

A COMPARATIVE AND COMBINED EFFICACY OF HARISHANKAR RAS AND KHADIR-KRAMUK KWATH IN MADHUMEHA (DIABETES TYPE 2)

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ABSTRACT

Diabetes is a disease known from the dawn of civilization. Sedentary life style, Lack of exercise, Faulty food habits and improper medication and urbanization precipitate the disease. The ancient *Ayurveda* classics texts namely the *Samhitas* of *Charak*, *Sushruta* and *Vagbhata* and the subsequent treatises have invariably given detailed description of the disease *Madhumeha* (Diabetes mellitus), its causes, types, pathology and the line of management and treatment both preventive and curative. In present study, drugs were selected with the help of textual references of *Rasendra Sara Sangraha prameha Chikitsa-1 (Harishankar-Ras)* and *Sushruta Samhita Chikitsa sthana 11-8 (Khadir-Kramuka Kwatha)*. 30 clinically diagnosed patients were randomly divided into 3 Groups of 10 each. In Group A, 10 patients were administered *Harishankar Ras* in dose of 125 mg twice a day with luke warm water in empty stomach for 30 days. In Group B, 10 patients were administered *Khadir-Kramuk Kwath* for 30 days in the dose of 40 ml twice a day in empty stomach and in Group C, 10 patients were administered *Harishankar Ras* 125 mg twice a day in empty stomach with luke warm water and *Khadir-Kramuk Kwatha* 40 ml for twice a day in empty stomach for 30 days. From outcomes of this study it can be said that the proposed medicines *Harishankar Ras* and *Khadir-Kramuk Kwath* shows positive response on various parameters of *Madhumeha* (Diabetes Mellitus Type II) which indicates that these drugs have good *Madhumehaghna* (Antidiabetic) effect when used alone or as combine therapy; where results were more marked.

Keywords: *Madhumeha*, Diabetes Mellitus, *Harishankar Ras*, *Khadir-Kramuk Kwath*

INTRODUCTION

Diabetes mellitus is a common chronic metabolic disorder prevalent all over the world. Although diabetes has been a known morbidity since time immemorial, its incidence has been growing notably in recent years. The rising prevalence of diabetes is closely associated with industrialization and socio-economic development. Some 382 million people worldwide¹, or 8.3% of adults, are esti-

ated to have diabetes. About 80% lives in low- and middle-income countries. If these trends continue, by 2035, some 592 million people, or one adult in 10, will have diabetes. This equates to approximately three new cases every 10 seconds or almost 10 million per year.

According to the Diabetes Atlas 2013 published by the International Diabetes Federation, the number of people

with diabetes in India currently around 65.1 million is expected to rise to 109.0 million by 2035 unless urgent preventive steps are taken. The so called “Asian Indian Phenotype”² refers to certain unique clinical and biochemical abnormalities in Indians which include increased insulin resistance, greater abdominal adiposity *i.e.*, higher waist circumference despite lower body mass index, lower adiponectin and higher high sensitive C-reactive protein levels. This phenotype makes Asian Indians more prone to diabetes and premature coronary artery disease. At least a part of this is due to genetic factors.

Diabetes is a chronic disease that occurs when the body cannot produce enough insulin or cannot use insulin effectively³. Insulin is a hormone produced in the pancreas that allows glucose from food to enter the body’s cells where it is converted into energy needed by muscles and tissues to function. A person with diabetes does not absorb glucose properly, and glucose remains circulating in the blood (a condition known as hyperglycaemia) damaging body tissues over time. This damage can lead to disabling and life-threatening health complications.

According to etiological factors, Clinical features and pathogenesis, *Madhumeha* can be correlated with Diabetes Mellitus.

Material and Methods:

Selection of Cases: The study was conducted on 30 clinically and pathologically diagnosed patients of *Madhumeha* (DM Type II). The selection of patients was made randomly from OPD/IPD of Arogyashala, National Institute of Ayurveda and SSBH, Jaipur (Raj.).

Inclusion Criteria: Diagnosed and confirmed cases of Diabetes Mellitus type II, on the basis of the laboratory investiga-

tions of age group of 20-60 years and patients willing to sign the consent form.

Exclusion Criteria: Patients having DM Type I [IDDM], Patient of DM Type II who is on Insulin therapy, any type of Malignancy, DM with complications, patient having any serious illness, FBS [$>200\text{mg/dl}$], PPBS [$>250\text{mg/dl}$] and Hypertension.

