna*	*Vipaka*	*Veerya*	*Doshaghnata*
1.	***Daruharidra***[1]	*Tikta, Kashaya*	*Laghu, Ruksha*	*Katu*	*Ushna*	*Kaphapitta Shamak*
2.	***Madhuyasthi***[2]	*Madhura*	*Guru,Snigdha*	*Madhura*	*Sheeta*	Vata-Pitta Shamaka
3.	***Chitraka***[3]	*Katu*	*Laghu, Ruksha,Tikshna*	*Katu*	*Ushna*	*Kaphavaata shamak*
4.	***Triphala-***					
	1. *Haritaki*[4]	*Madhura, Amla, Katu, Tikta, Kashaya*	*Laghu, Ruksha*	*Madhura*	*Ushna*	*Tridoshashamaka (Visheshta Vatashamaka)*
	2. *Vibhitaki*[5]	*Kashaya*	*Ruksha, Laghu*	*Madhura*	*Ushna*	*Tridoshashamaka (Visheshta Kaphashamak)*
	3. *Aamalki*[6]	*Madhura, Amla, Katu, Tikta, Kashaya*	*Guru, Ruksha, Sheeta*	*Madhura*	*Sheeta*	*Tridoshashamaka(especially Pittashamaka)*

From the above table it is clear that maximum no. of drugs of *Katankateryadi Kwath* contain *Kashaya* and *Tikta Rasa* with *Laghu* and *Ruksha Guna.* Most of the drugs have *Tridoshashamaka Doshkarma* and are *Rasayana, Mutrala, Shothahar, Deepana* and *Aamapachan.* They effect may be helpful in *Samprapti Vighatana* of *Madhumeha*.

When we tell about *Daruharidra*, it poses hypoglycaemic, anticancer, gastro-irritant, antifatigue, anticoagulant, antipyretic, local anaesthetic, antiprotozoal, anti T.B., antibacterial, antitumour, hypotensive, anti-inflammatory, antitrachoma and CNS depresent properties while, Yasthimadhu posses Antimicrobial, Antiviral, Hepatoprotective, Spasmolytic, Antidiuretic, Antipyretic, Antioxident and Antiinfilammatory properties and its root are sweet, refrigerant tonic, diuretic, demulcent, alterant, intellect promoting and mild laxative.

Chitrak posses *Lekhana, Visphotajanana, Uttejaka, Madak, Deepana, Pachana, Pittasaraka, Grahi, Krimighana, Raktapittakopaka, Shothahara, Kaphaghna, Kanthya, Garbhashaya sankochaka, Garbhasravakara, Vajikarana, Swedajanana, Jwaraghna, Katupaushtika* and *Rasayana karma.*

Triphala posses *Rasayana, Malabhedaka, Vranaropaka, Kushtha, Prameha, Medoroga Nashak, Deepana, Hridya, Ruchi vardhaka, Shukra vardhaka* and *Netrarogahara* properties with *Tridoshashamaka Doshkarma.*

In *Ayurveda* '*Madhumeha*' is considered as disease of vitiated *Vata* and *Kapha Dosha* and *Agnimandya* is also present in *Madhumeha*. *Aacharya Charaka* has used term **"bahudrava *shleshma tatha avabadha meda*"** in the description of *Prameha* and *Dushyas* involved in it are mainly *Meda, Mamsa, Kleda, Shukra, Shonita, Vasa, Majja* etc. are all *Kapha vargiya*. So ideally, such drugs should be used in its treatment which possess *Agnideepana* properties and should pacify the effects of aggravated *Dosha* like *Katu, Tikta, Kashaya,* and *Ruksha Dravyas*. Drugs chosen in the proposed herbal formulation bear such qualities. With this point of view the clinical study entitled **"Clinical evaluation of the *Katankateryadi Kwath* in the management of *Madhumeha* (Diabetes Mellitus Type 2)."** is framed in search of safe and effective remedy in *Ayurveda*.

Discussion on Effect of Treatments on The Clinical Symptomatology

After observation and calculation following facts reveals that the patients showed statistically **Highly Significant** changes in symptoms of *Prabhuta Mutrata, Pipasadhikya, Kara-Pada-Tala- Daha, Kara-Pada-Tala Supti, Alasya/Utsahahani, Pindiko-udveshatan*. Statistically **Significant** changes in the symptoms of *Kshudhadhikya, Avila Mutrata, Daurbalyta, Pandurvarna mutrata, Mutramadhurya*.

Discussion on Effect Of Treatments on the lab Investigations

After observation and calculation following facts reveals that the patients showed statistically Highly Significant changes in Fasting Blood Sugar, Random Blood Sugar. Statistically Significant changes was found in Post Prandial Blood, Total Protien, Albumin, Globulin. Statistically Not Significant changes was found in S. Bilirubin Total, S. Bilirubin Direct, SGOT, SGPT, Blood Urea, Sr. Creatinine, Sr.Uric Acid, Alkaline Phosphatase, Specific Gravity of Urine, Ph of Urine, WBC Count, RBC Count, Platelat Count.

CONCLUSION

- *Katankateryadi Kwath* are effective in management of *Madhumeha* when used with therapeutic lifestyle changes. It is definitely reduce all the symptoms of *Madhumeha* (Diabetes Mellitus) that include *Prabhuta Mutrata* (Polyuria), *Pipasaadhikya* (Polydipsia), *Kshudha* (Appetite), *Avila Mutrata*, *Daurbalya* (Weekness), *Kara-Pada-Tala-Daha* (Burning sensation in palm and soles), *Kara-Pada-Tala-Supti* (Numbness in palm and soles), *Alasaya/ Utsahahani* (General Debility), *Pindiko-udveshtan* (Cramps in claves), *Mutramadhurya* (Glycosuria). These improvements in symptoms is brought about by *Samprapti Vighatana* of the disease. It proves that the trial drug posses hypoglycemic effects.
- The trial drugs were effective in reducing Fasting Blood Sugar, Post Prandial Blood Sugar and Urine Sugar.

- Therapy was well tolerated by all the patients and no toxic or unwanted effects were noticed in any patient, suggesting that the drugs selected for current clinical trial are absolutely safe for internal use.
- It can be concluded that in current research work the proposed medicines *Katankateryadi Kwath* exhibit significant hypoglycemic activity individually more effective when are used safely in patients of *Madhumeha* (Diabetes Mellitus) with success.

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