Subjective parameters for assessment^{4, 5,}

⁶: *Prabhoot mutrata* (Polyurea), *Pipasa* (Polydypsia), *Avil mutrata* (Turbid urine), *Sharira Gaurava* (Heavyness in body), *Tandra* (Drowsiness), *Hastpaadtal daah* (Burning sensation in palm and sole), *Kara Pada Suptata* (Numbness in palms and sole) *Saad* (Lethargy) and *Panduvarna Mutra* (Yellowish white urine) were assessed before and after of trial study.

Objective parameters for assessment:

Routine hematological, erythrocyte sedimentation rate, renal function test, liver function test, blood sugar level: fasting and 2 hour post prandial, glycosylated hemoglobin and urine routine & microscopy were recorded in all patients before and after of trial study.

Diet and restrictions: No diet and restrictions were advised.

Trial Drugs: The raw material was purchased by National Institute of Ayurveda Pharmacy, Jaipur. Both trial drugs were prepared in the National Institute of Ayurveda Pharmacy, Jaipur by following classical guidelines. Composition of both trial drugs is shown in Table 1.

Grouping and Posology: A total of 30 patients were randomly grouped into A, B and C. Group A (n = 10) received *Harishankar Ras* in dose of 125 mg with luke warm water, Group B (n = 10) received *Khadir-Kramuk Kwath* in dose of 40 ml and Group C (n = 10) received *Harishankar Ras* 125 mg with luke warm water and

Khadir-Kramuk Kwatha 40 ml. Drugs were given twice a day in the morning and evening for the duration of 30 days. Follow-up period was 14 days in both groups.

Statistical analysis: Obtained data were statistically analyzed using Wilcoxon signedrank test, Paired t-test, unpaired t-test, and Chi-square test.

Table No.1:Contents of trial drug.

<i>Harishankar Ras</i> ⁷			
<i>Ras sindoor</i>	Red sulphide of mercury	1 part	
<i>AbhrakaBhasma</i>	Biotite(mica)	1 part	
<i>Dhatri</i>	<i>Emblicaofficinalis</i>	QS	<i>Bhavana</i>
<i>Haridra</i>	<i>Curcuma longa</i>	QS	<i>Dravya</i>
<i>Khadira-Kramuka Kwatha</i> ⁸			
<i>Khadira</i>	<i>Acacia catechu</i>	1 part	
<i>Kramuka</i>	<i>Areca Catechu</i>	1 part	

Observations and Results

Effect of therapy on cardinal symptoms:

The results of therapeutic trial reveal that **patients of group-A** showed statistically **significant** changes in the symptoms of *Saad* (P<0.05), *Kara Pada Daha* (P<0.05) and *Kara Pada Suptata* (P<0.05) while in rest other parameters result were statistically insignificant. **In patients of group B**, showed statistically **highly significant** changes in *Saad* (P<0.01). Statistically **significant** changes was found in *Prabhoot Mutrata* (urine frequency) (P<0.05), *Avil Mutrata* (P<0.05), *Panduvarna Mutrata* (P<0.05), *Kara Pada Daha* (P<0.05) and *Kara Pada Suptata* (P<0.05). **In patients of group C**, showed statistically **highly significant** changes in symptoms *Prabhoot Mutrata* (P<0.01), *Saad* (P<0.01), *Tandra* (P<0.01), *Kara Pada Daha* (P<0.01) and *Kara Pada Suptata* (P<0.01).

Effect of therapy on objective parameters: The results of therapeutic trial on lab parameters reveals that the **patients of group A** showed **statistically no significant** (P>0.05) changes in Hb%, TLC,

ESR, Fasting Blood Sugar, Blood Urea, Serum Creatinine, SGOT, SGPT, Urine Sugar, Urine Protein and GHb. While statistically **significant** (P<0.05) change was found in PPBS. **In patients of group B** showed statistically **highly significant** (P<0.01) changes in FBS and Urine sugar. **Significant changes** (P<0.05) in PPBS and ESR. While statistically **no significant** (P>0.05) was found in rest other parameters. **In patients of group C**, showed statistically **highly significant** (P<0.001) changes in Fasting blood sugar and Post Prandial blood sugar. Group showed **highly significant** (P<0.01) results in Hb%, and Urine sugar. **Significant results** (P<0.05) for ESR and GHb while **statistically no significant** (P>0.05) changes were found in TLC, Blood Urea, Sr. Creatinine, SGOT, SGPT and Urine Protein.

The insignificant results in the Blood Urea, Sr. Creatinine, Urine protein, SGOT, SGPT and indicate that renal functions and liver functions were normal and *Harishankara Ras and Khadir-Kramuk Kwatha* does not cause any hepatic and renal impairment.

Table No. 2:Table showing Effect of therapeutic trial on clinical symptomatology in 30 patients of Madhumeha (Diabetes Mellitus) based on Intra Group comparison (PAIRED T-TEST):

Variable	Group	Mean		Mean Diff.	Percentage Relief	S.D.	S.E.	P Value	Significance
		BT	AT						
1.Prabhoot Mutrata (Frequency of Urine)	A	1.20	0.80	0.40	33.33	.5164	.1633	P>0.05	NS
	B	2.10	1.40	0.70	33.33	.4830	.1528	P<0.05	S
	C	2.10	0.60	1.50	71.42	.7071	.2236	P<0.01	HS
2.Prabhoot Mutrata (Quantity of Urine)	A	1.20	1.00	0.20	16	.6325	.200	P>0.05	NS
	B	0.70	0.30	0.40	57.14	.5164	.1633	P>0.05	NS
	C	1.20	0.20	1.00	83.33	.9428	.2981	P<0.01	HS
3. Pipasa Adhi- kya (Polydipsia)	A	1.10	0.70	0.40	36.36	.5164	.1633	P>0.05	NS
	B	1.00	0.50	0.50	50	.7071	.2236	P>0.05	NS
	C	1.50	0.50	1.00	66.66	.9428	.2981	P<0.05	S
4.Avil Mutrata (Turbidity in Urine)	A	0.30	0.40	-0.10	33	.7379	.2333	P>0.05	NS
	B	1.30	0.60	0.70	53.84	.6749	.2134	P<0.05	S
	C	1.20	0.60	0.90	60	.7379	.2333	P<0.05	S
5.Kara padasup- tata (Numbness in hands and Feet)	A	1.50	0.90	0.60	40	.5164	.1633	P<0.05	S
	B	1.20	0.50	0.70	58.33	.6749	.2134	P<0.05	S
	C	1.90	0.30	1.60	84.21	.5164	.1633	P<0.01	HS
6.Sharira Gauravata	A	0.55	0.33	0.22	39.92	.4410	.1470	P>0.05	NS
	B	0.60	0.40	0.20	33.33	.4216	.1333	P>0.05	NS
	C	1.30	0.60	0.70	53.84	.4830	.1528	P<0.05	S
7.Tandra (Drowsiness/Sleepiness)	A	1.10	0.70	0.40	36.36	.6992	.2211	P>0.05	NS
	B	0.60	0.30	0.30	50	.4830	.1528	P>0.05	NS
	C	1.90	0.70	1.20	63.15	.4216	.1333	P<0.01	HS
8.Saad (Fatigue)	A	1.20	0.60	0.60	50	.5164	.1633	P<0.05	S
	B	2.00	1.10	0.90	75	.5676	.1765	P<0.01	HS
	C	2.50	0.70	1.80	72	1.033	.3266	P<0.01	HS
9.Kara pada Daha (Burning sensation in hands and feet)	A	1.20	0.50	0.70	58.33	.6749	.2134	P<0.05	S
	B	1.00	0.20	0.80	80	.6325	.2000	P<0.05	S
	C	1.50	0.30	1.20	80	.4216	.1333	P<0.01	HS
10.Pandur- varna	A	0.44	0.33	0.11	25	0.33	0.11	P>0.05	NS
	B	0.90	0.30	0.60	66.66	.5164	.1633	P<0.05	S

Mutrata	C	1.10	0.50	0.60	54.54	.5164	.1633	P<0.05	S
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Table No. 3: Table showing Effect of therapeutic trial on lab parameters in 30 patients of Madhumeha (Diabetes Mellitus) based on intra group comparison (pair t-test):

Variable	Gp	Mean		Mean Diff.	S.D.	S.E.	P-Value	Paired t-test	Sign.
		BT	AT						
Hb%	A	11.57	11.42	0.15	0.5622	0.1778	P>0.05	0.8437	NS
	B	11.92	11.98	-0.06	0.1713	0.0514	P>0.05	1.108	NS
	C	11.74	12.58	-0.840	0.7011	0.2217	P<0.01	3.789	HS
TLC/ cumm	A	5956	5850	106	462.75	146.33	P>0.05	0.7244	NS
	B	5386	4613	716.20	1557.9	492.66	P>0.05	1.567	NS
	C	6420	6220	200	1119.5	354.02	P>0.05	0.5649	NS
ESR(mm/h)	A	11.3	10.1	1.2	2.48	0.786	P>0.05	1.527	NS
	B	9.9	8.5	1.4	1.647	0.5207	P<0.05	2.689	S
	C	16.2	8.1	8.1	8.517	2.693	P<0.05	3.007	S
1. Fasting Blood Sugar (mg/dl)	A	155.20	148.80	6.400	12.825	4.056	P<0.01	1.578	HS
	B	159.10	136.70	22.4	17.206	5.441	P<0.01	4.117	HS
	C	168.60	131.00	37.60	22.545	7.129	P<0.01	5.274	HS
Post Prandial Blood Sugar (mg/dl)	A	206.20	183.10	23.10	23.25	7.352	P<0.05	3.142	S
	B	215.5	180.4	32.1	32.695	10.339	P<0.05	3.105	S
	C	226.5	159.5	67	20.785	6.573	P<0.01	10.194	HS
Blood Urea	A	29.50	28.10	1.4	3.204	1.013	P>0.05	1.382	NS
	B	25.2	24.4	0.8	2.898	0.9165	P>0.05	0.8729	NS
	C	25.50	24.20	1.30	5.889	1.862	P>0.05	0.6981	NS
Sr. Creatinine	A	0.97	0.89	0.08	0.1751	0.055	P>0.05	1.445	NS
	B	0.87	0.77	0.10	0.2981	0.0942	P>0.05	1.061	NS
	C	0.97	0.874	0.13	0.1567	0.0495	P>0.05	1.506	NS
SGOT	A	32.2.	31.6.	0.6.	0.9661	0.3055	P>0.05	1.964	NS
	B	37	36.20	0.80	1.229	0.3887	P>0.05	2.058	NS
	C	39.9	36.40	3.50	6.115	1.934	P>0.05	1.810	NS
SGPT	A	33.70	32.60	1.01	1.792	0.5007	P>0.05	1.941	NS
	B	38.20	37.40	0.8	3.706	1.172	P>0.05	0.6827	NS
	C	32.40	29.40	3	15.909	5.031	P>0.05	0.5963	NS
Urine Sugar	A	0.22	0.33	0.11	0.33	0.11	P>0.05	1.00	NS
	B	1.25	0.30	0.90	0.8750	0.2769	P<0.01	3.25	HS
	C	1.1	0.3	0.8	0.0325	0.20	P<0.01	4	HS
Urine Protein	A	0.22	0.33	0.11	0.33	0.11	P>0.05	1	NS
	B	0.20	0.20	00	0.4714	0.141	P>0.05	0	NS
	C	0.30	0.20	0.10	0.3162	0.100	P>0.05	1	NS
G Hb. %	A	7.023	6.878	0.1550	0.2180	0.07280	P>0.05	2.135	NS
	B	6.550	6.380	0.17	0.3234	0.1023	P>0.05	1.663	NS
	C	6.70	6.05	0.050	0.7990	0.2527	P<0.05	2.573	S

DISCUSSION

*Ras sindoor*⁹ possess *Laghu*, *Ushna* and *tikshnaGuna*, have *ushnavirya*, *katupaka* with these properties it helps to alleviate *bahusleshma* and *abadhmeda* from body and obstruction of *srotasa* by their *shoshana* and *vilayana*. *Abhraka Bhasma*¹⁰ possesses *Guru*, *snigdha*, *sheetaguna*, with *sheetavirya* and *madhura vipaka*, all these properties, are similar to *oja*, which is lost in the pathology of *madhumeha*, with these properties it provides *bala* to *prakritaksheena*oja.

Harishankararas has predominance of *katu* and *tikta rasa*. *Katu*¹¹ rasa stimulates *pa-chakagni* desiccants the food removes obstruction and dilates the passages and allays *KaphaDoshas*. Its main pharmacological action is *Amapachana* and make *Ama* stable (it obstructs the processing of product of digestive impairment i.e. *Ama*) which helps in glucose uptake in insulin sensitive tissues like as muscle, fats etc. by enhancing activity of insulin receptor (*Aa-varanaghna* effects).

The *TiktaRasa*¹² has potency to improve the basic cellular metabolism due to their *Shodhana* properties. *Tikta rasa* with its *lekhana* and *shoshana* properties, it cleans *srotasa*, it helps in the *shoshana* of *bahu mutrata*, and *shodhana* of *Mutra vahasrotasa*. *Tikta* has a property of *shoshana* for *sharirakleda*, *meda*, *majja*, *lasika*, *mootra* and *kapha*.

Amalaki is potent *rasayanaushadha*, with its *rasayanaguna*, *amalaki* possess anti-diabetic effects through their antioxidant and free radical scavenging properties. Oxidants and free radicals are called to be responsible for the micro vascular damage in diabetes. *Ras sindoor* possess special property of *yogwahi* and *abhraka* is called to be have properties of *aakashmahabhoota*, with these two special properties, *Hari-*

shakar rasa, adds on the properties of *Amalaki* and *Haridra*, acts on the level of micro channels (*Srotasa*) and cellular level, as it can easily reach these places with these special properties.

Khadir-Kramuk Kwath has a maximum of *Kashaya Rasa*¹³ followed by *Tikta Rasa* and *Katuvipaka*.

Kasaya Rasa acts as a controller of excessive urination; *Dhatu kasaya* and *OjaKasaya* through urine by their *Stambhana* properties. It absorbs *Kleda*, *Meda*, *Vasa* and *KaphaDosha*. *Kasaya rasa* not only reduces the peripheral insulin resistance as well as clinical manifestation of the disease.

In pathogenesis of *Madhumeha*, *Vata Dosha* is predominant factor. For controlling of *Vata Dosha*, the contents of *Harishankar Rasa* and *Khadir-Kramuk Kwatha* have properties of *Rasayana* and *Yogvahi* effects. *Harishankar Rasas* contents of *Laghu*, *Ruksha*, and *TikshnaGuna* which balance with *Snigdha Guna*, *Guru Guna*. *LaghuGuna* is *Kaphaghna*, promotes *Vata Dosha* and depletes the quantum of *Dhatu*s in the body. *RukshaGuna* also promotes *Vata Dosha* and pacifies *Kapha* and *Meda Dhatu*s. *TikshnaGuna* promotes *Pitta Dosha* Pacifies *Kapha VataDoshas* and possesses *Srotoshodhaka* activities. All of these processes are balance with *Madhura Rasa*, *Rasayana* and *Yogvahi* properties of drug.

Total Drug effects by which the trial drugs is effective in *Madhumeha* is because of its various qualities like *Ojovardhaka*, *Rasayana* and *Yogvahi* which pacify the *Vata Dosha* and minimize the chances of the complication of DM whereas the other properties of the trial drug like *Kasaya-Tikta Rasa*, *KatuVipaka* may act synergistically to produce beneficial effects on the disease by virtue of its *Rasayana*, *Yogvahi*,

TridoshashamakaDoshakarma and are-
Grahi, Deepana and Amapachana as well
as *Pramehaghna* effects. These effects
may be helpful in *Samprapti Vighatana* of
Madhumeha.

CONCLUSIONS

The study confirms that *Harishankar Rasa*
and *Khadir-Kramuk Kwatha* are effective
in the management of *Madhumeha* when
used both of them reduce all the symptoms
of *Madhumeha* (Diabetes Mellitus) that
include *Prabhoota mutrata* (Polyuria), *Pi-
pasaadhikya* (Polydipsia), *Avila Mutrata*,
Kara padadaha (Burning sensation of
hands and feet), *Sharira Gauravata, Tan-
dra* (Drowsines/Sleepiness), *Saad* (Fa-
tigue), *Pandurvarna Mutrata* and *Kara
padasuptata* (Numbness of Extremities).
These improvements in symptoms are
brought about by *Samprapti Vighatana*of
the disease. The trial drugs were effective
in reducing Fasting Blood Sugar, Post
Prandial Blood Sugar and Urine Sugar.
Therapy was well tolerated by all the pa-
tients and no toxic or unwanted effects
were noticed in any patient.

It can be concluded that the pro-
posed medicines *Harishankar Ras* and
Khadir -Kramuk Kwath in current study
shows improvement in symptoms of *Mad-
humeha* (Diabetes Mellitus Type II) and
can be used safely in patients of *Madhu-
meha* (Diabetes Mellitus Type II).

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